

TITLE PAGE

FINAL FULL CLINICAL STUDY REPORT

Clinical Study Report Title:	Final Report: A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-CoV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals
Study Number:	C4591001
Study Phase:	Phase 1/2/3
Compound:	PF-07302048 (BNT162b2)
Trade Name:	Comirnaty®
Study Sponsor:	BioNTech SE
Study Agent:	Pfizer Inc.
Sponsor's Signatory:	Federico Mensa, MD Vice President Clinical Development, Infectious Diseases, BioNTech SE
Sponsor Agent's Signatory	Nicholas Kitchin, BSc, MB, BS, DA, FFPM Vice President, Vaccine Clinical R&D, Pfizer Inc.
Principal or Coordinating/Lead Investigator:	Stephen Thomas, MD SUNY Upstate Medical University Global Health Research Unit 4900 Broad Road, Onondaga County, POB North Suite 4U Syracuse, NY 13215 United States
Study Initiation Date (FPFV):	29 April 2020 (study start)
Primary Completion Date:	10 February 2023

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GOOD CLINICAL PRACTICE STATEMENT

This study was conducted in compliance with GCP guidelines and, where applicable, local country regulations relevant to the use of new therapeutic agents in the country/countries of conduct, including the archiving of essential documents.

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SYNOPSIS

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LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
AE	adverse event
CFR	Code of Federal Regulations
CI	confidence interval
CIOMS	Council for International Organizations of Medical Sciences
COVID-19	coronavirus disease 2019
CRF	case report form
CRO	contract research organization
CSR	Clinical Study Report
CT	computed tomography
DCT	data collection tool
EUA	Emergency Use Authorization
EudraCT	European Union Drug Regulating Authorities Clinical Trials Database (European Clinical Trials Database)
FDA	Food and Drug Administration
FPFV	first participant first visit
GCP	Good Clinical Practice
GMC	geometric mean concentration
GMFR	geometric mean fold rise
GMR	geometric mean ratio
GMT	geometric mean titer
HBV	hepatitis b virus
HCV	hepatitis c virus
HIPAA	Health Insurance Portability and Accountability Act
HIV	human immunodeficiency virus
ICD	informed consent document
ICH	International Council of Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IEC	Independent Ethics Committee
IgG	Immunoglobulin G
IR	Incidence rate
IRB	Institutional Review Board
IRC	Internal Review Committee
IRR	illness rate ratio
IRT	Interactive Response Technology
ISO	International Organization of Standardization
IWRS	Interactive Web Response System
LLOQ	lower limit of quantitation

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Abbreviation	Definition
MedDRA	Medical Dictionary for Regulatory Activities
n	number (subgroup or subpopulation)
N	total number, total sample size
NAAT	nucleic acid amplification test
NCT	national clinical trial
NT	neutralizing titer
PD	protocol deviation
PI	Principal Investigator
PT	Preferred Term
PY	patient-years
QC	quality control
QTL	quality tolerance limit
RBD	receptor-binding domain
RCDC	Reverse Cumulative Incidence Curves
RNA	ribonucleic acid
RT-PCR	reverse transcription-polymerase chain reaction
SA	South African
SAE	serious adverse event
SAP	Statistical Analysis Plan
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SD	standard deviation
SE	Societas Europaea
SoA	schedule of activities
SOC	System Organ Class
US	United States
USA	United States of America
VE	vaccine efficacy
VOC	variant of concern

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ETHICS

Independent Ethics Committee and/or Institutional Review Board

The protocol, protocol amendments, ICD, Investigator Brochure, and other relevant documents (eg, advertisements) were submitted to an IRB/IEC by the investigator and reviewed and approved by the IRB/IEC before the study was initiated. The IRBs/IECs are listed in Appendix 16.1.3.1.

Any amendments to the protocol required IRB/IEC approval before implementation of changes made to the study design, except for changes necessary to eliminate an immediate hazard to study participants.

Ethical Conduct of the Study

This study was conducted in accordance with the protocol and consensus ethical principles derived from international guidelines including the Declaration of Helsinki Council and CIOMS International Ethical Guidelines, applicable ICH GCP Guidelines, applicable ISO 14155 guidelines, medical device guidelines, and other applicable laws and regulations, including privacy laws.

Participant Information and Consent

In this clinical study report, the terms "participant" and "subject" are used interchangeably.

The investigator or his/her representative explained the nature of the study to the participant or his/her legally authorized representative and answered all questions regarding the study.

Participants or their legally authorized representative were informed that their participation was voluntary. Participants or their legally authorized representative signed a statement of informed consent that met the requirements of 21 CFR 50, local regulations, ICH guidelines, HIPAA requirements, where applicable, and the IRB/IEC or study center.

Investigative sites were instructed to obtain written informed consent before the participant was enrolled in the study and document the date the written consent was obtained. The authorized person obtaining the informed consent was also instructed to sign the ICD. Participants were reconsented to the most current version of the ICD(s) during their participation in the study.

A copy of the ICD(s) was provided to the participant or the participant's legally authorized representative.

1. INTRODUCTION

In December 2019, a pneumonia outbreak of unknown cause occurred in Wuhan, China. In January 2020, it became clear that a novel coronavirus was the underlying cause. On 11 March 2020, the WHO characterized the COVID-19 outbreak as a pandemic,[1] which has spread rapidly globally. A prophylactic, RNA-based SARS-CoV-2 vaccine provides one of the most flexible and fastest approaches available to immunize against COVID-19.[2,3]

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Phase 1 evaluated safety and immunogenicity results in healthy adult participants across dose levels of 2 vaccine candidates, BNT162b1 and BNT162b2, and Phase 2/3 evaluated efficacy of BNT162b2 (30 µg), and provided additional safety, efficacy, and immunogenicity data in a larger population. Table 5 provides an overview of the study objectives and endpoint analyses that were previously reported in interim CSRs and ad hoc reports for Study C4591001.

This C4591001 final CSR includes the following analyses:

Phase 1

- Safety analysis (SAEs only) from Dose 1 (BNT162b1 or BNT162b2) to 6 months after Dose 2 (BNT162b1 or BNT162b2). Note SAEs from Dose 1 to 4 months after Dose 2 for Phase 1 were previously reported in the final analysis interim report (see Table 5).

- Safety analysis (AEs and SAEs only) of booster doses of BNT162b2 30 µg in Phase 1 participants as follows:

  - A booster dose (Dose 3) of BNT162b2 30 µg, administered to participants who originally received 2 doses of BNT162b1 or BNT162b2 (Dose 3 [first booster dose] to 1 month after Dose 3). Note AEs and SAEs from the first booster dose to 1 month and 4 months after the first booster dose for the Phase 1 original BNT162b2 (30 µg) participants were previously reported in the Phase 1 Booster (Dose 3) and Beta Variant Neutralization report and BNT162b2 (30 µg) Booster (Dose 3) – Phase 1 (4-Month Update) and Phase 3 (6-Month Update) interim report respectively (see Table 5).

  - An additional booster dose (Dose 4) of BNT162b2 30 µg, administered to participants at least 6 months after the third dose of BNT162b2 as part of protocol amendment 19 (additional booster dose to 1 month after the additional booster dose).

Phase 2/3

- Efficacy analysis of BNT162b2 30 µg against asymptomatic SARS-CoV-2 infection in participants without evidence of SARS-CoV-2 infection and in participants with evidence of SARS-CoV-2 infection up to the start of the asymptomatic surveillance period.

- Efficacy analysis of BNT162b2 30 µg against non-S-seroconversion to SARS-CoV-2 in participants without evidence of infection or confirmed COVID-19.

- Incidence of confirmed COVID-19 through the entire study follow-up period in participants who received BNT162b2 at initial randomization or subsequently.

- Immunogenicity analysis of a third dose of BNT162b2 at a lower dose of 5 or 10 µg administered to Phase 2/3 participants.

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- Safety analysis (SAEs only) of BNT162b2 administered to Phase 2/3 participants (12 through 15 years of age and ≥16 years of age) from Dose 1 to 6 months after the second dose. Note SAEs from Dose 1 to 1 month after Dose 2 for Phase 2/3 were previously reported in the adolescent report and 6-month update report (see Table 5).

- Safety analysis (AEs and SAEs only) of a booster dose (Dose 3) of BNT162b2 30 µg, administered to participants at least 3 months after the second dose of BNT162b2 (or $BNT162b2_{SA}$) as part of protocol amendment 18 (from Dose 3 to 1 month after Dose 3).

- Safety analysis (reactogenicity, AEs, and SAEs) of a third dose of BNT162b2 at a lower dose of 5 or 10 µg administered to Phase 2/3 participants ≥18 years of age (from first lower dose booster to 1 and 6 months after lower dose booster).

- Safety analysis (AEs and SAEs only) of additional booster dose(s) (Dose 4 and Dose 5) of BNT162b2 30 µg, administered to participants ≥18 years of age at least 6 months after the third or fourth dose as part of protocol amendment 19 (from additional booster dose to 1 month after additional booster dose).

2. STUDY OBJECTIVES, ENDPOINTS, AND ESTIMANDS

2.1. Phase 1

The study objectives, estimands, and endpoints presented in Table 1 are from Appendix 16.1.1, protocol amendment 20. This report summarizes safety data as described in Section 1 .

Study objectives and endpoint analyses that were previously reported are indicated with gray shading and per the 'reference' column in Table 1.

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Table 1. Phase 1 Objectives, Estimands, and Endpoints

Objectives	Estimands	Endpoints	Reference
Primary:	**Primary:**	**Primary:**	
To describe the safety and tolerability profiles of prophylactic BNT162 vaccines in healthy adults after 1 or 2 doses	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • Adverse events (AEs) from Dose 1 to 1 month after the last dose • Serious AEs (SAEs) from Dose 1 to 6 months after the last dose	• Local reactions (pain at the injection site, redness, and swelling) • Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs	Interim data are reported in the interim Phase 1 CSR dated 12 November 2020, and the final analysis interim CSR dated 03 December 2020. AEs and SAEs from Dose 1 to the unblinding date for the BNT162b2 30 µg group only are reported in the interim 6-month update CSR dated 29 April 2021. SAEs from Dose 1 (BNT162b1 or BNT162b2) to 6 months after Dose 2 (BNT162b1 or BNT162b2) are reported in this final CSR.
	In addition, the percentage of participants with: • Abnormal hematology and chemistry laboratory values 1 and 7 days after Dose 1; and 7 days after Dose 2 • Grading shifts in hematology and chemistry laboratory assessments between baseline and 1 and 7 days after Dose 1; and before Dose 2 and 7 days after Dose 2	Hematology and chemistry laboratory parameters detailed in Appendix 16.1.1, Protocol Section 10.2	Interim data are reported in final analysis interim CSR dated 03 December 2020.

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Table 1. Phase 1 Objectives, Estimands, and Endpoints

Objectives	Estimands	Endpoints	Reference
Secondary:	**Secondary:**	**Secondary:**	
To describe the immune responses elicited by prophylactic BNT162 vaccines in healthy adults after 1 or 2 doses[a]	In participants complying with the key protocol criteria (evaluable participants) at the following time points after receipt of study intervention: 7 and 21 days after Dose 1; 7 and 14 days and 1 and 6 months after Dose 2		Interim data reported up to 1 month after Dose 2 in final analysis interim CSR dated 03 December 2020. Interim data reported up to 6 months after Dose 2 for the BNT162b2 30 µg group only in 6-month update interim CSR dated 29 April 2021.
	• Geometric mean titers (GMTs) at each time point • Geometric mean fold rise (GMFR) from before vaccination to each subsequent time point after vaccination • Proportion of participants achieving ≥4-fold rise from before vaccination to each subsequent time point after vaccination	SARS-CoV-2 neutralizing titers	

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Table 1. Phase 1 Objectives, Estimands, and Endpoints

Objectives	Estimands	Endpoints	Reference
	• Geometric mean concentrations (GMCs) at each time point • GMFR from prior to first dose of study intervention to each subsequent time point • Proportion of participants achieving ≥4-fold rise from before vaccination to each subsequent time point after vaccination	S1-binding IgG levels and RBD binding IgG levels	
	• Geometric mean ratio (GMR) estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers to the geometric mean of binding IgG levels at each time point	• SARS-CoV-2 neutralizing titers • S1-binding IgG levels • RBD-binding IgG levels	

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Table 1. Phase 1 Objectives, Estimands, and Endpoints

Objectives	Estimands	Endpoints	Reference
Exploratory:	**Exploratory:**	**Exploratory:**	
To describe the immune responses elicited by a third dose of prophylactic BNT162b2 administered to healthy adults at least 6 months after the second dose of either BNT162b1 or BNT162b2	• GMCs/GMTs at the time of Dose 3, 7 days and 1 month after Dose 3, and 12 months after Dose 2 • GMFRs from before Dose 3 to 7 days and 1 month after Dose 3 and 12 months after Dose 2	• SARS-CoV-2 reference-strain neutralizing titers • SARS-CoV-2 SA-variant neutralizing titers • Full-length S-binding or S1-binding IgG levels[b]	Interim data for BNT162b2 given as a third dose to BNT162b2 30 µg participants only are reported in 19 May 2022 interim CSR for SARS-CoV-2 reference strain neutralizing titers. Interim data for BNT162b2 given as a third dose to BNT162b2 30 µg participants only are reported in the Phase 1 Booster (Dose 3) and Beta Variant Neutralization Report dated 13 August 2021 for SARS-CoV-2 SA variant neutralizing titers.
	• GMR of SARS-CoV-2 reference strain neutralizing titers 1 month after Dose 3 to 1 month after Dose 2	• SARS-CoV-2 reference-strain neutralizing titers	Interim data for BNT162b2 given as a third dose to BNT162b2 30 µg participants only are reported in the Phase 1 Booster (Dose 3) and Beta Variant Neutralization Report dated 13 August 2021 for SARS-CoV-2 reference-strain neutralizing titers.
	• GMR of SARS-CoV-2 SA-variant neutralizing titers 1 month after Dose 3 to SARS-CoV-2 reference strain neutralizing titers 1 month after Dose 2	• SARS-CoV-2 reference-strain neutralizing titers • SARS-CoV-2 SA-variant neutralizing titers	Interim data for BNT162b2 given as a third dose to BNT162b2 30 µg participants only are reported in the Phase 1 Booster (Dose 3) and Beta Variant Neutralization Report dated 13 August 2021 for SARS-CoV-2 reference-strain neutralizing titers.

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Table 1. Phase 1 Objectives, Estimands, and Endpoints

Objectives	Estimands	Endpoints	Reference
To describe the safety profile of a third dose of prophylactic BNT162b2 administered to healthy adults 6 to 12 months after the second dose of either BNT162b1 or BNT162b2	In participants receiving a third dose of BNT162b2, the percentage of participants reporting: • Local reactions for up to 7 days after Dose 3 • Systemic events for up to 7 days after Dose 3 • AEs and SAEs from Dose 3 to 1 month after Dose 3	• Local reactions (pain at the injection site, redness, and swelling) • Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs	Interim data for BNT162b2 given as a third dose to BNT162b2 participants only are reported in the 19 May 2022 interim CSR for AEs and SAEs. Local reaction and systemic events in the BNT162b2 booster participants 7 days after Dose 3 are reported in the Phase 1 Booster (Dose 3) and Beta Variant Neutralization Report dated 13 August 2021. Final data for BNT162b2 given as a third dose to participants are reported in this final CSR for AEs and SAEs.
To describe the safety and tolerability profile of BNT162b2 given as a fourth dose at least 6 months after the third dose of BNT162b2 for participants who received a fourth dose as part of protocol amendment 19	In participants receiving a fourth dose of study intervention, the percentage of participants reporting: • AEs and SAEs from Dose 4 to 1 month after Dose 4	• AEs • SAEs	Final data are reported in this final CSR.

a. The secondary objective for the 6 months after Dose 2 time point was analyzed for the BNT162b2 30 µg group only, and not for the other BNT162b1 or BNT162b2 groups. This was due to the BNT162b2 30 µg vaccine candidate being selected for use in the C459 program.
b. S-binding IgG testing not performed due to the robustness of the data provided by the SARS-CoV-2 neutralization assays.
Source: Appendix 16.1.1, Protocol Section 3.1

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2.2. Phase 2/3

The study objectives, estimands, and endpoints presented in Table 2 are from Appendix 16.1.1, Protocol Amendment 20. This report summarizes the safety and efficacy data as described in Section 1.

Study objectives and endpoint analyses that were previously reported are indicated with gray shading and per the 'reference' column in Table 2.

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Table 2. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
Primary Efficacy			
To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after the second dose in participants without evidence of infection before vaccination	In participants complying with the key protocol criteria (evaluable participants) at least 7 days after receipt of the second dose of study intervention: 100 × (1 − IRR) [ratio of active vaccine to placebo]	COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT in participants with no serological or virological evidence (up to 7 days after receipt of the second dose) of past SARS-CoV-2 infection	Prespecified complete efficacy data are reported in final analysis interim CSR dated 03 December 2020. Updated efficacy data are reported in the 6-month update interim CSR dated 29 April 2021. Updated efficacy data for participants 12 through 15 years of age only are reported in the adolescents interim CSR dated 14 April 2021 and adolescent 6-month update interim CSR dated 12 December 2021.
To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after the second dose in participants with and without evidence of infection before vaccination	In participants complying with the key protocol criteria (evaluable participants) at least 7 days after receipt of the second dose of study intervention: 100 × (1 − IRR) [ratio of active vaccine to placebo]	COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT	Prespecified complete efficacy data are reported in final analysis interim CSR dated 03 December 2020. Updated efficacy data are reported in the 6-month update interim CSR dated 29 April 2021. Updated efficacy data for participants 12 through 15 years of age only are reported in the adolescents interim CSR dated 14 April 2021 and adolescent 6-month update interim CSR dated 12 December 2021.

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Table 2. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
Primary Safety			
To define the safety profile of prophylactic BNT162b2 in the first 360 participants randomized (Phase 2)	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 to 7 days after the second dose • SAEs from Dose 1 to 7 days after the second dose	• Local reactions (pain at the injection site, redness, and swelling) • Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs	Interim data are reported in final analysis interim CSR dated 03 December 2020

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Table 2. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference

To define the safety profile of prophylactic BNT162b2 in all participants randomized in Phase 2/3	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting:
	• Local reactions for up to 7 days following each dose
	• Systemic events for up to 7 days following each dose
	• AEs from Dose 1 to 1 month after the second dose
	• SAEs from Dose 1 to 6 months after the second dose
		• AEs
		• SAEs
		• In a subset of at least 6000 participants:
		  • Local reactions (pain at the injection site, redness, and swelling)
		  • Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain)
			Interim data are reported up to 1 month after Dose 2 and to the data cutoff date (14 November 2020) in final analysis interim CSR dated 03 December 2020.
			Cumulative interim data up to cutoff date (13 March 2021) are reported in the 6-month update interim CSR dated 29 April 2021.
			Final data are reported for SAEs from Dose 1 to 6 months after the second dose in this final CSR.

To define the safety profile of prophylactic BNT162b2 in participants 12 to 15 years of age in Phase 3	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 to 1 month after the second dose • SAEs from Dose 1 to 6 months after the second dose	Local reactions (pain at the injection site, redness, and swelling) • Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs	Interim data are reported up to 1 month after Dose 2 and to the data cutoff date (13 March 2021) in the adolescent interim CSR dated 14 April 2021. Interim data for AEs and SAEs are reported up to 6 months after Dose 2 and to the data cutoff date (02 September 2021) in the adolescent 6-month update interim CSR dated 12 December 2021. Final data are reported for SAEs from Dose 1 to 6 months after the second dose in this final CSR.

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To describe the safety and tolerability profile of BNT162b2$_{SA}$ given as 1 or 2 doses to BNT162b2-experienced participants, or as 2 doses to BNT162b2-naïve participants To describe the safety and tolerability profile of BNT162b2 given as a third dose to BNT162b2-experienced participants in the subset for evaluation of boostability and protection against emerging VOCs	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 to 1 month after the last dose • SAEs from Dose 1 to 5 or 6 months after the last dose	• Local reactions (pain at the injection site, redness, and swelling) • Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs	Interim data for BNT162b2 30 µg given as a third dose to BNT162b2-experienced participants only are reported up to 1 month after Dose 3 and to the data cutoff date (17 June 2021) in the booster interim CSR dated 23 August 2021. Interim data for BNT162b2 30 µg given as a third dose to BNT162b2-experienced participants only are reported in the interim booster Phase 1 (4-Month Update) and Phase 3 (6-Month Update) CSR date 19 May 2022 for AEs and SAEs only. Interim data for BNT162b2$_{SA}$ given as 2 doses to BNT162b2-experienced participants are reported up to 5 months after Dose 4, and BNT162b2$_{SA}$ given as 1 dose to BNT162b2-experienced participants, or as 2 doses to BNT162b2-naïve participants, and BNT162b2 given as a third dose to BNT162b2-experienced participants are reported up to 6 months after the last dose in the VOC Booster Subset interim CSR dated 20 May 2022. Final data for BNT162b2 5 or 10 µg given as a third dose to BNT162b2-experienced participants are reported in this final CSR.

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Table 2. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
To describe the safety and tolerability profile of BNT162b2 given as a third dose at least 3 months after the second dose of BNT162b2 (or BNT162b2$_{SA}$) for participants who received a third dose as part of protocol amendment 18	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting: • AEs and SAEs from Dose 3 to 1 month after Dose 3	• AEs • SAEs	Data for BNT162b2 given as a third dose to BNT162b2-experienced participants 12 to 15 years of age only are reported in the 6-Month Analysis BNT162b2 Booster Interim CSR dated 13 January 2023. Final data for BNT162b2 for participants ≥12 years of age are reported in this final CSR.
To describe the safety and tolerability profile of BNT162b2 given as a fourth (or fifth) dose at least 6 months after the third (or fourth) dose of BNT162b2 (or BNT162b2$_{SA}$) for participants who received a fourth (or fifth) dose as part of protocol amendment 19	In participants receiving a fourth (or fifth) dose of study intervention, the percentage of participants reporting: • AEs and SAEs from Dose 4 (or Dose 5) to 1 month after Dose 4 (or Dose 5)	• AEs • SAEs	Final data are reported in this final CSR.

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Table 2. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
Primary Immunogenicity *BNT162b2-experienced participants*			
To demonstrate the noninferiority of the anti–reference strain immune response after a third dose of BNT162b2 at 30 µg compared to after 2 doses of BNT162b2, in the same individuals	GMR of reference strain NT 1 month after the third dose of BNT162b2 at 30 µg to 1 month after the second dose of BNT162b2 The difference in percentages of participants with seroresponse to the reference strain at 1 month after the third dose of BNT162b2 at 30 µg and 1 month after the second dose of BNT162b2	• SARS-CoV-2 reference strain NTs in participants with no serological or virological evidence (up to 1 month after receipt of the third dose of BNT162b2 at 30 µg) of past SARS-CoV-2 infection	Prespecified immunogenicity analysis for BNT162b2 given as a third dose to BNT162b2-experienced participants are reported up to 1 month after Dose 3 and to the data cutoff date (17 June 2021) in the booster interim CSR dated 23 August 2021. In the booster interim CSR dated 23 August 2021, an error was identified in a subset of immunogenicity tables based on analyses that used a qualified LLOQ value (20) for the SARS-CoV-2 neutralization assay endpoints, rather than the updated validated LLOQ value (41). This endpoint was reanalyzed using the updated LLOQ value and reported in the BNT162b2$_{SA}$ VOC Booster Subset interim CSR dated 20 May 2022. This resulted in minor numerical changes but did not alter the conclusions.

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Table 2. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
To demonstrate the noninferiority of the anti-SA immune response after 1 dose of BNT162b2$_{SA}$ compared to the anti–reference strain immune response after 2 doses of BNT162b2, in the same individuals	GMR of SA NT 1 month after 1 dose of BNT162b2$_{SA}$ to the reference strain NT 1 month after the second dose of BNT162b2 The difference in percentages of participants with seroresponse to the SA strain at 1 month after 1 dose of BNT162b2$_{SA}$ and seroresponse to the reference strain at 1 month after the second dose of BNT162b2	• SARS-CoV-2 SA and reference strain NTs in participants with no serological or virological evidence (up to 1 month after receipt of 1 dose of BNT162b2$_{SA}$) of past SARS-CoV-2 infection	Prespecified immunogenicity analysis for BNT162b2 given as a third dose of BNT162b2-experienced participants are reported in the BNT162b2$_{SA}$ VOC Booster Subset interim CSR dated 20 May 2022.
BNT162b2-naïve participants			
To demonstrate the noninferiority of the anti-SA immune response after 2 doses of BNT162b2$_{SA}$ compared to the anti–reference strain immune response after 2 doses of BNT162b2	GMR of SA NT 1 month after the second dose of BNT162b2$_{SA}$ to the reference strain NT 1 month after the second dose of BNT162b2 The difference in percentages of participants with seroresponse to the SA strain at 1 month after the second dose of BNT162b2$_{SA}$ and seroresponse to the reference strain at 1 month after the second dose of BNT162b2	• SARS-CoV-2 SA and reference strain NTs in participants with no serological or virological evidence (up to 1 month after receipt of the second dose of BNT162b2$_{SA}$ or BNT162b2 as appropriate) of past SARS-CoV-2 infection	Prespecified immunogenicity analysis for BNT162b2 given as a third dose of BNT162b2 - experienced participants are reported in the BNT162b2$_{SA}$ VOC Booster Subset interim CSR dated 20 May 2022.

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Table 2. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
Secondary Efficacy			
To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 14 days after the second dose in participants without evidence of infection before vaccination	In participants complying with the key protocol criteria (evaluable participants) at least 14 days after receipt of the second dose of study intervention: 100 × (1 – IRR) [ratio of active vaccine to placebo]	• COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT in participants with no serological or virological evidence (up to 14 days after receipt of the second dose) of past SARS-CoV-2 infection	Prespecified complete efficacy data are reported in final analysis interim CSR dated 03 December 2020.
To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 14 days after the second dose in participants with and without evidence of infection before vaccination	In participants complying with the key protocol criteria (evaluable participants) at least 14 days after receipt of the second dose of study intervention: 100 × (1 – IRR) [ratio of active vaccine to placebo]	• COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT	Prespecified complete efficacy data are reported in final analysis interim CSR dated 03 December 2020.

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Table 2. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
To evaluate the efficacy of prophylactic BNT162b2 against confirmed severe COVID-19 occurring from 7 days and from 14 days after the second dose in participants without evidence of infection before vaccination	In participants complying with the key protocol criteria (evaluable participants) • at least 7 days and • at least 14 days after receipt of the second dose of study intervention: 100 × (1 – IRR) [ratio of active vaccine to placebo]	• Confirmed severe COVID-19 incidence per 1000 person-years of follow-up in participants with no serological or virological evidence (up to 7 days and up to 14 days after receipt of the second dose) of past SARS-CoV-2 infection	Prespecified complete efficacy data are reported in final analysis interim CSR dated 03 December 2020. Updated efficacy data occurring from at least 7 days after the second dose only are reported in the 6-month update interim CSR dated 29 April 2021. Updated efficacy data occurring from at least 7 days after the second dose for participants 12 through 15 years of age only are reported in the adolescent interim CSR dated 14 April 2021
To evaluate the efficacy of prophylactic BNT162b2 against confirmed severe COVID-19 occurring from 7 days and from 14 days after the second dose in participants with and without evidence of infection before vaccination	In participants complying with the key protocol criteria (evaluable participants) • at least 7 days and • at least 14 days after receipt of the second dose of study intervention: 100 × (1 – IRR) [ratio of active vaccine to placebo]	• Confirmed severe COVID-19 incidence per 1000 person-years of follow-up	Prespecified complete efficacy data are reported in final analysis interim CSR dated 03 December 2020. Updated efficacy data occurring from at least 7 days after the second dose only are reported in the 6-month update interim CSR dated 29 April 2021. Updated efficacy data occurring from at least 7 days after the second dose for participants 12 through 15 years of age only are reported in the adolescent interim CSR dated 14 April 2021.

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Table 2. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 (according to the CDC-defined symptoms) occurring from 7 days and from 14 days after the second dose in participants without evidence of infection before vaccination	In participants complying with the key protocol criteria (evaluable participants) • at least 7 days and • at least 14 days after receipt of the second dose of study intervention: 100 × (1 – IRR) [ratio of active vaccine to placebo]	• COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT in participants with no serological or virological evidence (up to 7 days and up to 14 days after receipt of the second dose) of past SARS-CoV-2 infection	Prespecified complete efficacy data are reported in final analysis interim CSR dated 03 December 2020.
To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 (according to the CDC-defined symptoms) occurring from 7 days and from 14 days after the second dose in participants with and without evidence of infection before vaccination	In participants complying with the key protocol criteria (evaluable participants) • at least 7 days and • at least 14 days after receipt of the second dose of study intervention: 100 × (1 – IRR) [ratio of active vaccine to placebo]	• COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT	Prespecified complete efficacy data are reported in final analysis interim CSR dated 03 December 2020.
To evaluate the efficacy of prophylactic BNT162b2 against non-S seroconversion to SARS-CoV-2 in participants without evidence of infection or confirmed COVID-19	In participants complying with the key protocol criteria (evaluable participants): 100 × (1 – IRR) [ratio of active vaccine to placebo]	• Incidence of asymptomatic SARS-CoV-2 infection per 1000 person-years of follow-up based on N-binding antibody seroconversion in participants with no serological or virological evidence of past SARS-CoV-2 infection or confirmed COVID-19	Efficacy data is reported in this final CSR.

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Table 2. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
To evaluate the efficacy of prophylactic BNT162b2 against asymptomatic SARS-CoV-2 infection in participants without evidence of infection up to the start of the asymptomatic surveillance period	In participants complying with the key protocol criteria (evaluable participants): 100 × (1 – IRR) [ratio of active vaccine to placebo]	• Incidence of asymptomatic SARS-CoV-2 infection per 1000 person-years of follow-up based on central laboratory–confirmed NAAT in participants with no serological or virological evidence (up to the start of the asymptomatic surveillance period) of past SARS-CoV-2 infection	Efficacy data is reported in this final CSR.
Secondary Immunogenicity			
To demonstrate the noninferiority of the immune response to prophylactic BNT162b2 in participants 12 to 15 years of age compared to participants 16 to 25 years of age	GMR, estimated by the ratio of the geometric mean of SARS-CoV-2 neutralizing titers in the 2 age groups (12-15 years of age to 16-25 years of age) 1 month after completion of vaccination	• SARS-CoV-2 neutralizing titers in participants with no serological or virological evidence (up to 1 month after receipt of the second dose) of past SARS-CoV-2 infection	Prespecified immunogenicity analysis are reported in the adolescent interim CSR dated 14 April 2021.
BNT162b2-experienced participants			
To demonstrate the noninferiority of the anti-SA immune response after a third dose of BNT162b2 at 30 µg compared to the anti–reference strain immune response after 2 doses of BNT162b2, in the same individuals	GMR of SA NT 1 month after the third dose of BNT162b2 at 30 µg to the reference strain NT 1 month after the second dose of BNT162b2 The difference in percentages of participants with seroresponse to the SA strain at 1 month after the third dose of BNT162b2 at 30 µg and seroresponse to the reference strain at 1 month after the second dose of BNT162b2	• SARS-CoV-2 SA and reference strain NTs in participants with no serological or virological evidence (up to 1 month after receipt of the third dose of BNT162b2 at 30 µg) of past SARS-CoV-2 infection	Prespecified immunogenicity analysis are reported in the interim $BNT162b2_{SA}$ VOC Booster Subset CSR dated 20 May 2022

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Table 2. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
To demonstrate the noninferiority of the anti–reference strain immune response after 1 dose of BNT162b2$_{SA}$ compared to after 2 doses of BNT162b2, in the same individuals	GMR of reference strain NT 1 month after 1 dose of BNT162b2$_{SA}$ to 1 month after the second dose of BNT162b2 The difference in percentages of participants with seroresponse to the reference strain at 1 month after 1 dose of BNT162b2$_{SA}$ and 1 month after the second dose of BNT162b2	• SARS-CoV-2 reference strain NTs in participants with no serological or virological evidence (up to 1 month after receipt of 1 dose of BNT162b2$_{SA}$) of past SARS-CoV-2 infection	Prespecified immunogenicity analysis are reported in the interim BNT162b2$_{SA}$ VOC Booster Subset CSR dated 20 May 2022
To descriptively compare the anti-SA immune response after 1 dose of BNT162b2$_{SA}$ and a third dose of BNT162b2 at 30 µg	GMR of SA NT 1 month after 1 dose of BNT162b2$_{SA}$ to 1 month after the third dose of BNT162b2 at 30 µg The difference in percentages of participants with seroresponse to the SA strain at 1 month after 1 dose of BNT162b2$_{SA}$ and 1 month after the third dose of BNT162b2 at 30 µg	• SARS-CoV-2 SA NT in participants with no serological or virological evidence (up to 1 month after receipt of 1 dose of BNT162b2$_{SA}$ or the third dose of BNT162b2 at 30 µg) of past SARS-CoV-2 infection	Prespecified immunogenicity analysis are reported in the interim BNT162b2$_{SA}$ VOC Booster Subset CSR dated 20 May 2022
To descriptively compare the anti-SA immune response after 2 doses of BNT162b2$_{SA}$ and the anti–reference strain immune response after 2 doses of BNT162b2, in the same individuals	GMR of SA NT 1 month after the second dose of BNT162b2$_{SA}$ to the reference strain NT 1 month after the second dose of BNT162b2 The difference in percentages of participants with seroresponse to the SA strain at 1 month after the second dose of BNT162b2$_{SA}$ and seroresponse to the reference strain at 1 month after the second dose of BNT162b2	• SARS-CoV-2 SA and reference strain NTs in participants with no serological or virological evidence (up to 1 month after receipt of the second dose of BNT162b2$_{SA}$) of past SARS-CoV-2 infection	Prespecified immunogenicity analysis are reported in the interim BNT162b2$_{SA}$ VOC Booster Subset CSR dated 20 May 2022

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Table 2. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
BNT162b2-naïve participants			
To demonstrate a statistically greater anti-SA immune response after 2 doses of BNT162b2$_{SA}$ compared to after 2 doses of BNT162b2	GMR of SA NT 1 month after the second dose of BNT162b2$_{SA}$ to 1 month after the second dose of BNT162b2 The difference in percentages of participants with seroresponse to the SA strain at 1 month after the second dose of BNT162b2$_{SA}$ and 1 month after the second dose of BNT162b2	• SARS-CoV-2 SA NTs in participants with no serological or virological evidence (up to 1 month after receipt of the second dose of BNT162b2$_{SA}$ or BNT162b2 as appropriate) of past SARS-CoV-2 infection	Prespecified immunogenicity analysis are reported in the interim BNT162b2$_{SA}$ VOC Booster Subset CSR dated 20 May 2022
To descriptively compare the anti-reference strain immune response after 2 doses of BNT162b2$_{SA}$ and after 2 doses of BNT162b2	GMR of reference strain NT 1 month after the second dose of BNT162b2SA to 1 month after the second dose of BNT162b2 The difference in percentages of participants with seroresponse to reference strain at 1 month after the second dose of BNT162b2$_{SA}$ and 1 month after the second dose of BNT162b2	• SARS-CoV-2 reference strain NTs in participants with no serological or virological evidence (up to 1 month after receipt of the second dose of BNT162b2$_{SA}$ or BNT162b2 as appropriate) of past SARS-CoV-2 infection	Prespecified immunogenicity analysis are reported in the interim BNT162b2$_{SA}$ VOC Booster Subset CSR dated 20 May 2022
Exploratory			
To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after the second dose through the blinded follow-up period in participants without, and with and without, evidence of infection before vaccination	In participants complying with the key protocol criteria (evaluable participants) after receipt of the second dose of study intervention: 100 × (1 – IRR) [ratio of active vaccine to placebo]	• COVID-19 incidence per 1000 person-years of blinded follow-up based on central laboratory or locally confirmed NAAT	Interim data are reported in the 6-month update interim CSR dated 29 April 2021. Updated efficacy data from 7 days after Dose 2 through the blinded follow-up period for participants 12 through 15 years of age are reported in the adolescent 6-month update CSR dated 12 December 2021.

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Table 2. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
To describe the incidence of confirmed COVID-19 through the entire study follow-up period in participants who received BNT162b2 at initial randomization or subsequently	In participants after receipt of each dose of BNT162b2: Incidence per 1000 person-years of follow-up	• COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT	Data are reported in this final CSR.
To evaluate the immune response over time to prophylactic BNT162b2 and persistence of immune response in participants with and without serological or virological evidence of SARS-CoV-2 infection before vaccination	GMC/GMT and GMFR at baseline and 1, 6, 12, and 24 months after completion of vaccination	• Full-length S-binding or S1-binding IgG levels • SARS-CoV-2 neutralizing titers	Interim data for Phase 2 (first 360 participants) only up to 1 month after Dose 2 are reported for S1-binding IgG levels and SARS-CoV-2 neutralizing titers in final analysis interim CSR dated 03 December 2020. GMTs and GMFRs of SARS-CoV-2 neutralizing titers up to 1 month after Dose 2 in participants 12 through 15 and 16 through 25 years of age are reported in the adolescent interim CSR dated 14 April 2021.
To describe the efficacy of prophylactic BNT162b2 against asymptomatic SARS-CoV-2 infection in participants with evidence of infection up to the start of the asymptomatic surveillance period	In participants complying with the key protocol criteria (evaluable participants): 100 × (1 – IRR) [ratio of active vaccine to placebo]	Incidence of asymptomatic SARS-CoV-2 infection per 1000 person-years of follow-up based on central laboratory–confirmed NAAT in participants with serological or virological evidence (up to the start of the asymptomatic surveillance period) of past SARS-CoV-2 infection	Efficacy data are reported in this final CSR.

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Table 2. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
To describe the serological responses to the BNT vaccine candidate and characterize the SARS-CoV-2 isolate in cases of: • Confirmed COVID-19 cases that occur approximately 6 months after the second dose • Confirmed severe COVID-19 cases that occur through approximately 6 months after the second dose		• SARS-CoV-2 neutralizing titers • Identification of SARS-CoV-2 variant(s)	Data will be reported at a later time.
To describe the safety, immunogenicity, and efficacy of prophylactic BNT162b2 in individuals with confirmed stable HIV disease		All safety, immunogenicity, and efficacy endpoints described above	Safety data in participants with confirmed stable HIV disease are reported in the 6-month update interim CSR date 29 April 2021 Efficacy data in participants with confirmed stable HIV disease are included in the listings of COVID-19 cases in previous CSRs with efficacy analysis. Immunogenicity data will be reported at a later time.
To describe the immune response to any VOCs not already specified	Geometric mean NT for any VOCs not already specified, after any dose of $BNT162b2_{SA}$ or BNT162b2	SARS-CoV-2 NTs for any VOCs not already specified	Data will not be analyzed. Immune responses to VOCs not already specified were not assessed as part of this protocol.

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Table 2. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
To describe the immune response to a third dose of BNT162b2 (at 30 µg or a lower dose of 5 µg or 10 µg) or a third or fourth dose of $BNT162b2_{SA}$	• GMTs at Dose 3 and subsequent time points • GMFRs from Dose 3 to subsequent time points	SARS-CoV-2 reference strain NTs	Interim data for BNT162b2 30 µg given as a third dose to BNT162b2-experienced participants are reported in interim CSRs dated 23 August 2021 and 19 May 2022 Interim date for $BNT162b2_{SA}$ 30 µg given as a third or fourth dose was reported in the interim $BNT162b2_{SA}$ VOC Booster Subset CSR dated 20 May 2022. Data for BNT162b2 at lower dose of 5 or 10 µg are reported in this final CSR.
To describe the cell-mediated immune response, and additional humoral immune response parameters, to the reference strain and SA in a subset of participants: • 7 Days and 1 and 6 months after $BNT162b2_{SA}$ given as 1 or 2 doses to BNT162b2-experienced participants • 7 Days and 1 and 6 months after $BNT162b2_{SA}$ given as 2 doses to BNT162b2-naïve participants • 7 Days and 1 and 6 months after BNT162b2 given as a third dose to BNT162b2-experienced participants			Data will be reported at a later time.

a. HIV-positive participants in Phase 3 were not included in analyses of the objectives, with the exception of the specific exploratory objective.
Source: Appendix 16.1.1, Protocol Section 3.2.

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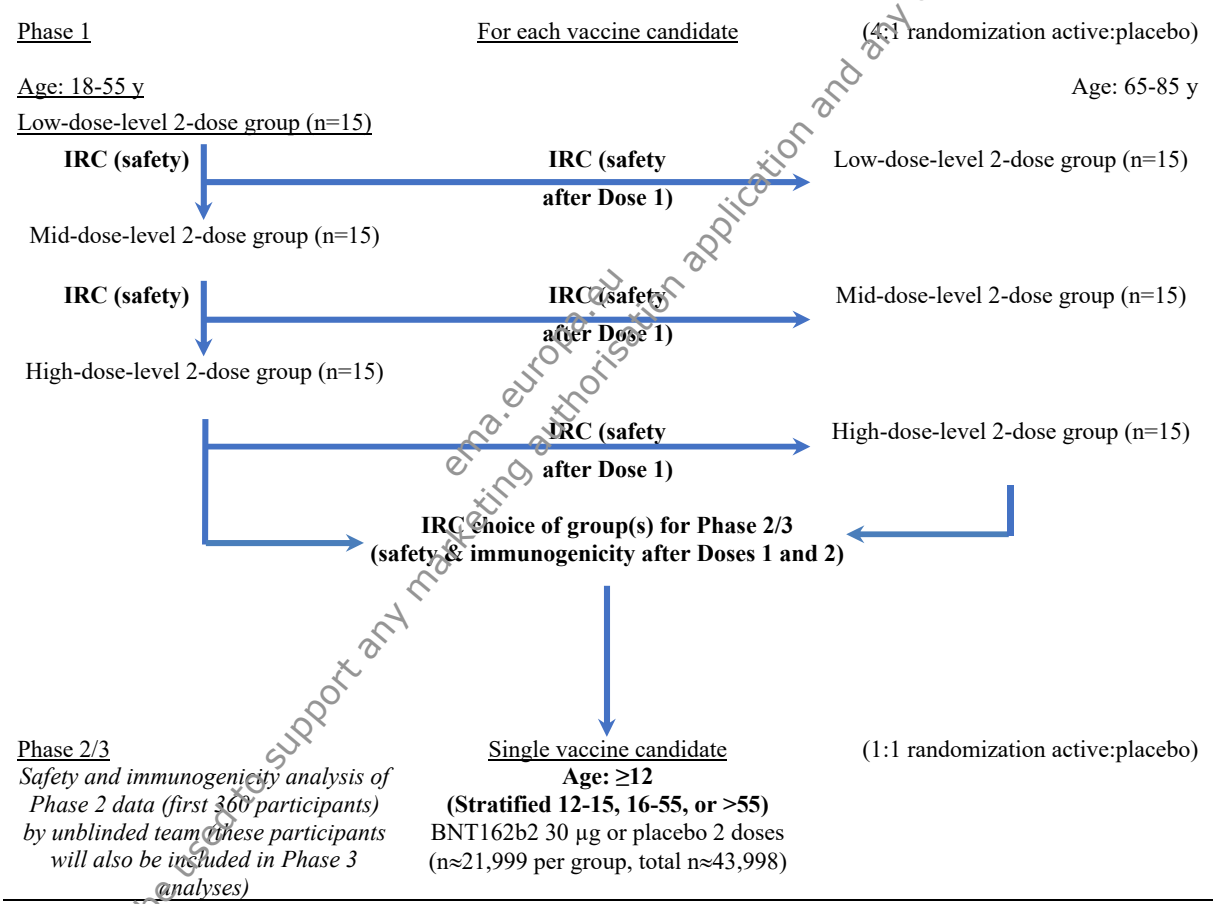
3. INVESTIGATIONAL PLAN

3.1. Overview of Study Design

This was a Phase 1/2/3, multicenter, multinational, randomized, placebo-controlled, observer-blind, dose finding, vaccine candidate–selection, and efficacy study in healthy individuals.

The study consisted of 2 parts: Phase 1 to identify preferred vaccine candidate(s) and dose level(s); and Phase 2/3 as an expanded cohort and efficacy part. These parts, and the progression between them, are detailed in Figure 1.

Figure 1. Study Schema



Abbreviation: IRC = internal review committee.
Source: Appendix 16.1.1, Protocol Section 1.2
Note: Participants who originally received placebo were offered the opportunity to receive BNT162b2 at defined points as part of the study.

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The study evaluated the safety, tolerability, and immunogenicity of 3 different SARS-CoV-2 RNA vaccine candidates against COVID-19 and the Phase 2/3 efficacy of 1 selected candidate based on Phase 1 results:

- As a 2-dose (separated by 21 days) schedule;
- At various dose levels in Phase 1;
- As a booster (Dose 3); (see Boostability and Variant Strain Evaluation)
- In various age groups:
  - Phase 1: 18 to 55 and 65 to 85 years of age;
  - Phase 2: ≥18 years of age (stratified as 18 to 55 years and >55 to 85 years);
  - Phase 3: ≥12 years of age (stratified as 12 to 15, 16 to 55, or >55 years of age).

To facilitate rapid review of data in real time, Pfizer and BioNTech SE staff were unblinded to vaccine allocation for the participants in Phase 1 and were blinded for the Phase 2/3 portion of study until 15 December 2021, once all unblinding time points were reached in the study.

Participants ≥16 years of age who originally received placebo and became eligible for receipt of BNT162b2 according to recommendations detailed separately, and available in the electronic study reference portal, had the opportunity to receive BNT162b2 in a phased manner as part of the study. The investigator ensured the participant met at least 1 of the recommendation criteria based upon US recommendation.

Any Phase 1 placebo recipient who had not already been offered the opportunity to receive BNT162b2 was given this opportunity no later than at the approximate time participants in Phase 2/3 reached Visit 4. Any Phase 2/3 placebo recipient ≥16 years of age who had not already been offered the opportunity to receive BNT162b2 was given this opportunity no later than 6 months after Vaccination 2 (at the time of the originally planned Visit 4).

Any participant who originally received placebo but then went on to receive BNT162b2 was moved to a new visit schedule to receive both doses of BNT162b2 at each of 2 additional vaccination visits (Visits 101 and 102) (Appendix 16.1.1, Protocol Section 1.3.3).

Refer to Appendix 16.1.1, Protocol Section 4.1 for further detail on the overall study design.

Boostability and Variant Strain Evaluation

To evaluate boostability, an additional dose of BNT162b2 (30 µg) was given to Phase 1 participants 18 to 55 years of age and 65-85 years of age, approximately 6 to 12 months after their second dose of BNT162b2. This provided an early assessment of the safety of a third dose of BNT162b2, as well as its immunogenicity, and results are reported in the booster

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interim CSR dated 19 May 2022. A fourth dose of BNT162b2 at 30 µg was offered to these participants at least 6 months after the third dose. The safety analysis for the fourth dose is included in this report.

Evaluations of VOC strains of SARS-CoV-2 (in participants who received a SARS-CoV-2 variant encoding vaccine that encodes the Beta variant originally identified in South Africa [BNT162b2$_{SA}$] as a primary 2-dose series in BNT162b2-naïve participants and as third and fourth dose after 2 doses of BNT162b2 (30 µg) are reported in the interim BNT162b2$_{SA}$ VOC Booster Subset CSR dated 20 May 2022.

Immunogenicity and safety evaluations of a booster dose were conducted in a subset of Phase 3 participants 18 to 55 years of age at selected sites in the US who received a third dose of BNT162b2 (30 µg) at least 6 months after their second dose and results are reported in the booster interim CSRs dated 23 August 2021 and 19 May 2022.

Evaluations of boostability in a further subset of Phase 3 participants who received a third dose of BNT162b2 at the lower 5 or 10 µg dose level after receiving BNT162b2 as a primary 2-dose series (30 µg) are included in this report.

As part of protocol amendment 18, participants who had not yet received a third dose of BNT162b2 could receive a booster (Dose 3) at Visit 501, at least 3 months (84 days) after their second dose of BNT162. Safety evaluations of a booster dose in Phase 2/3 participants 12 through 15 years of age who received the booster dose (Dose 3) under protocol amendment 18 are reported in the interim CSR dated 13 January 2023. Final data for participants ≥12 years of age are included in this report.

As part of protocol amendment 19, eligible participants who received a third dose of BNT162b2 (or BNT162b2$_{SA}$) or a third and fourth dose of BNT162b2$_{SA}$ after receiving 2 doses of BNT162b2 under protocol amendments 13 to 15, were offered an additional 30-µg booster dose of BNT162b2 (Dose 4 or Dose 5). Safety evaluations of the additional booster dose in Phase 1 and Phase 3 participants are included in this report. Note that, BNT162-naïve participants who received 2 primary doses of 30 µg BNT162b2$_{SA}$ under protocol amendment 14 and were enrolled to receive a booster dose at Visit 501 under protocol amendment 18 were not eligible to receive an additional dose.

Refer to Appendix 16.1.1, Protocol Section 4.1.1 for further details on the booster dose (Dose 3) for Phase 1, and Appendix 16.1.1, Protocol Section 4.1.2 for further details on Phase 2/3.

Unblinding Considerations

The study was unblinded in stages once all ongoing participants either had been individually unblinded or had concluded their 6-month post–Dose 2 study visit, in the following sequence:

- Phase 1 (after Visit 8 [6-month post–Dose 2 visit]).
- Phase 2/3, ≥16 years of age (after Visit 4 [6-month post–Dose 2 visit]).

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- Phase 3, 12 through 15 years of age (after Visit 4 [6-month post–Dose 2 visit]).
- Original Phase 3 participants rerandomized to assess boostability and protection against emerging VOCs (after Visit 306).

3.1.1. Discussion of Study Design

The scientific rationale for features of the study design, including chosen control group(s), dose(s), and endpoint(s), as applicable, are discussed in the Study Design section of the protocol (Appendix 16.1.1, Protocol Section 4).

3.1.2. Changes in Study Conduct

Changes in the conduct of the study are described in Appendix 16.1.1, Protocol Amendment Summary of Changes Table. Changes to the original planned analysis are described in the SAP v10 (Appendix 16.1.9, SAP Section 1).

3.2. Investigators and Study Administrative Structure

The study was managed by Pfizer Inc. (sponsor agent) and conducted by investigators contracted by and under the direction of Pfizer. The investigators were responsible for adhering to the study procedures described in the protocol, for keeping records of study intervention, and for accurately completing and signing the CRFs/DCTs supplied by Pfizer. A list of investigators and sites (including participants by country), and service providers involved in this study is available in Appendix 16.1.4.

Two sites were terminated.

3.3. Selection of Study Population

3.3.1. Inclusion/Exclusion Criteria

Enrolled in this study were healthy male or female participants (or with preexisting stable disease) between the ages of 18 and 55 years, inclusive, and 65 and 85 years, inclusive (Phase 1), or ≥12 (Phase 2/3), at randomization.

For participants in the boostability and protection-against-VOCs subset:

- Existing participants enrolled to receive a third dose of BNT162b2 at 30 µg or BNT162b2$_{SA}$; male or female participants between the ages of 18 and 55 years, inclusive, at rerandomization.
- Newly enrolled participants enrolled to receive 2 doses of BNT162b2$_{SA}$; male or female participants between the ages of 18 and 55 years, inclusive, at enrollment.
- Existing participants enrolled to receive a third dose of BNT162b2 at 5 or 10 µg; male or female participants ≥18 years at rerandomization.

Detailed inclusion and exclusion criteria are provided in Appendix 16.1.1, Protocol Section 5.

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3.3.2. Removal of Participants From Intervention or Study

The specific criteria and procedures for early discontinuation from study intervention(s) or withdrawal from the study are described in Appendix 16.1.1, Protocol Section 7.

3.4. Study Intervention

3.4.1. Study Interventions Administered

The manufacturing lot numbers for the study intervention(s) dispensed in this study are provided in Table 3. Appendix 16.1.6 provides a listing of sites receiving study intervention(s) from specific batches. The justification for the dose(s) selected is described in Appendix 16.1.1, Protocol Section 4.3. Note that the table below presents all lots of study intervention used for the entire study.

Table 3. Study Intervention Lot Numbers – Final

Study Intervention	Manufacturer	Vendor Lot Number (Manufacturer)	Lot Number[a] (Pfizer)
BNT162b1	BioNTech	BCV10320-A BCV10420-A	E220395-0001L E220395-0006L004/P220395-0009L
BNT162b2$_{SA}$	BioNTech	21-DP-00481	PA2096820/P220395-0078L
BNT162b2	BioNTech	BCV40420-A	E220395-0035L002/P220395-0048L E220395-0035L003/P220395-0048L EU2065896/E220395-0004L PA2070104/P220395-0008L E220395-0006L003/P220395-0012L E220395-0004L
		BCV40620-A	PA2071394/P220395-0029L PA2072393/P220395-0019L
		BCV40720-A	PA2074172/P220395-0053L PA2074998/P220395-0060L
		BCV40620-B	PA2071395/P220395-0016L PA2072396/P220395-0016L
		BCV40720-B	PA2074173/P220395-0051L
		BCV40620-C	PA2071396/P220395-0047L PA2072439/P220395-0047L
		BCV40720-C	PA2074071/P220395-0052L
		BCV40620-D	PA2072442/P220395-0042L PA2072765/P220395-0042L
		ED3938	PA2074300/P220395-0021L PA2074300/P220395-0023L PA2074300/P220395-0022L EU2074330/E220395-0036L
		EE3813	PA2074838/P220395-0020L NC2075485/P220395-0077L PA2074838/P220395-0024L NC2075485/P220395-0068L NC2075485/P220395-0074L
		EE8493Y	PA2087473/P220395-0073L
		EE8493Z	PA2077905/P220395-0026L
		EL1491Z	PA2089539/P220395-0091L
		EL8723Y	PA2092203/P220395-0092L
		EJ0553Z	PA2085061/P220395-0070L

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Table 3. Study Intervention Lot Numbers – Final

Study Intervention	Manufacturer	Vendor Lot Number (Manufacturer)	Lot Number[a] (Pfizer)
			PA2085061/P220395-0089L
		EJ1685Z	PA2086021/P220395-0090L
		ER9449Z	PA2096794/P220395-0079L PA2096794/P220395-0082L
		FG3535C	PA2126116/P220395-0084L PA2126116/P220395-0085L PA2126116/P220395-0087L
		FG8041	PA2120160/P220395-0086L
Diluent (0.9% sodium chloride solution)	Pfizer	DK2074 DK2074;20-002221	20-002221 20-002957 PA2069407OTH/E220395-0059L
		DK1589	20-001776 20-001592
		EC6817	21-AE-00141
		EX2624	21-AE-00230 PA2115725/P220395-0088L
		FG8096	21-AE-00325
Placebo (0.9% sodium chloride solution)	Pfizer	DK1589;20-001592	PA2064251/P220395-0005L
		DK2074;20-002108	PA2067774/P220395-0013L
		DK2074;20-002221	PA2069407/P220395-0031L PA2069407/P220395-0054L PA2069407/P220395-0056L PA2069407OTH/E220395-0049L PA2069407/P220395-0044L PA2069407/P220395-0062L PA2069407/P220395-0065L PA2069407/P220395-0034L PA2069407/P220395-0046L PA2069407/P220395-0032L PA2069407/P220395-0033L PA2069407/P220395-0045L PA2069407/P220395-0055L
		DK1589;20-001776	PA2065311/P220395-0007L
		DK2074;20-002029	PA2067775/P220395-0030L

Note: C4591001 End of Study Information and Quality Control (QC) Record for Study Drug Appendix (Section D) dated 20Apr2023 was used to create this table.
a. Lot number assigned to the study intervention by Pfizer Global Clinical Supply.
Protocol C4591001 Study Intervention Lot Numbers Table – Final, Version 2.0, 08May2023.

3.4.2. Measures to Minimize Bias

Allocation

All participants initially enrolled in the study were centrally assigned to randomized study intervention using an IRT system. The method used to assign/allocate participants is further described in Appendix 16.1.1, Protocol Section 6.3.1.

Under protocol amendments 18 and 19, participants who met the eligibility criteria and consented were assigned to receive a booster dose of BNT162b2 (30 µg).

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Blinding

This was initially an observer-blinded study. Refer to Appendix 16.1.1, Protocol Section 6.3.2 for details on blinding of the site personnel, Protocol Section 6.3.3 for details on blinding of Pfizer and BioNTech SE personnel, Protocol Section 6.3.4 for circumstances when the blind could be broken, and Section 3.1 for further details on unblinding.

As part of protocol amendment 18, participants who had not yet received a third dose of BNT162b2 may have received one at least 3 months (84 days) after their second dose of BNT162 in an open-label manner. As a result, the requirement for an unblinded dispenser/administrator did not apply to this vaccination.

As part of protocol amendment 19, eligible participants who received a third dose of BNT162b2 (or BNT162b2$_{SA}$) or a third and fourth dose of BNT162b2$_{SA}$ under protocol amendments 13 to 15 may have received an additional dose of 30 µg BNT162b2 at Visit 601 or 604, at least 6 months after their last dose of BNT162 in an open-label manner; therefore, the requirement for an unblinded preparer, dispenser, and administrator did not apply to this vaccination.

3.4.3. Study Intervention Compliance

The method(s) used to assess study intervention compliance were described in Appendix 16.1.1, Protocol Section 6.4.

3.4.4. Prior and Concomitant Vaccines, Medication, and Procedures

Participants may have been excluded from the per-protocol analysis and may not have received further required study vaccinations upon receipt of the vaccines and medications prohibited during the time periods specified in Appendix 16.1.1, Protocol Section 6.5.1; however, participants were not withdrawn from the study. Medications were not withheld if required for a participant's medical care.

Prophylactic antipyretics and other pain medication to prevent symptoms associated with study intervention administration were not permitted. However, if a participant was taking a medication for another condition, even if it had antipyretic or pain-relieving properties, it was not withheld prior to study vaccination.

Permitted During the Study

The use of antipyretics and other pain medication to treat symptoms associated with study intervention administration or ongoing conditions was permitted.

Medication other than that described as prohibited in Appendix 16.1.1, Protocol Section 6.5.1 required for treatment of preexisting stable conditions was permitted.

Inhaled, topical, or localized injections of corticosteroids (eg, intra-articular or intrabursal administration) were permitted.

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Refer to Appendix 16.1.1, Protocol Section 6.5.2 for details on prior and concomitant vaccines, medications, and procedures that were allowed.

3.5. Study Assessments and Procedures

3.5.1. Planned Measurements and Timing of Assessments

The specific efficacy and safety assessments and the schedule and measurement/collection methods were provided in the protocol SoA and described in the protocol (Appendix 16.1.1, Protocol Section 8.1 and 8.2).

Asymptomatic Efficacy and Incidence of Confirmed COVID-19

The incidence of asymptomatic SARS-CoV-2 infection in participants per 1000 person-years based on N-binding antibody seroconversion and central laboratory-confirmed NAAT was assessed to evaluate the asymptomatic efficacy of BNT162b2. In addition, the incidence of confirmed COVID-19 per 1000 person-years of follow-up through the entire study follow-up period was assessed for participants who received BNT162b2 at initial randomization or subsequently. The assessments included a nasal (midturbinate) swab, which was tested at a central laboratory using an RT-PCR test, or other equivalent nucleic acid amplification–based test (ie, NAAT), to detect SARS-CoV-2. In addition, clinical information and results from local standard-of-care tests were assessed. The central laboratory NAAT result was used for the case definition, unless no result was available from the central laboratory, in which case a local NAAT result could be used in the COVID-19 case definition. Refer to Appendix 16.1.1, Protocol Section 8.1 for further details.

Safety

The collection and assessment of safety information during the study (evaluation, definitions, recording, and reporting of AEs, SAEs, and other reportable safety events) were detailed in Appendix 16.1.1, Protocol Section 8.3.

Safety evaluations were as described in Appendix 16.1.1, Protocol Section 8.2.

3.5.2. Appropriateness of Measures

The safety endpoints used in this study were consistent with those used for other vaccine studies conducted by Pfizer, with regulatory guidance, and considered to be reliable, and relevant to the objectives set forth in the protocol (Appendix 16.1.1, Protocol Section 3).

3.6. Data Quality Assurance

The sections below summarize the steps taken to ensure quality of the data throughout the study.

3.6.1. Study Monitoring

Study centers were monitored by Pfizer and ICON. Centers were visited at regular intervals and a Visit Log was maintained. Monitors were responsible for reviewing adherence to the protocol; compliance with GCP; and the completeness, accuracy, and consistency of the data.

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Direct access to participant medical and laboratory records was permitted to verify entries on the study specific CRFs.

3.6.2. Investigator Meetings and Staff Training

Investigator staff training was provided by Pfizer and ICON during the investigator meetings, site initiation visit, and routine monitoring visits. The sponsor agent organized investigator and clinical research associate meetings before study start and during the study to provide information on the study intervention, the study rationale and design, responsibilities under ICH/FDA/GCP, and training on the detailed study requirements.

3.6.3. Laboratory Procedures

A central laboratory, Pfizer Vaccine Research & Development, was used to analyze the immunogenicity samples and to test for COVID-19 (eg, N-binding antibody assay [serum], RT-PCR [nasal swab], and SARS-CoV-2 neutralization assay [serum]) (Appendix 16.1.10). Where local laboratories were used, their participation in internal and external quality control, quality assurance, and accreditation schemes was evaluated by the study monitors.

3.6.4. Investigator Responsibilities

The investigators were responsible for all data entered in the CRFs and DCTs and documented their review and approval of the data, verifying the validity and completeness of the data. The investigator was responsible for appropriate retention of essential study documents.

3.6.5. Clinical Data Management

CRF data were captured via data entry in a sponsor agent database system. Data quality checks were applied using manual and electronic verification methods. An audit trail was maintained to support data query resolution and any modification to the data.

3.6.6. Clinical Quality Assurance Audits

Audits of this study were included as part of the independent sponsor agent quality assessment performed by Pfizer's own independent quality assurance group or by a CRO and/or individual contract personnel under the group's direction. The audit certificates for the study are provided in Appendix 16.1.8.

3.6.7. Quality Tolerance Limits

The quality management approach used in this study identified risks significant to human participant protection or reliability of trial results. The quality risk management plan used in this study documents risks and controls that are in place throughout the life of the study. In this study, QTLs were defined during the quality risk management planning.

For the endpoints that are evaluated in this final report, the QTLs were routinely assessed, and no important deviations were observed.

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3.7. Statistical Analysis

3.7.1. Statistical Analysis Plan

The analysis populations presented in this report are defined in Table 4. Refer to Appendix 16.1.9, SAP Section 4 for details of other planned analysis sets to be reported at a later time.

Table 4. Analysis Populations

Population	Description
Enrolled	All participants who had signed ICD.
Randomized	All participants who were assigned a randomization number in the IWR system
Dose 3 booster evaluable immunogenicity	All eligible randomized participants who receive 2 doses of BNT162b2 (or BNT162b1 for Phase 1) as initially randomized, with Dose 2 received within the predefined window (within 19-42 days after Dose 1), receive a third dose of BNT162b2 or BNT162b2$_{SA}$ as rerandomized (or receive a third dose of BNT162b2 for Phase 1), have at least 1 valid and determinate immunogenicity result after Dose 3 from a blood collection within an appropriate window (within 28-42 days after Dose 3), and have no other important protocol deviations as determined by the clinician.
Dose 3 booster all-available immunogenicity	All randomized participants who receive 2 doses of BNT162b2 (or BNT162b1 for Phase 1) at initial randomization, receive a third dose of BNT162b2 or BNT162b2$_{SA}$ at rerandomization (or receive a third dose of BNT162b2 for Phase 1), and have at least 1 valid and determinate immunogenicity result after Dose 3.
Evaluable efficacy (seroconversion)	All eligible randomized participants who receive all vaccination(s) as randomized, with Dose 2 received within the predefined window (within 19-42 days after Dose 1), have at least 1 N-binding antibody test result available at a post−Dose 2 visit, and have no other important protocol deviations as determined by the clinician prior to the first post−Dose 2 N-binding antibody test.
Evaluable efficacy (asymptomatic surveillance)	All eligible randomized participants who receive all vaccination(s) as randomized, with Dose 2 received within the predefined window (within 19-42 days after Dose 1), consented to participate in the asymptomatic surveillance, and have no other important protocol deviations as determined by the clinician on or before the start of the asymptomatic surveillance period.
All-available efficacy	Dose 1 all-available efficacy: All randomized participants who receive at least 1 vaccination. Dose 2 all-available efficacy: All randomized participants who complete 2 vaccination doses. Dose 3 all-available: All randomized participants who complete 3 vaccination doses.
Safety	All randomized participants who receive at least 1 dose of the study intervention. Analyses of reactogenicity endpoints will be based on a subset of the safety population that includes participants with any e-diary data reported after vaccination.
Booster safety	All participants who received at least 1 booster dose of the study intervention

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Determination of Sample Size

Refer to Appendix 16.1.1, Protocol Section 9.2, and Appendix 16.1.9, SAP Section 5.1.3 for details of the sample size determination.

3.7.2. Changes in Planned Analyses Prior to Unblinding or Database Lock

The secondary objective and estimand to describe the immune responses elicited by prophylactic BNT162 vaccines 6 months after the Dose 2 time point (Table 1 and Table 5) was analyzed for the BNT162b2 30 µg group only, and not for the other BNT162b1 or BNT162b2 groups. This was due to the BNT162b2 30 µg vaccine candidate being selected for use in the C459 program.

4. STUDY PARTICIPANTS

Note that Phase 1/2/3 results were previously reported in the reports listed in Table 5. This final CSR summarizes the study objectives, estimands, and endpoints that were not fully evaluated before (see Table 1 and Table 2).

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Table 5. Previously Reported Results in C4591001 Phase 1/2/3 Participants

Reports	Date	Scope
CSR: Interim Phase 1 Report	01 October 2020	Interim Phase 1 analyses of safety and immunogenicity for BNT162b1 and BNT162b2 in the candidate- and dose level-finding part of the study for each dose level and age group, and it is based on an analysis data cutoff date of 24 August 2020 (safety data available up to the data cutoff date), and serology completion date of 17 September 2020 (immunogenicity at 1 month after Dose 2 for the BNT162b1 and BNT162b2 vaccine candidates at the 10-µg, 20-µg, and 30-µg dose levels, and up to 7 weeks after Dose 1 at the 100-µg dose level [BNT162b1 only]).
CSR: Interim Report	12 November 2020	Interim data summary of: • Phase 1 results of safety and immunogenicity for BNT162b1 and BNT162b2 in the candidate- and dose level-finding part of the study for each dose level, age group, and vaccine group (data cutoff date 24 August 2020). • Phase 2 primary safety analyses (7 days after Dose 2) for the first 360 participants (180 randomized to active vaccine BNT162b2 and 180 to placebo, and stratified approximately equally between 18 to 55 years and >55 to 85 years) dosed at the commencement of the Phase 2/3 part of the study (data cutoff date 02 September 2020). • Phase 2/3 primary safety analysis (1 month after Dose 2) for the first 6610 participants (data cutoff date 06 October 2020). • Phase 2/3 safety analysis for all 36,855 participants, including the 6610 participant cohort (data cutoff date 06 October 2020, data summarized as is). • Phase 2/3 first successful interim analysis (data cutoff date 04 November 2020) for the primary efficacy analysis of prophylactic BNT162b2 against confirmed COVID-19 among participants without evidence of infection before vaccination 18 to 85 years of age.

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Table 5. Previously Reported Results in C4591001 Phase 1/2/3 Participants

Reports	Date	Scope
CSR: Final Analysis Interim Report	03 December 2020	Interim data summary of: • Phase 1 results of safety and immunogenicity for BNT162b1 and BNT162b2 in the candidate- and dose level-finding part of the study for each dose level, age group, and vaccine group (data cutoff date 24 August 2020) and long-term safety follow-up (approximately 4 months after Dose 2 [as of cutoff date 14 November 2020]) for BNT162b2 30-µg. • Phase 2 primary safety analyses (7 days after Dose 2) for the first 360 participants (180 randomized to active vaccine BNT162b2 and 180 to placebo, and stratified approximately equally between 18 to 55 years and >55 to 85 years) dosed at the commencement of the Phase 2/3 part of the study (data cutoff date 02 September 2020) and long-term safety follow-up (includes at least 2 months of follow-up after Dose 2 [as of the cutoff date of 14 November 2020]). • Phase 2 exploratory immunogenicity analyses for the first 360 participants 1 month after Dose 2 (data cutoff date 12 October 2020) • Phase 2/3 primary safety analysis (1 month after Dose 2) for 37,706 participants who had a median of at least 2 months of follow-up after Dose 2 (data cutoff date 14 November 2020). Safety data are also presented separately for a subset of this cohort of 19,067 participants who had at least 2 months of safety follow-up after Dose 2. • Phase 2/3 safety analysis for all 43,448 participants, including the 37,706 participant cohort (data cutoff date 14 November 2020, data summarized as is). • Phase 2/3 first successful interim analysis (data cutoff date 04 November 2020) for the primary efficacy analysis of prophylactic BNT162b2 against confirmed COVID-19 among participants without evidence of infection before vaccination 18 to 85 years of age, and final efficacy analysis after the accrual of at least 164 cases of confirmed COVID-19 (data cutoff date 14 November 2020) among participants without evidence of infection before vaccination 12 to 91 years of age.

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Table 5. Previously Reported Results in C4591001 Phase 1/2/3 Participants

Reports	Date	Scope
CSR: Interim Report - Adolescents	14 April 2021	Interim descriptive efficacy analyses during blinded placebo-controlled follow-up period conducted on all confirmed COVID-19 cases accrued up to the data cutoff date of 13 March 2021 and interim immunobridging and safety data for the following participant age groups: • Adolescents (12-15 years of age): immunobridging and safety (median ≥2 months follow-up); descriptive efficacy analyses during blinded placebo-controlled follow-up period conducted on all confirmed COVID-19 cases accrued up to the data cutoff date of 13 March 2021 • Young adults (16-25 years of age): reference group for 12-15 years immunogenicity and descriptive safety analysis comparisons • Adults (16-55 years of age): protocol specified 'younger adult' age stratum, to provide reference safety data from analyses of participants with longer-term follow-up.

CSR: Interim Report - 6-Month Update	29 April 2021	Based on a data cutoff date of 31 March 2021, updated efficacy analyses on an accrued 927 COVID-19 cases for the first primary endpoint during blinded follow-up to evaluate duration of protection and the following immunogenicity and safety data:
		• Blinded placebo-controlled follow-up period: from Dose 1 to 1 month after Dose 2 and to the date of unblinding:
		  • Phase 1 follow-up of safety from Dose 1 to the unblinding date (up to approximately 6 months after Dose 2) and immunogenicity 6 months after Dose 2 for the BNT162b2 30-µg group only in participants ≥18 through 55 and 65 through 85 years of age.
		  • Phase 2/3 safety analysis for participants ≥16 years of age, including participants with confirmed stable HIV disease, from Dose 1 to 1 month after Dose 2 (no exposure adjustment because all participants have the same follow-up period) and from Dose 1 to the unblinding date (exposure adjusted).
		• Open-label observational follow-up period: from time of unblinding to the data cutoff date:
		  • Phase 2/3 safety analysis for original BNT162b2 participants ≥16 years of age
		  • Phase 2/3 safety analysis for original placebo participants ≥16 years of age who then received BNT162b2
		• Cumulative safety from Dose 1 to at least 6 months after Dose 2: for Phase 2/3 original BNT162b2 participants ≥16 years of age (inclusive of blinded data and open-label data) that includes at least 3000 in each age group (16 through 55 years of age, >55 years of age)

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Table 5. Previously Reported Results in C4591001 Phase 1/2/3 Participants

Reports	Date	Scope
COVID-19 Case Strain Sequencing Report Study C4591001	04 June 2021	Summary of sequencing data for the SARS-CoV-2 lineages identified among the confirmed COVID-19 cases as of the data cutoff date of 13 March 2021.
Phase 1 Booster (Dose 3) Immunogenicity at 1 Month Post-Dose 3 in Study C4591001: SARS-CoV-2 Wild-Type and Beta Variant Neutralization Data	13 August 2021	Preliminary safety and immunogenicity data for C4591001 Phase 1 participants who completed the two-dose BNT162b2 30 µg series and then received a third (booster) dose of BNT162b2 30 µg, including SARS-CoV-2 serum neutralizing titers against wild-type (USA-WA1/2020) and B.1.351 lineage target strains determined before and after booster vaccination.
CSR: C4591001 Interim Report - BNT162b2 Booster (Dose 3)	23 August 2021	Based on a data cutoff date of 17 June 2021, a summary of safety and immunogenicity data of a third dose of BNT162b2 (30 µg). Reporting includes approximately 300 participants 18 to 55 years of age who were originally randomized to the active vaccine group in Phase 3, completed the original BNT162b2 (30 µg) two-dose series, and were rerandomized to receive a third dose of BNT162b2 (30 µg) approximately 6 months after receiving Dose 2. Analyses include: • Immunobridging analysis for SARS-CoV-2 reference strain of Dose 3 of BNT162b2 30 µg at 1 month after Dose 3 vs 1 month after Dose 2. • Safety analysis of participants of Dose 3 of BNT162b2 30 µg from Dose 3 to the data cutoff date.
CSR: Interim Report - Adolescent 6-Month Update	12 December 2021	Updated descriptive efficacy analyses from 7 days after Dose 2 and the following interim safety data for participants 12 through 15 years of age: • Blinded placebo-controlled follow-up period from Dose 1 to the date of unblinding for BNT162b2 and placebo participants, including new AEs that were reported after the EUA snapshot date (based on events on or after the data cutoff date of 13 March 2021) • Open-label observational follow-up period of original BNT162b2 recipients from the date of unblinding to the data cutoff date • Cumulative safety from Dose 1 to at least 6 months after Dose 2, inclusive of blinded data and open-label data for original BNT162b2 recipients, including new AEs that were reported after the EUA snapshot date • Open-label observational follow-up period for original placebo recipients who then received BNT162b2 from the first dose of BNT162b2 to the data cutoff date

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Table 5. Previously Reported Results in C4591001 Phase 1/2/3 Participants

Reports	Date	Scope
CSR: Interim Report - BNT162b2 (30 µg) Booster (Dose 3) – Phase 1 (4-Month Update) and Phase 3 (6-Month Update)	19 May 2021	Interim analyses of safety and immunogenicity data which includes: • Descriptive analysis of the immune response through 6 months after booster (Dose 3) of BNT162b2 at 30 µg for the SARS-CoV-2 reference strain for Phase 3 participants. • Descriptive analysis of the immune response through 4 months after booster (Dose 3) of BNT162b2 at 30 µg for the SARS-CoV-2 reference strain for Phase 1 participants. • Safety analysis of Phase 3 participants from Dose 3 of BNT162b2 30 µg to 6 months after Dose 3 and to the data cutoff date. • Safety analysis of Phase 1 participants from Dose 3 of BNT162b2 30 µg to approximately 4 months after Dose 3 and to the data cutoff date.
CSR: C4591001 Interim Report - BNT162b2$_{SA}$ VOC Booster Subset	20 May 2022	Safety and immunogenicity data of: • BNT162b2-naïve participants who received 2 dose of BNT162b2$_{SA}$ 30 µg Immunogenicity analysis 1 month after Dose 2 of BNT162b2$_{SA}$ 30 µg compared with 1 month after Dose 2 of BNT162b2 30 µg. Long-term safety analysis of BNT162b2$_{SA}$ 30 µg from Dose 1 to 6 months after Dose 2 and to the data cutoff date. • BNT162b2-experienced participants rerandomized to receive 1 booster dose of BNT162b2 or BNT162b2$_{SA}$ 30 µg at least 6 months after Dose 2 of the 2-dose series of BNT162b2 30 µg Immunogenicity analysis 1 month after Dose 3 of BNT162b2 30 µg or BNT162b2$_{SA}$ 30 µg compared with 1 month after Dose 2 of BNT162b2 30 µg, and 1 month after Dose 3 of BNT162b2$_{SA}$ 30 µg compared with 1 month after Dose 3 of BNT162b2 30 µg. Long-term safety analysis of BNT162b2 30 µg and BNT162b2$_{SA}$ 30 µg from Dose 1 to 6 months after Dose 3. • BNT162b2-experienced participants assigned to receive 2 booster doses of BNT162b2$_{SA}$ 30 µg, approximately 1 month apart Immunogenicity analysis 1 month after the second booster (Dose 4) of BNT162b2$_{SA}$ 30 µg compared with 1 month after Dose 2 of BNT162b2 30 µg. Long-term safety analysis of BNT162b2$_{SA}$ 30 µg from Dose 3 to 5 months after Dose 4.
CSR: Interim Report - 6-Month Analysis – BNT162b2 Booster (Dose 3) – Participants 12 through 15 Years of Age	13 January 2023	Interim safety data (AEs and SAEs) in Phase 3 participants 12 through 15 years of age from Dose 3 of BNT162b2 (30 µg) to 6 months after Dose 3 and to the data cutoff date (Protocol Amendment 18).

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4.1. Phase 1

This part of the study was conducted at 4 sites in the United States (Appendix 16.1.4.1).

4.1.1. Disposition of Participants

4.1.1.1. Disposition of Participants from Dose 1 to Before Booster Dose

Disposition of all randomized Phase 1 participants is presented in Table 6. See Table 5 for interim reporting.

All randomized participants received 2 doses and completed the 1-month post–Dose 2 visit during the blinded, placebo-controlled period. Note that for the BNT162b1 100-µg group, the IRC determined not to administer the second dose of 100 µg to this group of participants due to reactogenicity and as per IRC decision, these participants were instead given Dose 2 of BNT162b1 at the 10-µg dose level.

During the open-label follow-up period, 25.0% to 100.0% of participants originally randomized to receive BNT162b1 or BNT162b2, completed the 6-month post–Dose 2 visit. Most participant withdrawals were due to either no longer meeting eligibility criteria or protocol deviations.

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Table 6. Disposition of All Randomized Subjects – From Dose 1 to Before Booster Dose – Phase 1 Subjects

	Vaccine Group (as Randomized)								
	BNT162b1				BNT162b2				
	10µg (N[a]=24) n[b] (%)	20µg (N[a]=24) n[b] (%)	30µg (N[a]=24) n[b] (%)	100µg (N[a]=12) n[b] (%)	10µg (N[a]=24) n[b] (%)	20µg (N[a]=24) n[b] (%)	30µg (N[a]=24) n[b] (%)	Placebo (N[a]=39) n[b] (%)	Total (N[a]=195) n[b] (%)
Randomized	24 (100.0)	24 (100.0)	24 (100.0)	12 (100.0)	24 (100.0)	24 (100.0)	24 (100.0)	39 (100.0)	195 (100.0)
Not vaccinated	0	0	0	0	0	0	0	0	0
Original blinded, placebo-controlled follow-up period									
Vaccinated	24 (100.0)	24 (100.0)	24 (100.0)	12 (100.0)	24 (100.0)	24 (100.0)	24 (100.0)	39 (100.0)	195 (100.0)
Dose 1	24 (100.0)	24 (100.0)	24 (100.0)	12 (100.0)	24 (100.0)	24 (100.0)	24 (100.0)	39 (100.0)	195 (100.0)
Dose 2	24 (100.0)	24 (100.0)	24 (100.0)	12 (100.0)	24 (100.0)	24 (100.0)	24 (100.0)	39 (100.0)	195 (100.0)
Discontinued from the original blinded, placebo-controlled vaccination period[c]	0	0	0	0	0	0	0	0	0
Unblinded before the 1-month post–Dose 2 visit	0	0	0	0	0	0	0	0	0
Completed the 1-month post–Dose 2 visit	24 (100.0)	24 (100.0)	24 (100.0)	12 (100.0)	24 (100.0)	24 (100.0)	24 (100.0)	39 (100.0)	195 (100.0)
Completed the study	0	0	0	0	0	0	0	0	0
Withdrawn from the study	0	0	0	0	0	0	0	0	0
Open-label follow-up period									
Originally randomized to BNT162b1/BNT162b2	24 (100.0)	24 (100.0)	24 (100.0)	12 (100.0)	24 (100.0)	24 (100.0)	24 (100.0)		
Received Dose 2/unplanned dose	0	0	0	0	0	0	0		
Completed the 1-month post–Dose 2 visit	0	0	0	0	0	0	0		

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Table 6. Disposition of All Randomized Subjects – From Dose 1 to Before Booster Dose – Phase 1 Subjects

	Vaccine Group (as Randomized)								
	BNT162b1				BNT162b2				
	10µg (N[a]=24) n[b] (%)	20µg (N[a]=24) n[b] (%)	30µg (N[a]=24) n[b] (%)	100µg (N[a]=12) n[b] (%)	10µg (N[a]=24) n[b] (%)	20µg (N[a]=24) n[b] (%)	30µg (N[a]=24) n[b] (%)	Placebo (N[a]=39) n[b] (%)	Total (N[a]=195) n[b] (%)
Completed the 6-month post–Dose 2 visit	6 (25.0)	19 (79.2)	8 (33.3)	12 (100.0)	16 (66.7)	12 (50.0)	21 (87.5)		
Withdrawn from the study	3 (12.5)	0	0	3 (25.0)	1 (4.2)	1 (4.2)	0		
Withdrawn before the 6-month post–Dose 2 visit	0	0	0	0	0	0	0		
Withdrawn after the 6-month post–Dose 2 visit	3 (12.5)	0	0	3 (25.0)	1 (4.2)	1 (4.2)	0		
Reason for withdrawal from the study									
Protocol deviation	1 (4.2)	0	0	2 (16.7)	0	1 (4.2)	0		
No longer meets eligibility criteria	2 (8.3)	0	0	1 (8.3)	1 (4.2)	0	0		
Originally randomized to placebo								39 (100.0)	
Withdrawn from the study after unblinding and before receiving BNT162b2								3 (7.7)	
Received first dose of BNT162b2 [30 µg]								35 (89.7)	
Received second dose of BNT162b2 [30 µg]								35 (89.7)	
Discontinued from the open-label vaccination period[c]								0	
Completed the 1-month post–second dose of BNT162b2 visit								35 (89.7)	
Withdrawn from the study								5 (12.8)	
Withdrawn after first dose of BNT162b2 and before second dose of BNT162b2								0	
Withdrawn after second dose of BNT162b2 and before the 1-month post–second dose of BNT162b2 visit								0	
Withdrawn after the 1-month post–second dose of BNT162b2 visit								5 (12.8)	
Reason for withdrawal from the study									
No longer meets eligibility criteria								4 (10.3)	
Protocol deviation								1 (2.6)	

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Table 6. Disposition of All Randomized Subjects – From Dose 1 to Before Booster Dose – Phase 1 Subjects

	Vaccine Group (as Randomized)								
	BNT162b1				BNT162b2				
	10µg (N^a=24) n^b (%)	20µg (N^a=24) n^b (%)	30µg (N^a=24) n^b (%)	100µg (N^a=12) n^b (%)	10µg (N^a=24) n^b (%)	20µg (N^a=24) n^b (%)	30µg (N^a=24) n^b (%)	Placebo (N^a=39) n^b (%)	Total (N^a=195) n^b (%)

a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Original blinded, placebo-controlled vaccination period: from Dose 1 to the 1-month post–Dose 2 visit.
d. Open-label vaccination period: from first dose of BNT162b2 [30 µg] to the 1-month post–second dose of BNT162b2 [30 µg] visit.
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4.1.1.2. Disposition of Participants Who Received Booster Dose of BNT162b2

Disposition of all Phase 1 participants who received the first booster dose (Dose 3) of BNT162b2 (30 µg) and an additional booster dose (Dose 4) of BNT162b2 (30 µg) is presented in Table 7. See Table 5 for interim reporting.

Among the participants in BNT162b1, BNT162b2, and placebo groups who received the first booster (Dose 3), all completed the first booster vaccination period except for the BNT162b1 100-µg dose group, with 88.9% of participants in this group completing the first booster vaccination period.

As part of protocol amendment 19, participants in the 10-µg, 20-µg, and 30-µg dose groups who received a first booster dose of BNT162b2 30 µg were eligible to receive an additional booster vaccination (Dose 4). Of the eligible participants, 42.9% to 69.6% received the additional booster vaccination and completed the additional booster vaccination period.

Overall, the most frequent reasons for withdrawals were protocol deviations or no longer meeting eligibility criteria.

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Table 7. Disposition of Subjects – Phase 1 – Subjects Who Received Booster Dose of BNT162b2 (30 µg)

	Initial Vaccine Group (as Administered)								
	BNT162b1				BNT162b2				
	10µg (N[a]=21) n[b] (%)	20µg (N[a]=24) n[b] (%)	30µg (N[a]=24) n[b] (%)	100µg (N[a]=9) n[b] (%)	10µg (N[a]=22) n[b] (%)	20µg (N[a]=23) n[b] (%)	30µg (N[a]=24) n[b] (%)	Placebo (N[a]=28) n[b] (%)	Total (N[a]=175) n[b] (%)
Received the first booster vaccination	21 (100.0)	24 (100.0)	24 (100.0)	9 (100.0)	22 (100.0)	23 (100.0)	24 (100.0)	28 (100.0)	175 (100.0)
Completed the first booster vaccination period[c]	21 (100.0)	24 (100.0)	24 (100.0)	8 (88.9)	22 (100.0)	23 (100.0)	24 (100.0)	28 (100.0)	174 (99.4)
Received the additional booster vaccination	9 (42.9)	13 (54.2)	13 (54.2)	0	14 (63.6)	16 (69.6)	15 (62.5)	0	80 (45.7)
Completed the additional booster vaccination period[d]	9 (42.9)	13 (54.2)	12 (50.0)	0	14 (63.6)	16 (69.6)	15 (62.5)	0	79 (45.1)
Completed the 6-month post–additional booster vaccination visit	0	0	0	0	0	0	0	0	0
Completed the study	14 (66.7)	18 (75.0)	13 (54.2)	8 (88.9)	19 (86.4)	19 (82.6)	16 (66.7)	20 (71.4)	127 (72.6)
Withdrawn from the study	7 (33.3)	6 (25.0)	11 (45.8)	1 (11.1)	3 (13.6)	4 (17.4)	8 (33.3)	8 (28.6)	48 (27.4)
Withdrawn after the first booster vaccination and before the 1-month post–first booster vaccination visit	0	0	0	1 (11.1)	0	0	0	0	1 (0.6)
Withdrawn after the 1-month post–first booster vaccination visit and before the additional booster vaccination visit	6 (28.6)	6 (25.0)	9 (37.5)	0	3 (13.6)	2 (8.7)	6 (25.0)	8 (28.6)	40 (22.9)
Withdrawn after the additional booster vaccination visit	1 (4.8)	0	2 (8.3)	0	0	2 (8.7)	2 (8.3)	0	7 (4.0)
Reason for withdrawal									
Protocol deviation	4 (19.0)	5 (20.8)	4 (16.7)	0	0	2 (8.7)	2 (8.3)	4 (14.3)	21 (12.0)
No longer meets eligibility criteria	3 (14.3)	0	5 (20.8)	0	2 (9.1)	1 (4.3)	4 (16.7)	2 (7.1)	17 (9.7)
Withdrawal by subject	0	1 (4.2)	2 (8.3)	0	0	0	0	1 (3.6)	4 (2.3)
Lost to follow-up	0	0	0	1 (11.1)	0	0	1 (4.2)	0	2 (1.1)
Other	0	0	0	0	1 (4.5)	1 (4.3)	1 (4.2)	1 (3.6)	4 (2.3)

Table 7. Disposition of Subjects – Phase 1 – Subjects Who Received Booster Dose of BNT162b2 (30 µg)

	Initial Vaccine Group (as Administered)								
	BNT162b1				BNT162b2				
	10µg (N[a]=21) n[b] (%)	20µg (N[a]=24) n[b] (%)	30µg (N[a]=24) n[b] (%)	100µg (N[a]=9) n[b] (%)	10µg (N[a]=22) n[b] (%)	20µg (N[a]=23) n[b] (%)	30µg (N[a]=24) n[b] (%)	Placebo (N[a]=28) n[b] (%)	Total (N[a]=175) n[b] (%)

a. N = number of assigned subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. First booster vaccination period: from the first booster vaccination to the 1-month follow-up visit after the first booster vaccination.
d. Additional booster vaccination period: from the additional booster vaccination to the 1-month follow-up visit after the additional booster vaccination.
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4.1.2. Important Protocol Deviations

PDs were identified throughout the study by monitoring of informed consent documentation, source documents, and other clinical trial-related documents. In addition, PDs were identified by remote monitoring of electronic CRFs, and review of the project databases (interactive response technology, clinical and safety databases, vendor database for e-diary data, and programmatic output from the clinical database). All PDs were documented in a designated clinical trial management system.

Appendix 16.2.2.1 includes important PDs in all participants in the Phase 1 groups listed in this final report that may have significantly impacted the completeness, accuracy, and/or reliability of the study data or that may have significantly affected a participant's rights, safety, or well-being.

A formal acknowledgment by the study team was made that deviations were reviewed and GCP compliance was maintained.

Important PDs can be found in the following:

Important Protocol Deviations After the First Booster Dose – Phase 1 – Subjects Who Received the First Booster Dose of BNT162b2 (30 µg) – Booster Safety Population	Supplemental Table 14.1
Important Protocol Deviations After the Additional Booster Dose – Phase 1 – Subjects Who Received the Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population	Supplemental Table 14.2

4.1.3. Populations Analyzed

The BNT162b2 booster safety population for placebo, BNT162b1, and BNT162b2 dose groups is presented in Table 8. See Table 5 for interim reporting.

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Table 8. Booster Safety Population – Phase 1 – Subjects Who Received Booster Dose of BNT162b2 (30 µg)

	Initial Vaccine Group (as Administered)							
	BNT162b1				BNT162b2			
	10µg n[a] (%)	20µg n[a] (%)	30µg n[a] (%)	100µg n[a] (%)	10µg n[a] (%)	20µg n[a] (%)	30µg n[a] (%)	Placebo n[a] (%)
Received the first booster vaccination[b]	21	24	24	9	22	23	24	28
BNT162b2 (30 µg)	21 (100.0)	24 (100.0)	24 (100.0)	9 (100.0)	22 (100.0)	23 (100.0)	24 (100.0)	28 (100.0)
Received the additional booster vaccination	9 (42.9)	13 (54.2)	13 (54.2)	0	14 (63.6)	16 (69.6)	15 (62.5)	0
Booster safety population	21 (100.0)	24 (100.0)	24 (100.0)	9 (100.0)	22 (100.0)	23 (100.0)	24 (100.0)	28 (100.0)

a. n = Number of subjects with the specified characteristic.
b. This value is the denominator for the percentage calculations.
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Median follow-up time for participants that received the first booster vaccination to the end of the study ranged from 12.3 to 21.4 months and 5.3 to 6.4 months for the additional booster vaccination to the end of the study (Table 9).

Table 9. Follow-up Time After Booster Dose – Phase 1 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Initial Vaccine Group (as Administered)							
	BNT162b1				BNT162b2			
	10µg n[a] (%)	20µg n[a] (%)	30µg n[a] (%)	100µg n[a] (%)	10µg n[a] (%)	20µg n[a] (%)	30µg n[a] (%)	Placebo n[a] (%)
Total exposure from the additional booster vaccination to the end of study								
Received the additional booster vaccination[b]	9	13	13	0	14	16	15	0
<3 Months	0	0	1 (7.7)		0	0	0	
≥3-<6 Months	9 (100.0)	13 (100.0)	12 (92.3)		1 (7.1)	1 (6.3)	1 (6.7)	
≥6 Months	0	0	0		13 (92.9)	15 (93.8)	14 (93.3)	
Mean (SD)	5.5 (0.29)	5.6 (0.25)	5.0 (1.22)		6.3 (0.34)	6.3 (0.25)	6.3 (0.41)	
Median	5.6	5.7	5.3		6.3	6.4	6.4	
Min, max	(5.0, 5.9)	(5.3, 6.0)	(1.1, 5.8)		(5.3, 6.7)	(5.6, 6.5)	(4.9, 6.5)	
Total exposure from the first booster vaccination to the end of study								
Received the first booster vaccination[b]	21	24	24	9	22	23	24	28
<12 Months	4 (19.0)	1 (4.2)	1 (4.2)	2 (22.2)	0	1 (4.3)	4 (16.7)	9 (32.1)
≥12-<15 Months	3 (14.3)	5 (20.8)	5 (20.8)	7 (77.8)	2 (9.1)	1 (4.3)	2 (8.3)	19 (67.9)
≥15-<18 Months	5 (23.8)	5 (20.8)	6 (25.0)	0	6 (27.3)	5 (21.7)	2 (8.3)	0
≥18-<21 Months	8 (38.1)	13 (54.2)	12 (50.0)	0	0	0	2 (8.3)	0
≥21 Months	1 (4.8)	0	0	0	14 (63.6)	16 (69.6)	14 (58.3)	0
Mean (SD)	16.7 (4.07)	18.1 (3.30)	17.7 (3.31)	11.1 (3.02)	19.8 (2.73)	19.7 (4.07)	18.4 (4.98)	11.1 (2.52)
Median	17.0	20.4	18.6	12.3	21.2	21.4	21.4	12.4
Min, max	(8.6, 21.5)	(9.9, 20.8)	(9.5, 20.8)	(3.3, 12.8)	(14.3, 22.3)	(4.1, 22.3)	(5.7, 22.3)	(6.0, 13.5)

a. n = Number of subjects with the specified characteristic.
b. This value is the denominator for the percentage calculations for the subcategories.
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4.1.4. Demographic and Other Baseline Characteristics

Demographic characteristics of participants in Phase 1 who received the first booster dose of BNT162b2 (30 µg) are shown in Table 10. Demographic characteristics for Phase 1 participants who received the additional booster dose were similar to those participants that received the first booster dose (Supplemental Table 14.3).

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Table 10. Demographic Characteristics – Phase 1 – Subjects Who Received the First Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Initial Vaccine Group (as Administered)								
	BNT162b1				BNT162b2				
	10µg (N[a]=21) n[b] (%)	20µg (N[a]=24) n[b] (%)	30µg (N[a]=24) n[b] (%)	100µg (N[a]=9) n[b] (%)	10µg (N[a]=22) n[b] (%)	20µg (N[a]=23) n[b] (%)	30µg (N[a]=24) n[b] (%)	Placebo (N[a]=28) n[b] (%)	Total (N[a]=175) n[b] (%)
Sex									
Male	9 (42.9)	13 (54.2)	10 (41.7)	3 (33.3)	5 (22.7)	11 (47.8)	9 (37.5)	12 (42.9)	72 (41.1)
Female	12 (57.1)	11 (45.8)	14 (58.3)	6 (66.7)	17 (77.3)	12 (52.2)	15 (62.5)	16 (57.1)	103 (58.9)
Race									
White	17 (81.0)	22 (91.7)	20 (83.3)	8 (88.9)	21 (95.5)	21 (91.3)	21 (87.5)	28 (100.0)	158 (90.3)
Black or African American	1 (4.8)	2 (8.3)	0	0	0	2 (8.7)	1 (4.2)	0	6 (3.4)
Asian	3 (14.3)	0	4 (16.7)	1 (11.1)	1 (4.5)	0	2 (8.3)	0	11 (6.3)
Ethnicity									
Hispanic/Latino	1 (4.8)	0	1 (4.2)	0	0	0	0	0	2 (1.1)
Non-Hispanic/non-Latino	20 (95.2)	24 (100.0)	22 (91.7)	9 (100.0)	22 (100.0)	23 (100.0)	24 (100.0)	28 (100.0)	172 (98.3)
Not reported	0	0	1 (4.2)	0	0	0	0	0	1 (0.6)
Country									
USA	21 (100.0)	24 (100.0)	24 (100.0)	9 (100.0)	22 (100.0)	23 (100.0)	24 (100.0)	28 (100.0)	175 (100.0)
Age at booster vaccination (years)									
Mean (SD)	49.1 (20.89)	58.4 (14.95)	53.6 (18.71)	39.7 (10.48)	55.6 (16.99)	56.1 (18.26)	53.8 (17.33)	55.1 (17.82)	53.9 (17.73)
Median	42.0	60.5	59.0	37.0	66.0	65.0	60.0	60.5	54.0
Min, max	(25, 83)	(31, 82)	(24, 77)	(26, 54)	(22, 74)	(24, 82)	(24, 75)	(20, 78)	(20, 83)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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4.1.5. Concomitant Therapy

Concomitant vaccines received after the booster doses during the study are reported in the following:

Nonstudy Vaccines Received After the First Booster Dose – Phase 1 – Subjects Who Received the First Booster Dose of BNT162b2 (30 µg) – Booster Safety Population	Supplemental Table 14.4
Nonstudy Vaccines Received After the Additional Booster Dose – Phase 1 – Subjects Who Received the Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population	Supplemental Table 14.5

4.1.6. Exposure

Participants who received the first and additional booster vaccinations of BNT162b2 (30 µg) are presented in (Table 11). See Table 5 for interim reporting.

For the BNT162b1, BNT162b2, and placebo groups, the median time between Dose 2 and the first booster vaccination ranged from 8.3 to 15.5 months. Other than the BNT162b1 100-µg dose group, most participants received the booster dose of BNT162b2 either <9 months after Dose 2 or ≥9 to <12 months after Dose 2. All participants receiving the booster dose in the BNT162b1 100-µg dose group received the first booster vaccination ≥15 to <18 months after Dose 2.

For participants in the BNT162b1 and BNT162b2 dose groups who received the additional booster vaccination, the median time between the first booster vaccination and the additional booster vaccination ranged from 14.9 to 15.7 months. Most participants received the additional booster dose of BNT162b2 ≥15 to <18 months after the first booster vaccination.

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Table 11. Vaccine Administration Timing – Phase 1 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Initial Vaccine Group (as Administered)							
	BNT162b1				BNT162b2			
	10µg n[a] (%)	20µg n[a] (%)	30µg n[a] (%)	100µg n[a] (%)	10µg n[a] (%)	20µg n[a] (%)	30µg n[a] (%)	Placebo n[a] (%)
First booster vaccination[b]								
N[c]	21	24	24	9	22	23	24	28
<9 Months	3 (14.3)	24 (100.0)	12 (50.0)	0	21 (95.5)	22 (95.7)	23 (95.8)	3 (10.7)
≥9-<12 Months	18 (85.7)	0	12 (50.0)	0	1 (4.5)	1 (4.3)	0	24 (85.7)
≥12-<15 Months	0	0	0	0	0	0	0	1 (3.6)
≥15-<18 Months	0	0	0	9 (100.0)	0	0	0	0
≥18-<21 Months	0	0	0	0	0	0	1 (4.2)	0
Mean (SD)	9.6 (0.67)	8.5 (0.28)	9.3 (0.60)	15.8 (0.63)	8.5 (0.56)	8.4 (0.18)	8.7 (2.21)	9.7 (0.82)
Median	10.0	8.5	9.2	15.5	8.4	8.4	8.3	9.4
Min, max	(8.8, 10.8)	(8.0, 8.8)	(8.5, 10.1)	(15.3, 17.3)	(7.8, 10.3)	(8.3, 9.0)	(7.9, 19.0)	(8.7, 12.3)
Additional booster vaccination[d]								
N[c]	9	13	13	0	14	16	15	0
<15 Months	4 (44.4)	7 (53.8)	3 (23.1)		4 (28.6)	0	1 (6.7)	
≥15-<18 Months	5 (55.6)	6 (46.2)	10 (76.9)		10 (71.4)	16 (100.0)	14 (93.3)	
Mean (SD)	15.1 (0.43)	15.0 (0.23)	15.3 (0.36)		15.4 (0.46)	15.4 (0.34)	15.5 (0.40)	
Median	15.0	14.9	15.3		15.6	15.6	15.7	
Min, max	(14.7, 15.9)	(14.7, 15.3)	(14.8, 15.8)		(14.8, 16.0)	(15.0, 15.9)	(14.8, 15.9)	

a. n = Number of subjects with the specified characteristic.
b. Months calculated since the second dose of BNT162b1/BNT162b2.
c. This value is the denominator for the percentage calculations of the subcategories.
d. Months calculated since the first booster dose of BNT162b2.

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4.2. Phase 2/3

This part of the study was conducted at 153 sites in the United States, Brazil, Argentina, Germany, South Africa, and Turkey (Appendix 16.1.4.1).

4.2.1. Disposition of Participants

4.2.1.1. Disposition of Participants from Dose 1 of BNT162b2 30 µg to Before Booster Dose

Final disposition of all randomized Phase 2/3 participants 12 through 15 years of age and ≥16 years of age is presented in Table 12 for the blinded placebo-controlled and open-label follow-up periods. See Table 5 for interim reporting.

Final disposition of all randomized Phase 2/3 HIV-positive participants is presented in Table 13 for the blinded placebo-controlled and open-label follow-up periods.

The following is noted for these participants:

- Individuals 12 through 15 years of age and ≥ 16 years of age were unblinded as they became locally eligible and wished to know their vaccine assignment to confirm prior vaccination with BNT162b2 (if randomized to this group), or to receive BNT162b2 (if randomized to placebo). Unblinded recipients originally randomized to BNT162b2 were followed in an open-label manner. Unblinded recipients originally randomized to placebo were offered BNT162b2 vaccination (Doses 3 and 4 [first and second dose of BNT162b2 30 µg, respectively]) and were also followed in an open-label manner.
- Seventeen participants were inadvertently enrolled at multiple sites (see Appendix 16.2.1.2 for further details) and they were excluded from all data summaries.

Participants 12 Through 15 Years of Age

During the blinded placebo-controlled follow-up period, most participants 12 through 15 years of age that were randomized to the BNT162b2 and placebo groups received Doses 1 and 2 (Table 12). There were 3 participants (0.3%) in the BNT162b2 group and 14 participants (1.2%) in the placebo group who discontinued from the vaccination period (Dose 1 to the 1-month post–Dose 2 visit). Most participants completed the 1-month post-Dose 2 visit (≥97.8%). Few participants in the BNT162b2 and placebo groups were withdrawn from the study (0.8% and 1.5%, respectively), and all were because of withdrawal by the participant, withdrawal by parent/guardian, being lost to follow-up, other reasons, or participant no longer meeting eligibility criteria.

During the open-label follow-up period, 402 participants (35.4%) 12 through 15 years of age in the BNT162b2 group and 235 participants (20.8%) in the placebo group withdrew from the study, mostly due to other reasons or no longer meeting eligibility criteria (Appendix 16.2.1.1).

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Participants ≥16 Years of Age

During the blinded placebo-controlled follow-up period most participants ≥16 years of age that were randomized to the BNT162b2 and placebo groups received Doses 1 and 2 (Table 12). There were 335 participants (1.5%) in the BNT162b2 group and 527 participants (2.4%) in the placebo group who discontinued from the vaccination period (Dose 1 to the 1-month post–Dose 2 visit). Most participants completed the 1-month post-Dose 2 visit (≥97.1%). Few participants in the BNT162b2 and placebo groups were withdrawn from the study (2.2% and 1.9%, respectively), and most were due to withdrawals by the participant or being lost to follow-up.

During the open-label follow-up period, 11,764 participants (53.3%) ≥16 years of age in the BNT162b2 group and 5158 participants (23.4%) in the placebo group withdrew from the study, and the most common reason for withdrawal was due to other reasons (Appendix 16.2.1.1).

Participants With Confirmed Stable HIV Disease

During the blinded placebo-controlled follow-up period, most HIV-positive participants randomized to the BNT162b2 and placebo groups received Doses 1 and 2 (Table 13). There were 4 participants (4.0%) in the BNT162b2 group and 4 participants (4.0%) in the placebo group who discontinued from the vaccination period (Dose 1 to 1 month after Dose 2). Most participants completed the 1-month post–Dose 2 visit (≥97.0%). Few participants in the BNT162b2 and placebo groups were withdrawn from the study (2.0% and 4.0%, respectively). The reasons were withdrawal by the participant, lost to follow-up, and death.

In the BNT162b2 (30 µg) group, during the open-label follow-up period, there were 58 participants (58.0%) withdrawn from the study, and most were due to other reasons.

In the placebo group, during the open-label follow-up period, most participants originally randomized to placebo received Doses 1 and 2 (89.1% and 88.1%, respectively) of BNT162b2. There were 19 participants (18.8%) in this group who were withdrawn from the study. The most common reason was “other” (Appendix 16.2.1.1).

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Table 12. Disposition of All Randomized Subjects – From Dose 1 to Before Booster Dose – Phase 2/3 Subjects

	Vaccine Group (as Randomized)				
	12-15 Years		≥16 Years		
	BNT162b2 (30 µg) (N[a]=1134) n[b] (%)	Placebo (N[a]=1130) n[b] (%)	BNT162b2 (30 µg) (N[a]=22071) n[b] (%)	Placebo (N[a]=22071) n[b] (%)	Total (N[a]=46406) n[b] (%)
Randomized	1134 (100.0)	1130 (100.0)	22071 (100.0)	22071 (100.0)	46406 (100.0)
Not vaccinated	3 (0.3)	1 (0.1)	55 (0.2)	48 (0.2)	107 (0.2)
Original blinded, placebo-controlled follow-up period					
Vaccinated	1131 (99.7)	1129 (99.9)	22016 (99.8)	22021 (99.8)	46297 (99.8)
Dose 1	1131 (99.7)	1129 (99.9)	22016 (99.8)	22021 (99.8)	46297 (99.8)
Dose 2	1124 (99.1)	1119 (99.0)	21661 (98.1)	21641 (98.1)	45545 (98.1)
Discontinued from the original blinded, placebo-controlled vaccination period[c]	3 (0.3)	14 (1.2)	335 (1.5)	527 (2.4)	879 (1.9)
Reason for discontinuation					
Lost to follow-up	0	0	156 (0.7)	152 (0.7)	308 (0.7)
Withdrawal by subject	0	1 (0.1)	107 (0.5)	181 (0.8)	289 (0.6)
No longer meets eligibility criteria	0	7 (0.6)	14 (0.1)	121 (0.5)	142 (0.3)
Adverse event	1 (0.1)	0	22 (0.1)	25 (0.1)	48 (0.1)
Physician decision	1 (0.1)	0	5 (0.0)	8 (0.0)	14 (0.0)
Protocol deviation	0	2 (0.2)	3 (0.0)	8 (0.0)	13 (0.0)
Pregnancy	0	0	4 (0.0)	6 (0.0)	10 (0.0)
Death	0	0	3 (0.0)	4 (0.0)	7 (0.0)
Medication error without associated adverse event	0	0	3 (0.0)	1 (0.0)	4 (0.0)
Withdrawal by parent/guardian	0	1 (0.1)	1 (0.0)	0	2 (0.0)
Other	1 (0.1)	3 (0.3)	17 (0.1)	21 (0.1)	42 (0.1)
Unblinded before the 1-month post–Dose 2 visit	12 (1.1)	21 (1.9)	262 (1.2)	245 (1.1)	540 (1.2)

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Table 12. Disposition of All Randomized Subjects – From Dose 1 to Before Booster Dose – Phase 2/3 Subjects

	Vaccine Group (as Randomized)				
	12-15 Years		≥16 Years		
	BNT162b2 (30 µg) (N[a]=1134) n[b] (%)	Placebo (N[a]=1130) n[b] (%)	BNT162b2 (30 µg) (N[a]=22071) n[b] (%)	Placebo (N[a]=22071) n[b] (%)	Total (N[a]=46406) n[b] (%)
Completed the 1-month post–Dose 2 visit	1119 (98.7)	1105 (97.8)	21473 (97.3)	21423 (97.1)	45120 (97.2)
Completed the study	3 (0.3)	2 (0.2)	21 (0.1)	37 (0.2)	63 (0.1)
Withdrawn from the study	9 (0.8)	17 (1.5)	495 (2.2)	635 (2.9)	1156 (2.5)
Withdrawn after Dose 1 and before Dose 2	0	0	186 (0.8)	217 (1.0)	403 (0.9)
Withdrawn after Dose 2 and before the 1-month post–Dose 2 visit	0	3 (0.3)	103 (0.5)	145 (0.7)	251 (0.5)
Withdrawn after the 1-month post–Dose 2 visit	9 (0.8)	14 (1.2)	206 (0.9)	273 (1.2)	502 (1.1)
Reason for withdrawal from the study					
Lost to follow-up	4 (0.4)	2 (0.2)	256 (1.2)	281 (1.3)	543 (1.2)
Withdrawal by subject	1 (0.1)	7 (0.6)	139 (0.6)	250 (1.1)	397 (0.9)
Protocol deviation	0	0	15 (0.1)	39 (0.2)	54 (0.1)
No longer meets eligibility criteria	0	2 (0.2)	16 (0.1)	21 (0.1)	39 (0.1)
Death	0	0	18 (0.1)	16 (0.1)	34 (0.1)
Adverse event	0	0	9 (0.0)	9 (0.0)	18 (0.0)
Physician decision	0	0	5 (0.0)	7 (0.0)	12 (0.0)
Withdrawal by parent/guardian	1 (0.1)	5 (0.4)	1 (0.0)	0	7 (0.0)
Refused further study procedures	0	0	2 (0.0)	0	2 (0.0)
Pregnancy	0	0	0	1 (0.0)	1 (0.0)
Medication error without associated adverse event	0	0	1 (0.0)	0	1 (0.0)
Other	3 (0.3)	1 (0.1)	33 (0.1)	11 (0.0)	48 (0.1)
Open-label follow-up period					
Originally randomized to BNT162b2	1119 (98.7)		21500 (97.4)		
Received Dose 2/unplanned dose	4 (0.4)		139 (0.6)		
Completed the 1-month post–Dose 2 visit	12 (1.1)		233 (1.1)		
Completed the 6-month post–Dose 2 visit	1003 (88.4)		20760 (94.1)		

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Table 12. Disposition of All Randomized Subjects – From Dose 1 to Before Booster Dose – Phase 2/3 Subjects

	Vaccine Group (as Randomized)				
	12-15 Years		≥16 Years		
	BNT162b2 (30 µg) (N[a]=1134) n[b] (%)	Placebo (N[a]=1130) n[b] (%)	BNT162b2 (30 µg) (N[a]=22071) n[b] (%)	Placebo (N[a]=22071) n[b] (%)	Total (N[a]=46406) n[b] (%)
Withdrawn from the study	402 (35.4)		11764 (53.3)		
Withdrawn before the 6-month post–Dose 2 visit	31 (2.7)		402 (1.8)		
Withdrawn after the 6-month post–Dose 2 visit	371 (32.7)		11362 (51.5)		
Reason for withdrawal from the study					
No longer meets eligibility criteria	106 (9.3)		796 (3.6)		
Withdrawal by subject	41 (3.6)		730 (3.3)		
Lost to follow-up	30 (2.6)		623 (2.8)		
Protocol deviation	21 (1.9)		493 (2.2)		
Death	0		43 (0.2)		
Physician decision	0		27 (0.1)		
Withdrawal by parent/guardian	14 (1.2)		2 (0.0)		
Refused further study procedures	0		7 (0.0)		
Adverse event	0		4 (0.0)		
Pregnancy	0		1 (0.0)		
Other	190 (16.8)		9038 (40.9)		
Originally randomized to placebo		1110 (98.2)		21351 (96.7)	
Withdrawn from the study after unblinding and before receiving BNT162b2		81 (7.2)		871 (3.9)	
Received first dose of BNT162b2 [30 µg]		1014 (89.7)		20358 (92.2)	
Received second dose of BNT162b2 [30 µg]		1001 (88.6)		20280 (91.9)	
Discontinued from the open-label vaccination period[d]		13 (1.2)		168 (0.8)	
Reason for discontinuation from the open-label vaccination period					
Lost to follow-up		2 (0.2)		89 (0.4)	
Withdrawal by subject		2 (0.2)		31 (0.1)	
Protocol deviation		6 (0.5)		14 (0.1)	

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Table 12. Disposition of All Randomized Subjects – From Dose 1 to Before Booster Dose – Phase 2/3 Subjects

	Vaccine Group (as Randomized)				
	12-15 Years		≥16 Years		
	BNT162b2 (30 µg) (N[a]=1134) n[b] (%)	Placebo (N[a]=1130) n[b] (%)	BNT162b2 (30 µg) (N[a]=22071) n[b] (%)	Placebo (N[a]=22071) n[b] (%)	Total (N[a]=46406) n[b] (%)
No longer meets eligibility criteria		0		10 (0.0)	
Adverse event		0		6 (0.0)	
Death		0		3 (0.0)	
Physician decision		0		3 (0.0)	
Pregnancy		0		1 (0.0)	
Refused further study procedures		1 (0.1)		0	
Other		2 (0.2)		11 (0.0)	
Completed the 1-month post–second dose of BNT162b2 visit		1001 (88.6)		20162 (91.4)	
Withdrawn from the study		235 (20.8)		5158 (23.4)	
Withdrawn after first dose of BNT162b2 and before second dose of BNT162b2		10 (0.9)		72 (0.3)	
Withdrawn after second dose of BNT162b2 and before the 1-month post–second dose of BNT162b2 visit		3 (0.3)		96 (0.4)	
Withdrawn after the 1-month post–second dose of BNT162b2 visit		222 (19.6)		4990 (22.6)	
Reason for withdrawal from the study					
No longer meets eligibility criteria		96 (8.5)		1345 (6.1)	
Lost to follow-up		31 (2.7)		638 (2.9)	
Withdrawal by subject		23 (2.0)		535 (2.4)	
Protocol deviation		15 (1.3)		530 (2.4)	
Death		1 (0.1)		38 (0.2)	
Physician decision		0		20 (0.1)	
Refused further study procedures		0		5 (0.0)	
Adverse event		0		3 (0.0)	
Withdrawal by parent/guardian		3 (0.3)		0	
Pregnancy		0		1 (0.0)	

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Table 12. Disposition of All Randomized Subjects – From Dose 1 to Before Booster Dose – Phase 2/3 Subjects

	Vaccine Group (as Randomized)				
	12-15 Years		≥16 Years		
	BNT162b2 (30 µg) (N[a]=1134) n[b] (%)	Placebo (N[a]=1130) n[b] (%)	BNT162b2 (30 µg) (N[a]=22071) n[b] (%)	Placebo (N[a]=22071) n[b] (%)	Total (N[a]=46406) n[b] (%)
Other		66 (5.8)		2043 (9.3)	

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
Note: Subjects randomized but did not sign informed consent or had a significant quality event due to lack of PI oversight are not included in any analysis population.
Note: Because of a dosing error, four subjects received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving 1 dose of BNT162b2 (30 µg) and 1 dose of placebo. Two subjects received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving 2 doses of BNT162b2 (30 µg).
a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Original blinded, placebo-controlled vaccination period: from Dose 1 to the 1-month post–Dose 2 visit. Subjects who missed the 1-month post–Dose 2 visit but completed subsequent visits were considered as completed vaccination period as well.
d. Open-label vaccination period: from first dose of BNT162b2 [30 µg] to the 1-month post–second dose of BNT162b2 [30 µg] visit. Subjects who missed the 1-month post–second dose of BNT162b2 [30 µg] visit but completed subsequent visits were considered as completed open-label vaccination period as well.
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Table 13. Disposition of All Randomized Subjects – From Dose 1 to Before Booster Dose – Phase 2/3 – HIV-Positive Subjects

	Vaccine Group (as Randomized)		
	≥16 Years		
	BNT162b2 (30 µg) (N^a=100) n^b (%)	Placebo (N^a=101) n^b (%)	Total (N^a=201) n^b (%)
Randomized	100 (100.0)	101 (100.0)	201 (100.0)
Not vaccinated	0	0	0
Original blinded, placebo-controlled follow-up period			
Vaccinated	100 (100.0)	101 (100.0)	201 (100.0)
Dose 1	100 (100.0)	101 (100.0)	201 (100.0)
Dose 2	96 (96.0)	97 (96.0)	193 (96.0)
Discontinued from the original blinded, placebo-controlled vaccination period[c]	4 (4.0)	4 (4.0)	8 (4.0)
Reason for discontinuation			
Lost to follow-up	1 (1.0)	2 (2.0)	3 (1.5)
No longer meets eligibility criteria	2 (2.0)	1 (1.0)	3 (1.5)
Pregnancy	1 (1.0)	0	1 (0.5)
Withdrawal by subject	0	1 (1.0)	1 (0.5)
Unblinded before the 1-month post–Dose 2 visit	1 (1.0)	0	1 (0.5)
Completed the 1-month post–Dose 2 visit	98 (98.0)	98 (97.0)	196 (97.5)
Completed the study	2 (2.0)	0	2 (1.0)
Withdrawn from the study	2 (2.0)	4 (4.0)	6 (3.0)
Withdrawn after Dose 1 and before Dose 2	1 (1.0)	3 (3.0)	4 (2.0)
Withdrawn after Dose 2 and before the 1-month post–Dose 2 visit	0	0	0
Withdrawn after the 1-month post–Dose 2 visit	1 (1.0)	1 (1.0)	2 (1.0)
Reason for withdrawal from the study			
Lost to follow-up	1 (1.0)	2 (2.0)	3 (1.5)

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Table 13. Disposition of All Randomized Subjects – From Dose 1 to Before Booster Dose – Phase 2/3 – HIV-Positive Subjects

	Vaccine Group (as Randomized)		
	≥16 Years		
	BNT162b2 (30 µg) (N^a=100) n^b (%)	Placebo (N^a=101) n^b (%)	Total (N^a=201) n^b (%)
Death	1 (1.0)	1 (1.0)	2 (1.0)
Withdrawal by subject	0	1 (1.0)	1 (0.5)
Open-label follow-up period			
Originally randomized to BNT162b2	96 (96.0)		
Received Dose 2/unplanned dose	0		
Completed the 1-month post–Dose 2 visit	1 (1.0)		
Completed the 6-month post–Dose 2 visit	88 (88.0)		
Withdrawn from the study	58 (58.0)		
Withdrawn before the 6-month post–Dose 2 visit	3 (3.0)		
Withdrawn after the 6-month post–Dose 2 visit	55 (55.0)		
Reason for withdrawal from the study			
Withdrawal by subject	7 (7.0)		
Lost to follow-up	3 (3.0)		
Protocol deviation	2 (2.0)		
No longer meets eligibility criteria	1 (1.0)		
Other	45 (45.0)		
Originally randomized to placebo		97 (96.0)	
Withdrawn from the study after unblinding and before receiving BNT162b2		6 (5.9)	
Received first dose of BNT162b2 [30 µg]		90 (89.1)	
Received second dose of BNT162b2 [30 µg]		89 (88.1)	
Discontinued from the open-label vaccination period[d]		1 (1.0)	
Reason for discontinuation from the open-label vaccination period			
Withdrawal by subject		1 (1.0)	

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Table 13. Disposition of All Randomized Subjects – From Dose 1 to Before Booster Dose – Phase 2/3 – HIV-Positive Subjects

	Vaccine Group (as Randomized)		
	≥16 Years		
	BNT162b2 (30 µg) (N[a]=100) n[b] (%)	Placebo (N[a]=101) n[b] (%)	Total (N[a]=201) n[b] (%)
Completed the 1-month post–second dose of BNT162b2 visit		89 (88.1)	
Withdrawn from the study		19 (18.8)	
Withdrawn after first dose of BNT162b2 and before second dose of BNT162b2		1 (1.0)	
Withdrawn after second dose of BNT162b2 and before the 1-month post–second dose of BNT162b2 visit		0	
Withdrawn after the 1-month post–second dose of BNT162b2 visit		18 (17.8)	
Reason for withdrawal from the study			
Protocol deviation		4 (4.0)	
No longer meets eligibility criteria		4 (4.0)	
Withdrawal by subject		2 (2.0)	
Lost to follow-up		1 (1.0)	
Other		8 (7.9)	

Note: Subjects randomized but did not sign informed consent or had a significant quality event due to lack of PI oversight are not included in any analysis population.
a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Original blinded, placebo-controlled vaccination period: from Dose 1 to the 1-month post–Dose 2 visit. Subjects who missed the 1-month post–Dose 2 visit but completed subsequent visits were considered as completed vaccination period as well.
d. Open-label vaccination period: from first dose of BNT162b2 [30 µg] to the 1-month post–second dose of BNT162b2 [30 µg] visit. Subjects who missed the 1-month post–second dose of BNT162b2 [30 µg] visit but completed subsequent visits were considered as completed open-label vaccination period as well.
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4.2.1.2. Disposition of Participants Who Received Booster Dose of BNT162b2 30 µg

4.2.1.2.1. Participants Who Received Booster Dose of BNT162b2 30 µg as Part of Protocol Amendment 18

The final disposition of Phase 2/3 participants 12 through 15 years of age and ≥16 years of age who received 2 doses of BNT162b2 30 µg and then received a booster dose of BNT162b2 30 µg as part of protocol amendment 18 is presented in Table 14. See Table 5 for interim reporting.

The final disposition of Phase 2/3 HIV-positive participants who received 2 doses of BNT162b2 30 µg and then received a booster dose of BNT162b2 30 µg as part of protocol amendment 18 is presented in Table 15

Participants 12 Through 15 Years of Age

Among the 825 participants 12 through 15 years of age who received a booster (Dose 3) of BNT162b2 in Phase 2/3, 819 (99.3%) completed the booster vaccination period from Dose 3 to the 1-month follow-up visit after Dose 3, and 649 participants (78.7%) completed the study (Table 14).

After receiving the booster dose, 176 participants (21.3%) withdrew from the study, including 25 (3.0%) who were lost to follow-up. There were 124 participants (15.0%) withdrawn from the study for "other" reasons (Appendix 16.2.1.1).

Participants ≥16 Years of Age

In Phase 2/3, in the ≥16 years of age group, 22430 participants (99.3%) completed the booster vaccination period from the third dose of BNT162b2 to the 1-month follow-up visit, and 14990 participants (66.4%) completed the study (Table 14).

After receiving the third dose of BNT162b2 30 µg, 7591 participants (33.6%) were withdrawn from the study. There were 2356 participants (10.4%) withdrawn from the study for protocol deviations (Appendix 16.2.1.1).

Participants With Confirmed Stable HIV Disease

Among the 99 HIV-positive participants who received a booster dose of BNT162b2 in Phase 2/3, 98 (99.0%) completed the booster vaccination period from the third dose of BNT162b2 to the 1-month follow-up visit, and 78 participants (78.8%) completed the study (Table 15).

After receiving the booster dose, 21 participants (21.2%) were withdrawn from the study mostly due to other reasons or protocol deviations (Appendix 16.2.1.1).

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Table 14. Disposition of Subjects – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18

	Vaccine Group (as Assigned)		
	BNT162b2 (30 µg)		
	12-15 Years (N^a=825) n^b (%)	≥16 Years (N^a=22581) n^b (%)	Total (N^a=23406) n^b (%)
Received the booster vaccination	825 (100.0)	22581 (100.0)	23406 (100.0)
Completed the booster vaccination period[c]	819 (99.3)	22430 (99.3)	23249 (99.3)
Completed the 6-month post–booster vaccination visit	677 (82.1)	20241 (89.6)	20918 (89.4)
Completed the study	649 (78.7)	14990 (66.4)	15639 (66.8)
Withdrawn from the study	176 (21.3)	7591 (33.6)	7767 (33.2)
Withdrawn after the booster vaccination and before the 1-month post–booster vaccination visit	5 (0.6)	146 (0.6)	151 (0.6)
Withdrawn after the 1-month and before the 6-month post–booster vaccination visit	95 (11.5)	1967 (8.7)	2062 (8.8)
Withdrawn after the 6-month post–booster vaccination visit	76 (9.2)	5478 (24.3)	5554 (23.7)
Reason for withdrawal			
Protocol deviation	20 (2.4)	2356 (10.4)	2376 (10.2)
Withdrawal by subject	6 (0.7)	1653 (7.3)	1659 (7.1)
Lost to follow-up	25 (3.0)	1043 (4.6)	1068 (4.6)
No longer meets eligibility criteria	0	252 (1.1)	252 (1.1)
Death	0	47 (0.2)	47 (0.2)
Physician decision	0	14 (0.1)	14 (0.1)
Refused further study procedures	0	3 (0.0)	3 (0.0)
Withdrawal by parent/guardian	1 (0.1)	2 (0.0)	3 (0.0)
Other	124 (15.0)	2221 (9.8)	2345 (10.0)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. N = number of assigned subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Booster vaccination period: from booster vaccination to the 1-month follow-up visit after the booster vaccination.
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Table 15. Disposition of Subjects – Phase 2/3 – HIV-Positive Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18

	Vaccine Group (as Assigned)
	BNT162b2 (30 µg)
	≥16 Years (N[a]=99) n[b] (%)
Received the booster vaccination	99 (100.0)
Completed the booster vaccination period[c]	98 (99.0)
Completed the 6-month post–booster vaccination visit	88 (88.9)
Completed the study	78 (78.8)
Withdrawn from the study	21 (21.2)
Withdrawn after the booster vaccination and before the 1-month post–booster vaccination visit	1 (1.0)
Withdrawn after the 1-month and before the 6-month post–booster vaccination visit	8 (8.1)
Withdrawn after the 6-month post–booster vaccination visit	12 (12.1)
Reason for withdrawal	
Protocol deviation	6 (6.1)
Lost to follow-up	4 (4.0)
Withdrawal by subject	3 (3.0)
Physician decision	1 (1.0)
No longer meets eligibility criteria	1 (1.0)
Other	6 (6.1)

a. N = number of assigned subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Booster vaccination period: from booster vaccination to the 1-month follow-up visit after the booster vaccination.
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4.2.1.2.2. BNT162b2-Naïve Participants Assigned to Receive BNT162b2$_{SA}$ and Received Booster Dose of BNT162b2 30 µg as Part of Protocol Amendment 18

The final disposition of all randomized Phase 3 BNT162b2-naïve participants assigned to receive BNT162b2$_{SA}$ is presented in Table 16. These participants were rerandomized to receive 1 or 2 booster doses of BNT162b2 or BNT162b2$_{SA}$. See Table 5 for interim reporting.

Among the 333 BNT162b2-naïve participants assigned to receive BNT162b2$_{SA}$, 278 participants (83.5%) completed the 6-month post–Dose 2 visit and 242 participants (72.7%) received a booster dose of BNT162b2 30 µg as part of protocol amendment 18. There were 102 participants (30.6%) who were withdrawn from the study, and most were because of

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withdrawal by the participant, lost to follow-up, and other reasons (most participants were enrolled into another clinical study) (Appendix 16.2.1.3).

Table 16. Disposition of Subjects – Phase 3 – BNT162b2-Naïve Subjects Assigned to Receive BNT162b2SA

	Vaccine Group (as Assigned)
	BNT162b2SA (30 µg) (N[a]=333) n[b] (%)
Assigned	333 (100.0)
Not vaccinated	3 (0.9)
Received Dose 1	330 (99.1)
Received Dose 2	329 (98.8)
Completed the vaccination period[c]	321 (96.4)
Completed the 6-month post–Dose 2 visit	278 (83.5)
Received the booster vaccination	242 (72.7)
Completed the booster vaccination period[d]	237 (71.2)
Completed the 6-month post–booster vaccination visit	221 (66.4)
Completed the study	228 (68.5)
Withdrawn from the study	102 (30.6)
Withdrawn after Dose 1 and before Dose 2	1 (0.3)
Withdrawn after Dose 2 and before the 1-month post–Dose 2 visit	8 (2.4)
Withdrawn after the 1-month post–Dose 2 visit and before the 6-month post–Dose 2 visit	20 (6.0)
Withdrawn after the 6-month post–Dose 2 visit and before the booster vaccination	31 (9.3)
Withdrawn after the booster vaccination and before the 1-month post–booster vaccination visit	5 (1.5)
Withdrawn after the 1-month post–booster vaccination visit and before the 6-month post–booster vaccination visit	12 (3.6)
Withdrawn after the 6-month post–booster vaccination visit	25 (7.5)
Reason for withdrawal	
Lost to follow-up	50 (15.0)
Withdrawal by subject	18 (5.4)
No longer meets eligibility criteria	8 (2.4)
Protocol deviation	2 (0.6)
Other	24 (7.2)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of assigned subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Vaccination period: from Dose 1 to the 1-month post–Dose 2 visit.
d. Booster vaccination period: from booster vaccination to the 1-month follow-up visit after the booster vaccination.
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4.2.1.2.3. BNT162b2-Experienced Participants Who Were Rerandomized to Receive Booster Dose(s) Under Protocol Amendments 14 and 15 and Received an Additional Booster Dose of BNT162b2 (30 µg)

The final disposition of Phase 2/3 BNT162b2-experienced participants who received the 2-dose primary series of BNT162b2 30 µg and were rerandomized/assigned to receive a booster (Dose 3) of BNT162b2 (30 µg, or lower dose of 5 or 10 µg), or 1 or 2 booster doses of BNT162b2$_{SA}$ 30 µg under protocol amendments 14 and 15, is presented in Table 17. Final disposition of Phase 3 BNT162b2-experienced participants who were rerandomized to receive a lower booster dose of BNT162b2 are also presented in Supplemental Table 14.6

All participants received the first booster vaccination. An additional booster vaccination of BNT162b2 30 µg (Dose 4/5) offered as part of protocol amendment 19 was received by 41.8% to 62.9% of these participants who had already received at least 1 booster, including 15 participants who received a total of 5 doses (2 booster doses of BNT162b2$_{SA}$ 30 µg [Dose 3 and Dose 4], followed by a third booster with BNT162b2 30 µg [Dose 5]). The most frequent reasons for withdrawals were:

- Withdrawal by participant (18 [5.8%] participants in BNT162b2 [30 µg] group, 4 [13.3%] participants in BNT162$_{SA}$ [30 µg, 2 doses] group, 11 [13.9%] in BNT162b2 [5 µg] group) and 12 [15.8%] in BNT162b2 [10 µg] group)
- No longer meeting eligibility criteria (17 [21.5%] participants in BNT162b2 [5 µg] group and 19 [25.0%] participants in BNT162b2 [10 µg] group)
- Lost to follow-up (24 [7.7%] participants in BNT162b2$_{SA}$ [30 µg] group)

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Table 17. Disposition of Subjects – Phase 2/3 – BNT162b2-Experienced Subjects Who Were Rerandomized/Assigned to Receive Booster Dose(s) – Booster Safety Population

	Booster Vaccine Group (as Rerandomized)				Booster Vaccine Group (as Assigned)
	BNT162b2 (30 µg) (N^a=312) n^b (%)	BNT162b2$_{SA}$ (30 µg) (N^a=313) n^b (%)	BNT162b2 (5 µg) (N^a=79) n^b (%)	BNT162b2 (10 µg) (N^a=76) n^b (%)	BNT162b2$_{SA}$ (30 µg, 2 Doses) (N^a=30) n^b (%)
Rerandomized/assigned	312 (100.0)	313 (100.0)	79 (100.0)	76 (100.0)	30 (100.0)
Did not receive the first booster vaccination	0	0	0	0	0
Did not receive the second booster vaccination					2 (6.7)
Did not receive the additional booster vaccination	128 (41.0)	116 (37.1)	46 (58.2)	38 (50.0)	15 (50.0)
Received the first booster vaccination	312 (100.0)	313 (100.0)	79 (100.0)	76 (100.0)	30 (100.0)
Completed the first booster vaccination period[c]	309 (99.0)	311 (99.4)	79 (100.0)	76 (100.0)	27 (90.0)
Completed the 6-month post–first booster vaccination visit	298 (95.5)	303 (96.8)	78 (98.7)	75 (98.7)	28 (93.3)
Received the additional booster vaccination	184 (59.0)	197 (62.9)	33 (41.8)	38 (50.0)	15 (50.0)
Completed the additional booster vaccination period[d]	183 (58.7)	190 (60.7)	33 (41.8)	38 (50.0)	15 (50.0)
Completed the 6-month post–additional booster vaccination visit	0	0	1 (1.3)	0	0
Completed the study	253 (81.1)	249 (79.6)	45 (57.0)	43 (56.6)	22 (73.3)
Withdrawn from the study	59 (18.9)	64 (20.4)	34 (43.0)	33 (43.4)	8 (26.7)
Withdrawn after the first booster vaccination and before the 1-month post–first/second[e] booster vaccination visit	3 (1.0)	2 (0.6)	0	0	1 (3.3)
Withdrawn after the 1-month post–first/second[e] booster vaccination visit and before the 6-month post–first booster vaccination visit	10 (3.2)	8 (2.6)	1 (1.3)	1 (1.3)	1 (3.3)
Withdrawn after the 6-month post–first booster vaccination visit and before the additional booster vaccination visit	36 (11.5)	38 (12.1)	33 (41.8)	31 (40.8)	5 (16.7)
Withdrawn after additional booster vaccination visit	10 (3.2)	16 (5.1)	0	1 (1.3)	1 (3.3)

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Table 17. Disposition of Subjects – Phase 2/3 – BNT162b2-Experienced Subjects Who Were Rerandomized/Assigned to Receive Booster Dose(s) – Booster Safety Population

	Booster Vaccine Group (as Rerandomized)				Booster Vaccine Group (as Assigned)
	BNT162b2 (30 µg) (N^a=312) n^b (%)	$BNT162b2_{SA}$ (30 µg) (N^a=313) n^b (%)	BNT162b2 (5 µg) (N^a=79) n^b (%)	BNT162b2 (10 µg) (N^a=76) n^b (%)	$BNT162b2_{SA}$ (30 µg, 2 Doses) (N^a=30) n^b (%)
Reason for withdrawal					
Withdrawal by subject	18 (5.8)	14 (4.5)	11 (13.9)	12 (15.8)	4 (13.3)
No longer meets eligibility criteria	10 (3.2)	9 (2.9)	17 (21.5)	19 (25.0)	0
Lost to follow-up	16 (5.1)	24 (7.7)	1 (1.3)	0	3 (10.0)
Protocol deviation	11 (3.5)	12 (3.8)	3 (3.8)	2 (2.6)	0
Physician decision	0	2 (0.6)	0	0	0
Other	4 (1.3)	3 (1.0)	2 (2.5)	0	1 (3.3)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of assigned subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. The first booster vaccination period: from the first booster vaccination to the 1-month follow-up visit after the first/second booster vaccination.
d. The additional booster vaccination period: from the additional booster vaccination to the 1-month follow-up visit after the additional booster vaccination(s).
e. The second booster vaccination is applicable to subjects who received 2 doses of $BNT162b2_{SA}$ (30 µg, 2 doses) during the first booster vaccination period.
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4.2.2. Important Protocol Deviations

PDs were identified throughout the study by monitoring of informed consent documentation, source documents, and other clinical trial-related documents. In addition, PDs were identified by remote monitoring of electronic CRFs, and review of the project databases (interactive response technology, clinical and safety databases, vendor database for e-diary data, and programmatic output from the clinical database). All PDs were documented in a designated clinical trial management system.

Appendix 16.2.2.1, Appendix 16.2.2.2, and Appendix 16.2.2.3 includes important PDs for all participants in the Phase 2/3 groups listed in this final report that may have significantly impacted the completeness, accuracy, and/or reliability of the study data or that may have significantly affected a participant's rights, safety, or well-being.

A formal acknowledgment by the study team was made that deviations were reviewed and GCP compliance was maintained.

Important PDs can be found in the following:

Important Protocol Deviations – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population	Supplemental Table 14.7
Important Protocol Deviations – Phase 3 – BNT162b2-Naïve Subjects Assigned to Receive BNA162b2SA Who Received Booster Dose of BNT162b2 (30 µg) – Booster Safety Population}	Supplemental Table 14.8
Important Protocol Deviations Phase 3 BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose)	Supplemental Table 14.9
Important Protocol Deviations After the Additional Booster Dose – Phase 3 – BNT162b2-Experienced Subjects Who Were Previously Rerandomized/Assigned to Receive Booster Dose(s), and Received an Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population	Supplemental Table 14.10

4.2.3. Populations Analyzed

4.2.3.1. Safety Population

4.2.3.1.1. Participants Who Received Booster Dose of BNT162b2 30 µg as Part of Protocol Amendment 18

The booster safety population of all randomized Phase 2/3 participants 12 through 15 years of age and ≥16 years of age is presented in Table 18. See Table 5 for interim reporting.

A total of 13 participants (0.1%) ≥16 years of age were excluded from the booster safety population mostly due to not providing booster vaccination informed consent.

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Table 18. Booster Safety Population – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18

	Vaccine Group (as Assigned)	
	BNT162b2 (30 µg)	
	12-15 Years n[a] (%)	≥16 Years n[a] (%)
Assigned[b]	825	22581
Received the booster vaccination	825 (100.0)	22581 (100.0)
BNT162b2 (30 µg)	825 (100.0)	22581 (100.0)
Booster safety population	825 (100.0)	22568 (99.9)
HIV-positive	0	98 (0.4)
Excluded from booster safety population	0	13 (0.1)
Reason for exclusion		
Did not provide informed consent	0	1 (0.0)
Did not provide booster vaccination informed consent	0	9 (0.0)
Unreliable data due to lack of PI oversight	0	3 (0.0)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of subjects with the specified characteristic.
b. This value is the denominator for the percentage calculations.
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Overall, median (min, max) follow-up time after booster vaccination was 9.5 (1.5, 10.7) months and 12.3 (0.0, 15.3) months for participants 12 through 15 years of age and ≥16 years of age, respectively (Table 19).

Table 19. Follow-up Time After Booster Dose – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	
	12-15 Years (N[a]=825) n[b] (%)	≥16 Years (N[a]=22581) n[b] (%)
Total exposure from the booster vaccination to the end of study		
<6 Months	108 (13.1)	1227 (5.4)
≥6-<9 Months	185 (22.4)	4006 (17.7)
≥9-<12 Months	532 (64.5)	4429 (19.6)
≥12-<15 Months	0	12901 (57.1)
≥15 Months	0	18 (0.1)
Mean (SD)	8.7 (1.70)	10.9 (2.63)
Median	9.5	12.3
Min, max	(1.5, 10.7)	(0.0, 15.3)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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4.2.3.1.2. BNT162b2-Naïve Participants Assigned to Receive BNT162b2$_{SA}$ and Received Booster Dose of BNT162b2 30 µg as Part of Protocol Amendment 18

The booster safety population of BNT162b2-naïve participants assigned to receive BNT162b2$_{SA}$ and received booster dose of BNT162b2 under protocol amendment 18 is presented in Table 20. See Table 5 for interim reporting.

Table 20. Booster Safety Population – Phase 3 – BNT162b2-Naïve Subjects Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg)

	Vaccine Group (as Assigned)
	BNT162b2 (30 µg) n[a] (%)
Assigned[b]	242
Received the booster vaccination	242 (100.0)
BNT162b2 (30 µg)	242 (100.0)
Booster safety population	242 (100.0)
HIV-positive	6 (2.5)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of subjects with the specified characteristic.
b. This value is the denominator for the percentage calculations.
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Overall, median (min, max) follow-up time after study vaccination was 12.3 (2.6, 14.6) months (Table 21).

Table 21. Follow-up Time After Booster Dose – Phase 3 – BNT162b2-Naïve Subjects Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg)

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=242) n[b] (%)
Total exposure from the booster vaccination to the end of study	
<9 Months	35 (14.5)
≥9-<12 Months	67 (27.7)
≥12-<15 Months	140 (57.9)
Mean (SD)	11.5 (2.22)
Median	12.3
Min, max	(2.6, 14.6)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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4.2.3.1.3. BNT162b2-Experienced Participants Who Were Rerandomized to Receive Booster Dose of BNT162b2 (Lower Dose of 5 or 10 µg) Under Protocol Amendment 15

The booster safety population of BNT162b2-experienced participants rerandomized to receive a booster dose of BNT162b2 (lower dose of 5 or 10 µg) under protocol amendment 15 included 155 participants 18 through 55 and >55 years of age (Table 22). There were no HIV-positive participants in the groups.

Table 22. Booster Safety Population – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose)

	Vaccine Group (as Administered)				
	BNT162b2 (5 µg)		BNT162b2 (10 µg)		Total
	18-55 Years n[a]	>55 Years n[a]	18-55 Years n[a]	>55 Years n[a]	n[a] (%)
Rerandomized[b]					155
Received booster vaccination	26	53	25	51	155 (100.0)
Booster safety population	26	53	25	51	155 (100.0)
HIV-positive	0	0	0	0	0

a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
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Most BNT162b2-experienced participants rerandomized to receive a booster dose of BNT162b2 (lower dose of 5 or 10 µg) had a follow-up time of ≥12 months after Dose 3 (5 or 10 µg) to before additional booster dose (Table 23). The median (min, max) follow-up time since Dose 2 was 20.1 (15.0, 26.8) and 19.8 (13.3, 26.8) months for participants in the BNT162b2 (5 µg) 18 through 55 and >55 years of age groups, respectively, and 20.5 (14.3, 25.9) and 20.1 (12.4, 26.7) months for participants in the BNT162b2 (10 µg) 18 through 55 and >55 years of age groups, respectively.

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Table 23. Follow-up Time After Booster Dose – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose)

	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N[a]=26) n[b] (%)	>55 Years (N[a]=53) n[b] (%)	18-55 Years (N[a]=25) n[b] (%)	>55 Years (N[a]=51) n[b] (%)
Total exposure from booster vaccination to before additional booster dose				
<6 Months	0	1 (1.9)	0	0
≥6-<8 Months	0	1 (1.9)	0	6 (11.8)
≥8-<10 Months	5 (19.2)	8 (15.1)	5 (20.0)	6 (11.8)
≥10-<12 Months	1 (3.8)	6 (11.3)	3 (12.0)	1 (2.0)
≥12 Months	20 (76.9)	37 (69.8)	17 (68.0)	38 (74.5)
Mean (SD)	13.6 (3.29)	13.0 (3.34)	13.0 (2.73)	12.4 (3.00)
Median	13.3	13.1	13.6	13.1
Min, max	(8.7, 19.6)	(5.9, 19.9)	(8.8, 19.9)	(6.1, 19.2)
Total exposure from Dose 2 to before additional booster dose				
≥12-<14 Months	0	1 (1.9)	0	3 (5.9)
≥14-<16 Months	4 (15.4)	3 (5.7)	3 (12.0)	5 (9.8)
≥16-<18 Months	2 (7.7)	11 (20.8)	4 (16.0)	4 (7.8)
≥18-<20 Months	5 (19.2)	13 (24.5)	5 (20.0)	13 (25.5)
≥20 Months	15 (57.7)	25 (47.2)	13 (52.0)	26 (51.0)
Mean (SD)	20.2 (3.43)	19.7 (3.20)	19.6 (2.84)	19.3 (3.00)
Median	20.1	19.8	20.5	20.1
Min, max	(15.0, 26.8)	(13.3, 26.8)	(14.3, 25.9)	(12.4, 26.7)

Note: End of study date is used to calculate follow-up time when subject did not receive additional booster dose.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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4.2.3.1.4. BNT162b2-Experienced Participants Who Were Rerandomized to Receive Booster Dose(s) Under Protocol Amendments 14 and 15 and Received an Additional Booster Dose of BNT162b2 (30 µg)

Participants that were rerandomized/assigned to receive booster vaccinations under protocol amendments 14 and 15 and received an additional booster dose of BNT162b2 (30 µg) as part of protocol amendment 19, had a median (min, max) follow-up time of 6.0 (0.9, 8.0) to 6.1 (4.8, 7.1) months from the additional booster dose to the end of the study. The median (min, max) follow-up time since the first/second booster dose was 19.1 (18.6, 20.5) to 20.1 (16.3, 21.8) months (Table 24). Note that the second booster vaccination is applicable to participants who received 2 doses of BNT162b2$_{SA}$ (30 µg, 2 doses) during the first booster vaccination period.

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Table 24. Follow-up Time After Booster Dose – Phase 3 – BNT162b2-Experienced Subjects Who Were Previously Rerandomized/Assigned to Receive Booster Dose(s), and Received an Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

	Previous Booster Vaccine Group (as Administered)				
	BNT162b2 (30 µg) (N[a]=182) n[b] (%)	BNT162b2$_{SA}$ (30 µg) (N[a]=199) n[b] (%)	BNT162b2 (5 µg) (N[a]=33) n[b] (%)	BNT162b2 (10 µg) (N[a]=38) n[b] (%)	BNT162b2$_{SA}$ (30 µg, 2 Doses) (N[a]=15) n[b] (%)
Total exposure from the additional booster dose to the end of study					
<3 Months	3 (1.6)	8 (4.0)	0	0	0
≥3-<6 Months	91 (50.0)	94 (47.2)	10 (30.3)	17 (44.7)	10 (66.7)
≥6-<9 Months	88 (48.4)	97 (48.7)	23 (69.7)	21 (55.3)	5 (33.3)
Mean (SD)	5.9 (0.69)	5.8 (0.97)	6.1 (0.44)	6.0 (0.49)	6.0 (0.56)
Median	6.0	6.0	6.1	6.0	5.9
Min, max	(1.7, 7.3)	(0.9, 8.0)	(4.8, 7.1)	(4.9, 7.0)	(5.4, 7.3)
Total exposure from the first/second[c] booster dose to the end of study					
≥15-<18 Months	3 (1.6)	9 (4.5)	0	0	0
≥18-<21 Months	143 (78.6)	153 (76.9)	33 (100.0)	38 (100.0)	15 (100.0)
≥21 Months	36 (19.8)	37 (18.6)	0	0	0
Mean (SD)	20.2 (0.72)	20.1 (1.00)	19.5 (0.41)	19.4 (0.41)	19.4 (0.64)
Median	20.1	20.0	19.5	19.5	19.1
Min, max	(16.3, 21.8)	(15.3, 21.9)	(18.8, 20.5)	(18.2, 20.3)	(18.6, 20.5)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. The second booster vaccination is applicable to subjects who received 2 doses of BNT162b2$_{SA}$ (30 µg, 2 doses) during the first booster vaccination period.
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4.2.3.2. Efficacy Populations

Asymptomatic SARS-CoV-2 Infection Based on Central Laboratory–Confirmed NAAT Result During the Asymptomatic Surveillance Period

In total, 4361 participants participated in the asymptomatic SARS-CoV-2 infection surveillance period with the proportions of participants included in the efficacy populations similar in both vaccine groups (Table 25). For participants who were excluded from the evaluable efficacy population, the most common reason was because participants did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19 to 42 days after Dose 1). Among the 4258 participants included in the evaluable efficacy population, 3921 participants (89.9%) had no evidence of infection prior to the start of the asymptomatic SARS-CoV-2 infection surveillance period.

Table 25. Efficacy Populations – Asymptomatic SARS-CoV-2 Infection Based on Central Laboratory–Confirmed NAAT Result During the Asymptomatic Surveillance Period

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Participated in asymptomatic SARS-CoV-2 infection surveillance[b]	2280 (100.0)	2081 (100.0)	4361 (100.0)
Dose 1 all-available efficacy population – asymptomatic surveillance	2280 (100.0)	2081 (100.0)	4361 (100.0)
Subjects without evidence of infection prior to the start of asymptomatic surveillance period[c]	2130 (93.4)	1871 (89.9)	4001 (91.7)
Subjects with evidence of infection prior to the start of asymptomatic surveillance period	83 (3.6)	144 (6.9)	227 (5.2)
Subjects excluded from Dose 1 all-available efficacy population – asymptomatic surveillance	0	0	0
Reason for exclusion[d]			
Did not receive at least 1 vaccination	0	0	0
Dose 2 all-available efficacy population – asymptomatic surveillance	2278 (99.9)	2074 (99.7)	4352 (99.8)
Subjects without evidence of infection prior to the start of asymptomatic surveillance period[c]	2130 (93.4)	1871 (89.9)	4001 (91.7)
Subjects with evidence of infection prior to the start of asymptomatic surveillance period	83 (3.6)	139 (6.7)	222 (5.1)
Subjects excluded from Dose 2 all-available efficacy population – asymptomatic surveillance	2 (0.1)	7 (0.3)	9 (0.2)
Reason for exclusion[d]			
Did not receive 2 vaccinations	2 (0.1)	7 (0.3)	9 (0.2)
Evaluable efficacy (asymptomatic surveillance) population	2234 (98.0)	2024 (97.3)	4258 (97.6)
Subjects without evidence of infection prior to the start of asymptomatic surveillance period[c]	2092 (91.8)	1829 (87.9)	3921 (89.9)
Subjects with evidence of infection prior to the start of asymptomatic surveillance period	80 (3.5)	133 (6.4)	213 (4.9)

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Table 25. Efficacy Populations – Asymptomatic SARS-CoV-2 Infection Based on Central Laboratory–Confirmed NAAT Result During the Asymptomatic Surveillance Period

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Subjects excluded from evaluable efficacy (asymptomatic surveillance) population	46 (2.0)	57 (2.5)	103 (2.4)
Reason for exclusion[d]			
Randomized but did not meet all eligibility criteria	0	1 (0.0)	1 (0.0)
Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	43 (1.9)	50 (2.4)	93 (2.1)
Did not consent to participate in the asymptomatic surveillance	0	0	0
Had other important protocol deviations prior to the start of asymptomatic surveillance period	4 (0.2)	7 (0.3)	11 (0.3)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Subjects who had no serological or virological evidence of past SARS-CoV-2 infection (i.e, negative N-binding antibody [serum] result at Visits 1 and 201, SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2, and negative NAAT [nasal swab] result at any unscheduled visits) prior to the start of the asymptomatic surveillance period were included in the analysis.
d. Subjects may have been excluded for more than 1 reason.
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Asymptomatic Infection Based on N-Binding Antibody Seroconversion

The proportions of participants included in the efficacy populations were similar in both vaccine groups (Table 26). For participants who were excluded from the evaluable efficacy population, the most common reason was because participants did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19 to 42 days after Dose 1), followed by the reason of not having N-binding test result at any post–Dose 2 visit. Among the 44101 participants included in the evaluable efficacy population, 41564 participants (90%) had no evidence of infection prior to the first post–Dose 2 N-binding test.

Table 26. Efficacy Populations – Asymptomatic Infection Based on N-Binding Antibody Seroconversion

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	23105 (100.0)	23100 (100.0)	46205 (100.0)
Dose 1 all-available efficacy population	23023 (99.6)	23027 (99.7)	46050 (99.7)
Subjects without evidence of infection prior to the first post–Dose 1 N-binding test[c]	21565 (93.3)	21201 (91.8)	42766 (92.6)
Subjects excluded from Dose 1 all-available efficacy population	82 (0.4)	73 (0.3)	155 (0.3)
Reason for exclusion[d]			
Did not receive at least 1 vaccination	58 (0.3)	51 (0.2)	109 (0.2)
Did not provide informed consent	2 (0.0)	0	2 (0.0)
Data considered potentially unreliable due to lack of PI oversight identified as significant quality event	22 (0.1)	22 (0.1)	44 (0.1)
Dose 2 all-available efficacy population	22705 (98.3)	22646 (98.0)	45351 (98.2)
Subjects without evidence of infection prior to the first post–Dose 2 N-binding test[e]	21376 (92.5)	21032 (91.0)	42408 (91.8)
Subjects excluded from Dose 2 all-available efficacy population	400 (1.7)	454 (2.0)	854 (1.8)
Reason for exclusion[d]			
Did not receive 2 vaccinations	378 (1.6)	439 (1.9)	817 (1.8)
Did not provide informed consent	2 (0.0)	0	2 (0.0)
Data considered potentially unreliable due to lack of PI oversight identified as significant quality event	22 (0.1)	22 (0.1)	44 (0.1)
Evaluable efficacy (seroconversion) population	22032 (95.4)	22069 (95.5)	44101 (95.4)
Subjects without evidence of infection prior to the first post–Dose 2 N-binding test[f]	20872 (90.3)	20692 (89.6)	41564 (90.0)
Subjects excluded from evaluable efficacy (seroconversion) population	1073 (4.6)	1031 (4.5)	2104 (4.6)
Reason for exclusion[d]			
Randomized but did not meet all eligibility criteria	32 (0.1)	26 (0.1)	58 (0.1)
Did not provide informed consent	2 (0.0)	0	2 (0.0)

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Table 26. Efficacy Populations – Asymptomatic Infection Based on N-Binding Antibody Seroconversion

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Data considered potentially unreliable due to lack of PI oversight identified as significant quality event	22 (0.1)	22 (0.1)	44 (0.1)
Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	726 (3.1)	744 (3.2)	1470 (3.2)
Did not have N-binding test result at any post–Dose 2 visit	505 (2.2)	637 (2.8)	1142 (2.5)
Had other important protocol deviations prior to the first post–Dose 2 N-binding test	248 (1.1)	113 (0.5)	361 (0.8)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Includes subjects who had no serological or virological evidence of past SARS-CoV-2 infection before Dose 1 (ie, negative N-binding antibody [serum] result at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visit 1) and had a negative NAAT (nasal swab) result at any unscheduled visit prior to the first post–Dose 1 N-binding test result.
d. Subjects may have been excluded for more than 1 reason.
e. Includes subjects who had no serological or virological evidence of past SARS-CoV-2 infection before Dose 2 (ie, negative N-binding antibody [serum] result at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2) and had a negative NAAT (nasal swab) result at any unscheduled visit prior to the first post–Dose 2 N-binding test result.
f. Includes subjects who had no serological or virological evidence of past SARS-CoV-2 infection before Dose 2 (ie, negative N-binding antibody [serum] result at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2) and had a negative NAAT (nasal swab) result at any unscheduled visit and without any important protocol deviation prior to the first post–Dose 2 N-binding test result.
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4.2.3.3. Immunogenicity Populations

The immunogenicity populations of BNT162b2-experienced participants who were rerandomized to receive a booster dose of BNT162b2 (5 or 10 µg) are presented in Table 27. One participant each was excluded from the Dose 3 booster evaluable immunogenicity population for not having at least 1 valid and determinate immunogenicity result within 28-42 days after booster vaccination in the BNT162b2 (5 µg) >55 years of age group and the BNT162b2 (10 µg) 18 through 55 years and >55 years of age groups. One additional participant in the BNT162b2 (5 µg) >55 years of age group was excluded from the Dose 3 booster evaluable immunogenicity population due to having an important protocol deviation(s) as determined by the clinician.

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Table 27. Immunogenicity Populations – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose)

	Vaccine Group (as Randomized)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18- 55 Years n[a] (%)	>55 Years n[a] (%)	18- 55 Years n[a] (%)	>55 Years n[a] (%)
Rerandomized[b]	26 (100.0)	53 (100.0)	25 (100.0)	51 (100.0)
Dose 3 booster all-available immunogenicity population	26 (100.0)	53 (100.0)	25 (100.0)	51 (100.0)
Dose 3 booster evaluable immunogenicity population	26 (100.0)	51 (96.2)	24 (96.0)	50 (98.0)
Without evidence of infection up to 1-month post–booster dose[c]	24 (92.3)	47 (88.7)	24 (96.0)	48 (94.1)
Subjects excluded from Dose 3 booster evaluable immunogenicity population	0	2 (3.8)	1 (4.0)	1 (2.0)
Reason for exclusion[d]				
Did not have at least 1 valid and determinate immunogenicity result within 28-42 days after booster vaccination	0	1 (1.9)	1 (4.0)	1 (2.0)
Had important protocol deviation(s) as determined by the clinician	0	1 (1.9)	0	0

a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Subjects who had no serological or virological evidence (up to 1 month after receipt of the booster vaccination) of past SARS-CoV-2 infection
(ie, N-binding antibody [serum] negative at Dose 1 visit, 1-month post–Dose 2 visit, booster dose visit, 1-month post–booster visit and SARS-CoV-2
not detected by NAAT [nasal swab] at Dose 1 visit, Dose 2 visit, booster dose visit) and had a negative NAAT (nasal swab) at any unscheduled visit
up to 1 month after booster vaccination were included in the analysis.
d. Subjects may have been excluded for more than 1 reason.
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(Data Cutoff Date: 22NOV2021, Database Snapshot Date: 10DEC2021) Output File: ./nda2_unblinded/C4591001_G4_LD/adva_s008_imm_g4_6m

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4.2.4. Demographics and Other Baseline Characteristics

Demographic characteristic of participants in Phase 2/3 of the study can be found in the following:

Demographic Characteristics – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population	Supplemental Table 14.11
Demographic Characteristics – Phase 2/3 – HIV-Positive Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population	Supplemental Table 14.12
Demographic Characteristics – Phase 3 – BNT162b2-Naïve Subjects Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg) – Booster Safety Population	Supplemental Table 14.13
Demographic Characteristics - Phase 3 BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) Booster Safety Population	Supplemental Table 14.14
Demographic Characteristics - Subjects Without Evidence of Infection Prior to the Start of the Asymptomatic Surveillance Period - Evaluable Efficacy (Asymptomatic Surveillance) Population	Supplemental Table 14.15
Demographic Characteristics - Subjects Without Evidence of Infection Prior to the First Post - Dose 2 N-Binding Test - Evaluable Efficacy (Seroconversion) Population	Supplemental Table 14.16
Demographic Characteristics - Phase 3 BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) Dose 3 Booster Evaluable Immunogenicity Population	Supplemental Table 14.17
Demographic Characteristics - Phase 3 BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) Dose 3 Booster All-Available Immunogenicity Population	Supplemental Table 14.18
Demographic Characteristics – Phase 3 – BNT162b2-Experienced Subjects Who Were Previously Rerandomized/Assigned to Receive Booster Dose(s), and Received an Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population	Supplemental Table 14.19

Medical history for Phase 3 – BNT162b2-experienced participants in the booster safety population who were rerandomized to receive 1 booster dose of BNT162b2 (5 or 10 µg) is presented in Supplemental Table 14.20.

4.2.5. Concomitant Therapy

Concomitant vaccines received after the booster doses during the study are reported in the following:

Nonstudy Vaccines Received After Booster Dose – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population	Supplemental Table 14.21
Nonstudy Vaccines Received After Booster Dose – Phase 3 – BNT162b2-Naïve Subjects Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg) – Booster Safety Population	Supplemental Table 14.22

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Concomitant Vaccines Received After Booster Dose - Phase 3 - BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population	Supplemental Table 14.23
Nonstudy Vaccines Received After the Additional Booster Dose – Phase 3 – BNT162b2-Experienced Subjects Who Were Previously Rerandomized/Assigned to Receive Booster Dose(s), and Received an Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population	Supplemental Table 14.24

4.2.6. Exposure and Study Intervention Compliance

4.2.6.1. Exposure

Participants 12 Through 15 Years of Age and Received Booster Dose of BNT162b2 30 µg as Part of Protocol Amendment 18

The median (min, max) time between Dose 2 and booster vaccination was 11.2 (6.3, 20.1) months. Most participants (93.9%) received the booster dose of BNT162b2 <15 months after Dose 2 (Table 28). See Table 5 for interim reporting.

Participants ≥16 Years of Age and Received Booster Dose of BNT162b2 30 µg as Part of Protocol Amendment 18

The median (min, max) time between Dose 2 and booster vaccination was 10.1 (4.8, 22.7) months. Most participants (85.7%) received the booster dose of BNT162b2 <15 months after Dose 2 (Table 28).

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Table 28. Vaccine Administration Timing – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18

	Vaccine Group (as Assigned)	
	BNT162b2 (30 µg)	
	12-15 Years (N[a]=825) n[b] (%)	≥16 Years (N[a]=22581) n[b] (%)
Assigned	825 (100.0)	22581 (100.0)
Booster vaccination[c]	825 (100.0)	22581 (100.0)
<6 Months	0	27 (0.1)
≥6-<9 Months	372 (45.1)	6481 (28.7)
≥9-<12 Months	46 (5.6)	7926 (35.1)
≥12-<15 Months	357 (43.3)	4918 (21.8)
≥15-<18 Months	43 (5.2)	3091 (13.7)
≥18 Months	7 (0.8)	136 (0.6)
Mean (SD)	10.8 (2.94)	11.2 (2.85)
Median	11.2	10.1
Min, max	(6.3, 20.1)	(4.8, 22.7)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Months calculated since second dose of BNT162b2.
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(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/advx_s002_p23_d3

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BNT162b2-Naïve Participants Assigned to Receive BNT162b2$_{SA}$ and Received Booster Dose of BNT162b2 30 µg as Part of Protocol Amendment 18

The median (min, max) time between Dose 2 and booster vaccination was 6.6 (6.1, 14.1) months. Most participants (83.9%) received the booster dose of BNT162b2 <9 months after Dose 2 (Table 29).

Table 29. Vaccine Administration Timing – Phase 3 – BNT162b2-Naïve Subjects Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg)

	Vaccine Group (as Assigned)
	BNT162b2 (30 µg) (N[a]=242) n[b] (%)
Assigned	242 (100.0)
Booster vaccination[c]	242 (100.0)
≥6-<9 Months	203 (83.9)
≥9-<12 Months	34 (14.0)
≥12-<15 Months	5 (2.1)
Mean (SD)	7.3 (1.52)
Median	6.6
Min, max	(6.1, 14.1)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Months calculated since second dose of BNT162b2.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adsl Table Generation: 05MAY2023 (01:26)
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BNT162b2-Experienced Participants Who Were Rerandomized to Receive Booster Dose of BNT162b2 (Lower Dose of 5 or 10 µg) Under Protocol Amendment 15

All BNT162b2-experienced participants, 18 through 55 and >55 years of age, who were rerandomized to receive a booster dose of BNT162b2 (5 or 10 µg) under protocol amendment 15 received the booster vaccination as assigned (Table 30). The median time (min, max) between Dose 2 and booster vaccination ranged from 6.8 (5.6, 7.4) to 7.2 (5.6, 7.5) months (Table 31).

Table 30. Vaccine as Administered – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose)

Vaccine (as Administered)	Vaccine Group (as Randomized)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N^a=26) n^b (%)	>55 Years (N^a=53) n^b (%)	18-55 Years (N^a=25) n^b (%)	>55 Years (N^a=51) n^b (%)
Received booster vaccination	26 (100.0)	53 (100.0)	25 (100.0)	51 (100.0)
Did not receive booster vaccination	0	0	0	0
Booster vaccination				
BNT162b2 (5 µg)	26 (100.0)	53 (100.0)	0	0
BNT162b2 (10 µg)	0	0	25 (100.0)	51 (100.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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Table 31. Vaccine Administration Timing – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose)

	Vaccine Group (as Randomized)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N[a]=26) n[b] (%)	>55 Years (N[a]=53) n[b] (%)	18-55 Years (N[a]=25) n[b] (%)	>55 Years (N[a]=51) n[b] (%)
Rerandomized	26 (100.0)	53 (100.0)	25 (100.0)	51 (100.0)
Did not receive booster vaccination	0	0	0	0
Booster vaccination[c]	26 (100.0)	53 (100.0)	25 (100.0)	51 (100.0)
≥5-<6 Months	8 (30.8)	8 (15.1)	8 (32.0)	7 (13.7)
≥6-<7 Months	10 (38.5)	17 (32.1)	7 (28.0)	12 (23.5)
≥7 Months	8 (30.8)	28 (52.8)	10 (40.0)	32 (62.7)
Mean (SD)	6.6 (0.65)	6.8 (0.61)	6.6 (0.70)	6.9 (0.57)
Median	6.8	7.0	6.9	7.2
Min, max	(5.6, 7.4)	(5.7, 7.5)	(5.5, 7.5)	(5.6, 7.5)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Months calculated since Dose 2.
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BNT162b2-Experienced Participants Who Were Rerandomized to Receive Booster Dose(s) Under Protocol Amendments 14 and 15 and Received an Additional Booster Dose of BNT162b2 (30 µg) As Part of Amendment 19

All BNT162b2-experienced participants who were previously rerandomized/assigned to receive booster dose(s) and received an additional booster vaccination of BNT162b2 (30 µg) as part of protocol amendment 19, received the additional booster of BNT162b2 (30 µg), as assigned (Table 32).

The median time (min, max) between the first/second booster vaccination and the additional booster vaccination ranged from 13.3 (12.9, 14.5) to 14.3 (13.5, 15.2) months. In the BNT162b2 (30 µg) and BNT162b2$_{SA}$ (30 µg) groups, most participants received the additional booster dose of BNT162b2 ≥14 months after the first booster vaccination. In the BNT162b2 (5 µg), BNT162b2 (10 µg), and BNT162b2$_{SA}$ (30 µg, 2 doses), most participants received the additional booster dose of BNT162b2 <14 months after the first/second booster vaccination.

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Table 32. Vaccine Administration Timing – Phase 3 – BNT162b2-Experienced Subjects Who Were Previously Rerandomized/Assigned to Receive Booster Dose(s), and Received an Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

	Previous Booster Vaccine Group (as Administered)				
	BNT162b2 (30 µg) (N[a]=182) n[b] (%)	BNT162b2$_{SA}$ (30 µg) (N[a]=199) n[b] (%)	BNT162b2 (5 µg) (N[a]=33) n[b] (%)	BNT162b2 (10 µg) (N[a]=38) n[b] (%)	BNT162b2$_{SA}$ (30 µg, 2 Doses) (N[a]=15) n[b] (%)
Additional booster dose[c]	182 (100.0)	199 (100.0)	33 (100.0)	38 (100.0)	15 (100.0)
≥12-<14 Months	37 (20.3)	54 (27.1)	29 (87.9)	34 (89.5)	15 (100.0)
≥14-<16 Months	145 (79.7)	145 (72.9)	4 (12.1)	4 (10.5)	0
Mean (SD)	14.3 (0.40)	14.3 (0.40)	13.4 (0.33)	13.5 (0.36)	13.3 (0.29)
Median	14.3	14.3	13.3	13.3	13.3
Min, max	(13.5, 15.2)	(13.5, 15.1)	(12.9, 14.5)	(12.9, 14.4)	(12.9, 13.8)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Months calculated since the first/second booster dose; the second booster vaccination is applicable to subjects who received 2 doses of
BNT162b2$_{SA}$ (30 µg, 2 doses) during the first booster vaccination period.
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4.2.6.2. Immunogenicity Blood Samples

Immunogenicity blood samples drawn for BNT162b2-experienced participants 18 through 55 and >55 years of age, who were rerandomized to receive a booster dose of BNT162b2 (5 or 10 µg) are presented in Supplemental Table 14.25. Most participants in any dose group had immunogenicity blood samples taken within the protocol-specified time frames.

4.2.6.3. E-Diary

Overall, transmission of e-diary data for Phase 3 - BNT162b2-experienced participants 18 through 55 and >55 years of age, who were rerandomized to receive a booster dose of BNT162b2 (5 or 10 µg) ranged from (Supplemental Table 14.26):

- 65.4% to 92.3% and 81.1% to 96.2% for each day during the 7 days after Dose 3 of BNT162b2 5 µg for participants 18 through 55 and >55 years of age, respectively

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- 76.0% to 96.0% and 86.3% to 98.0% for each day during the 7 days after Dose 3 of BNT162b2 10 µg for participants 18 through 55 and >55 years of age, respectively

5. EVALUATION OF RESPONSE TO STUDY INTERVENTION

5.1. Efficacy

5.1.1. Phase 2/3

5.1.1.1. Vaccine Efficacy Against Asymptomatic SARS-CoV-2 Infection

Vaccine Efficacy in Participants Without Evidence of SARS-CoV-2 Infection

For the secondary efficacy endpoint, VE for BNT162b2 30 µg (2-dose primary series) against asymptomatic SARS-CoV-2 infection was evaluated in participants without evidence of infection up to the start of the asymptomatic surveillance period (January 2021). Note that the median time between Dose 2 and the start of the asymptomatic surveillance period was 2.9 months for participants in the United States and 5.3 months for participants in Argentina. Cases were counted from the start of the asymptomatic surveillance period.

Among participants included in the evaluable efficacy (asymptomatic surveillance) population, 3921 participants (2092 in BNT162b2 group and 1829 in placebo group) did not have evidence of infection with SARS-CoV-2 prior to the start of the asymptomatic surveillance period (Table 25). There were 24 asymptomatic SARS-CoV-2 infections in the BNT162b2 (30 µg) group compared to 20 infections reported in the placebo group. The estimated VE was 37.2% (2-sided 95% CI: -20.0%, 66.7%) (Table 33). This descriptive analysis was limited by the accrual of only 44 cases total, resulting in a wide 2-sided 95% CI and limiting the precision of this estimate.

VE against asymptomatic SARS-CoV-2 infection was 40.4% (2-sided 95% CI: -10.8%, 67.8%) for Dose 2 all-available efficacy population (Supplemental Table 14.27 and Supplemental Table 14.28).

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Table 33. Vaccine Efficacy – Asymptomatic SARS-CoV-2 Infection Based on Central Laboratory–Confirmed NAAT Result – Subjects Without Evidence of Infection Prior to the Start of the Asymptomatic Surveillance Period – Evaluable Efficacy (Asymptomatic Surveillance) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=2092)		Placebo (N[a]=1829)			
Efficacy Endpoint	n[b]	Surveillance Time[c]	n[b]	Surveillance Time[c]	VE (%)	(95% CI[d])
Asymptomatic SARS-CoV-2 infection based on central laboratory–confirmed NAAT result during asymptomatic surveillance period	24	0.383	20	0.200	37.2	(-20.0, 66.7)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence of past SARS-CoV-2 infection (i.e, negative N-binding antibody [serum] result at Visits 1 and 201, SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2, and negative NAAT [nasal swab] result at any unscheduled visits) prior to the start of the asymptomatic surveillance period were included in the analysis.
a. N = number of subjects in the specified group.
b. n = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group. Time period for case accrual is from the start of the asymptomatic surveillance period to the end of the surveillance period.
d. Two-sided confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
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Vaccine Efficacy in Participants With Evidence of SARS-CoV-2 Infection

For the exploratory efficacy endpoint, VE for BNT162b2 30 µg (2-dose primary series) against asymptomatic SARS-CoV-2 infection was evaluated in participants with evidence of infection up to the start of the asymptomatic surveillance period. Cases were counted from the start of the asymptomatic surveillance period.

Among participants included in the evaluable efficacy (asymptomatic surveillance) population, 213 participants (80 in BNT162b2 group and 133 in placebo group) had evidence of infection with SARS-CoV-2 prior to the start of the asymptomatic surveillance period (Table 25). There were 10 asymptomatic SARS-CoV-2 infections in the BNT162b2 (30 µg) group compared to 35 infections reported in the placebo group. The estimated VE was 70.8% (2-sided 95% CI: 39.7%, 87.1%) for BNT162b2 (Table 34). This descriptive analysis was limited by the accrual of only 45 infections total, resulting in a wide 2-sided 95% CI and limiting the precision of this estimate.

VE of BNT162b2 for the same efficacy endpoint based on the Dose 2 all-available efficacy population was 65.6% (2-sided 95% CI: 32.3%, 83.7%) (Supplemental Table 14.29 and Supplemental Table 14.30).

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Table 34. Vaccine Efficacy – Asymptomatic SARS-CoV-2 Infection Based on Central Laboratory–Confirmed NAAT Result – Subjects With Evidence of Infection Prior to the Start of the Asymptomatic Surveillance Period – Evaluable Efficacy (Asymptomatic Surveillance) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=80)		Placebo (N[a]=133)			
Efficacy Endpoint	n[b]	Surveillance Time[c]	n[b]	Surveillance Time[c]	VE (%)	(95% CI[d])
Asymptomatic SARS-CoV-2 infection based on central laboratory–confirmed NAAT result during asymptomatic surveillance period	10	0.014	35	0.014	70.8	(39.7, 87.1)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had serological or virological evidence of past SARS-CoV-2 infection (i.e, N-binding antibody [serum] positive at either Visit 1 or asymptomatic surveillance consent visit, or SARS-CoV-2 positive detected by NAAT [nasal swab] at Visits 1 or 2, or had positive NAAT [nasal swab] at any unscheduled visit) prior to the start of the asymptomatic surveillance period were included in the analysis.
a. N = number of subjects in the specified group.
b. n = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group. Time period for case accrual is from the start of the asymptomatic surveillance period to the end of the surveillance period.
d. Two-sided confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
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5.1.1.2. Vaccine Efficacy Against Non-S-Seroconversion to SARS-CoV-2

For the secondary efficacy endpoint, VE for BNT162b2 30 µg (2-dose primary series) against non-S-seroconversion to SARS-CoV-2 infection was evaluated in participants without evidence of infection or confirmed COVID-19. Note that the surveillance time in the placebo group was shorter than in the BNT162b2 group and accounted for in the VE calculations. This difference is due to the placebo crossover resulting in a shorter duration of follow up for participants who originally received placebo.

Among participants included in the evaluable efficacy (seroconversion) population, 41564 participants (20872 in BNT162b2 group and 20692 in placebo group) did not have evidence of infection with SARS-CoV-2 prior to the first post–dose 2 N-binding test (Table 26). There were 612 cases of seroconversion of N-binding antibody, indicative of SARS-CoV-2 infection, in the BNT162b2 (30 µg) group compared to 608 cases in the placebo group. The estimated VE was 52.9% (2-sided 95% CI: 47.2%, 57.9%) for BNT162b2 (Table 35).

VE of BNT162b2 for the same efficacy endpoint based on the Dose 1 and Dose 2 all-available efficacy populations was 49.7% (2-sided 95% CI: 44.0%, 54.9%) and 52.3% (2-sided 95% CI: 46.7%, 57.3%), respectively (Supplemental Table 14.31 and Supplemental Table 14.32).

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Table 35. Vaccine Efficacy – Asymptomatic Infection Based on N-Binding Antibody Seroconversion – Subjects Without Evidence of Infection Prior to the First Post–Dose 2 N-Binding Test – Evaluable Efficacy (Seroconversion) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20872)		Placebo (N[a]=20692)			
Efficacy Endpoint	n[b]	Surveillance Time[c]	n[b]	Surveillance Time[c]	VE (%)	(95% CI[d])
Asymptomatic infection based on N-binding antibody seroconversion after Dose 2	612	13.840	608	6.481	52.9	(47.2, 57.9)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence of past SARS-CoV-2 infection before Dose 2 (ie, negative N-binding antibody [serum] result at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2) and had a negative NAAT (nasal swab) result at any unscheduled visit and without any important protocol deviation prior to the first post–Dose 2 N-binding test result were included in the analysis.
a. N = number of subjects in the specified group.
b. n = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group. Time period for case accrual is from Dose 2 to the end of the surveillance period.
d. Two-sided confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
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In the evaluable efficacy (seroconversion) population without evidence of SARS-CoV-2 infection, VE of BNT162b2 was 60.4% and 56.6% from Dose 2 to 1 month after Dose 2 and from >1 month after Dose 2, respectively (Table 36). The VE for cases confirmed after Dose 2 was 52.9% (2-sided 95% CI: 47.2%, 57.9%) based on 612 and 608 cases in the BNT162b2 (30 µg) and placebo groups, respectively. Note that >1 month after Dose 2, the surveillance time in the BNT162b2 (30 µg) group (11.961 [1000 person-years]) was more than twice the surveillance time in the placebo group (4.681 [1000 person-years]), which is accounted for in the VE calculations; this is due to the placebo crossover resulting in truncated follow-up time for participants who originally received placebo.

Table 36. Vaccine Efficacy by Time Interval – Asymptomatic Infection Based on N-Binding Antibody Seroconversion – Subjects Without Evidence of Infection – Evaluable Efficacy (Seroconversion) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg)		Placebo			
Efficacy Endpoint Subgroup	N[a]/n[b]	Surveillance Time[c]	N[a]/n[b]	Surveillance Time[c]	VE (%)	(95% CI[d])
Asymptomatic infection based on N-binding antibody seroconversion after Dose 2	20872/612	13.840	20692/608	6.481	52.9	(47.2, 57.9)
Dose 2 to 1 month after Dose 2	20697/34	1.750	20502/85	1.734	60.4	(40.4, 74.2)
>1 Month after Dose 2	19487/576	11.961	18012/519	4.681	56.6	(51.0, 61.5)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence of past SARS-CoV-2 infection before Dose 2 (ie, negative N-binding antibody [serum] result at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2) and had a negative NAAT (nasal swab) result at any unscheduled visit and without any important protocol deviation prior to the first post–Dose 2 N-binding test result were included in the analysis.
Note: Subjects who do not have a post–Dose 2 N-binding test at 1 month after Dose 2 or upto 42 days from Dose 2 were not included in the subgroup rows for time-interval analysis.
a. N = number of subjects in the specified group.
b. n = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group. Time period for case accrual is from Dose 2 to the end of the surveillance period for the overall row and from the start to the end of the ranges for each time interval.
d. Two-sided confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
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5.1.1.3. Incidence Rates of First COVID-19 Occurrence After Vaccination

Analyses were performed for COVID-19 cases accrued for the following groups and periods:

- Original BNT162b2 (30 µg) group during a period when multiple SARS-CoV-2 strains were circulating (ie, original/wild type strain and Alpha, Beta, Delta, Gamma, Omicron variants), pre-dominating at various times during the period from the Dose 1 vaccination date to the earliest of confirmed case, death, study withdrawal, study completion date, or the participant's first dose of BNT162b2$_{SA}$ vaccine.

- Original placebo prior to crossover group for the time between vaccination in the blinded period, and the crossover date. The original/wild type was the predominant strain during this period. Most of the Phase 2/3 participants were unblinded (April 2021) and transitioned to the crossover group when the Delta variant was the predominant strain. Crossover of Phase 2/3 participants was completed by October 2021.

- Placebo crossover to BNT162b2 (30 µg) group for the period from first BNT162b2 vaccination. Analyses were performed for COVID-19 cases accrued for the placebo crossover to BNT162b2 (30 µg) group when Alpha and Beta variants (01 December 2020 to 10 January 2021), Gamma variant (11 January 2021 to 03 April 2021), Delta variant (04 April 2021 to 26 November 2021), Omicron variant (27 November 2021 to LSLV) were predominant.

For cases of first COVID-19 occurrence after vaccination, the IRs for participants in the original BNT162b2, original placebo prior to crossover, and placebo crossover to BNT162b2 groups were 104.562, 125.722, and 169.138 per 1000 person-years of follow-up, respectively (Table 37).

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Table 37. Incidence Rates of First COVID-19 Occurrence After Vaccination – All-Available Efficacy Population

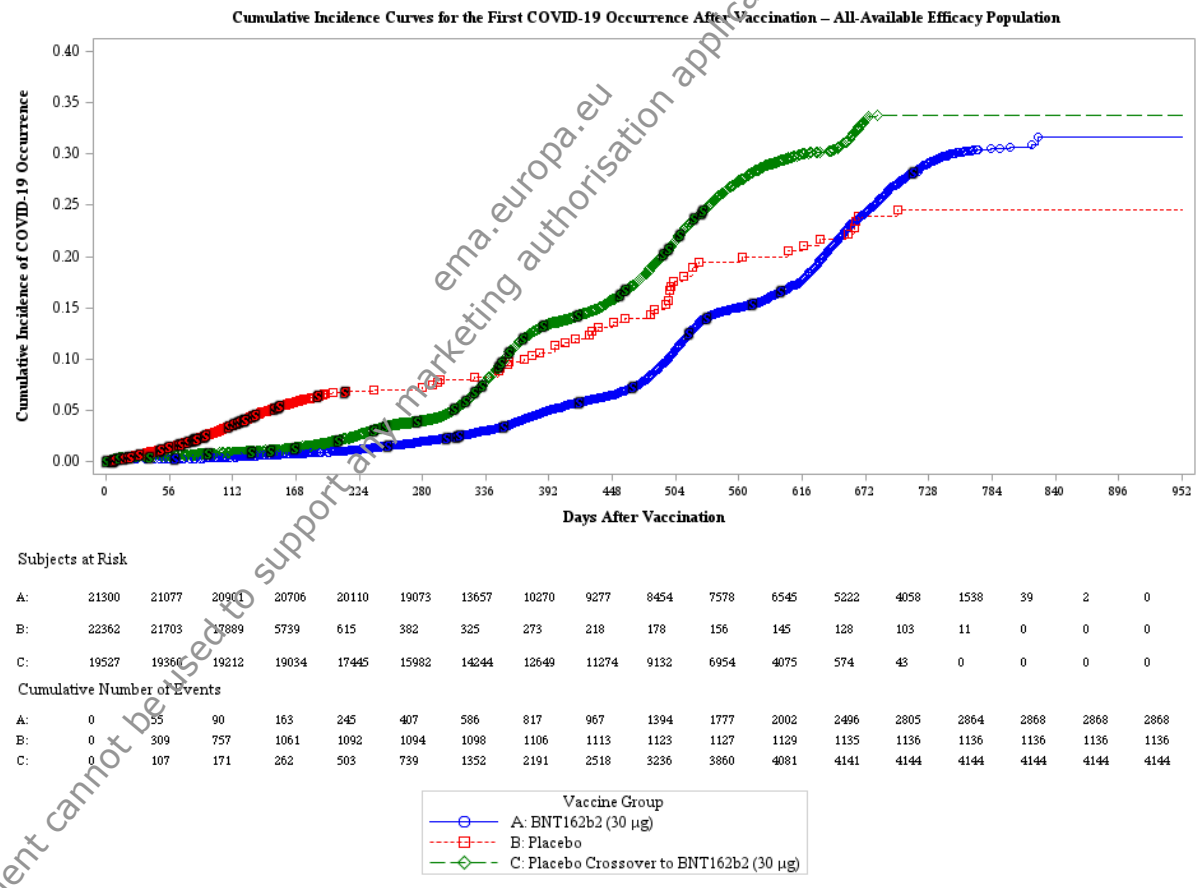
	Vaccine Group								
	Original BNT162b2 (30 µg)			Original Placebo Prior to Crossover			Placebo Crossover to BNT162b2 (30 µg)		
Efficacy Endpoint	n1[a]	Surveillance Time[b] (n2[c])	IR (/1000 PY)[d]	n1[a]	Surveillance Time[b] (n2[c])	IR (/1000 PY)[d]	n1[a]	Surveillance Time[b] (n2[c])	IR (/1000 PY)[d]
First COVID-19 occurrence after vaccination	2868	27.429 (21300)	104.562	1136	9.036 (22362)	125.722	4144	24.501 (19527)	169.138

a. n1 = Number of participants meeting the endpoint definition.
b. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. For the original BNT162b2 arm, time period for COVID-19 case accrual is from the dose 1 vaccination date to the earliest of confirmed case, death, withdrawn from the study, study completion date, or their first dose of BNT162b2SA vaccination. For original Placebo arm, the time period between vaccination in blinded period and the crossover date is considered. For the Placebo crossover to BNT162b2 (30 µg) arm, the time period from first BNT162b2 vaccination is considered as the starting point for surveillance.
c. n2 = Number of participants at risk for the endpoint.
d. Incidence rate (IR) is calculated as number of participants meeting the endpoint definition/total surveillance time across all participants at risk for the endpoint within the specific group.
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Kaplan-Meier curve shows the case accrual from vaccination up to the end of study date for the participants who received BNT162b2 originally (original BNT162b2 group), participants who received placebo originally prior to crossover (original placebo group), and participants who received placebo originally and then crossed over to receive BNT162b2 (placebo crossover to BNT162b2 group), with severe COVID-19 cases denoted with 'S' on the curves (Figure 2). During the entire study period, most participants were eligible to receive up to 4 vaccine doses (2 dose primary series and 2 booster doses). In the postvaccination period, there is clear evidence of better protection by BNT162b2 compared to placebo in the immediate months following vaccination before cross over occurred. After placebo crossover, case accrual increased for both the original BNT162b2 and placebo crossover groups following different variant waves. The curves steepen substantially around 470 and 300 days for the original BNT162b2 and placebo crossover groups, respectively, which likely represents when each group was exposed to the start of the Omicron waves.

Figure 2. Cumulative Incidence Curves for the First COVID-19 Occurrence After Vaccination – All Available Efficacy Population



Note: "S" indicates participants with severe COVID-19.
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5.1.2. Summary of Efficacy

A formal secondary efficacy analysis was performed to assess vaccine efficacy against asymptomatic SARS-CoV-2 infections and against non-S-seroconversion to SARS-CoV-2. The incidence of confirmed first COVID-19 through the entire study follow-up period in participants who received BNT162b2 was also described.

- In the evaluable efficacy (asymptomatic surveillance) population without evidence of SARS-CoV-2 infection prior to the start of the asymptomatic surveillance period, the VE for BNT162b2 30 µg (2-dose primary series) based on NAAT-confirmed infection was 37.2% (2-sided 95% CI: -20.0%, 66.7%) based on 24 asymptomatic SARS-CoV-2 infections in the BNT162b2 group and 20 infections reported in the placebo group.

- In the evaluable efficacy (asymptomatic surveillance) population with evidence of SARS-CoV-2 infection prior to the start of the asymptomatic surveillance period, the VE for BNT162b2 30 µg (2-dose primary series) was 70.8% (2-sided 95% CI: 39.7%, 87.1%) based on 10 asymptomatic SARS-CoV-2 infections in the BNT162b2 group and 35 infections reported in the placebo group.

- In the evaluable efficacy (seroconversion) population without evidence of SARS-CoV-2 infection prior to the first post–Dose 2 N-binding test, the VE for BNT162b2 30 µg (2-dose primary series) was 52.9% (2-sided 95% CI: 47.2%, 57.9%) for confirmed cases. From Dose 2 to 1 month after Dose 2 and from >1 month after Dose 2, the VE was 60.4% and 56.6%, respectively, and the overall VE was 52.9% (2-sided 95% CI: 47.2%, 57.9%) after Dose 2.

- Confirmed COVID-19 cases accrued through the entire study follow-up as multiple SARS-CoV-2 variants circulated, most notably following the emergence of Omicron. This prompted the development and implementation of variant-adapted vaccines: bivalent vaccines targeting the original/wild type strain and Omicron BA.1 or BA.4/BA.5, and most recently monovalent XBB.1.5.

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5.2. Immunogenicity

5.2.1. Phase 3

Summarized below are immunogenicity results for Phase 3 BNT162b2-experienced participants, 18 through 55 and >55 years of age, who received a lower booster dose (Dose 3) of BNT162b2 (5 or 10 µg).

5.2.1.1. SARS-CoV-2 Neutralizing Titers to Reference Strain

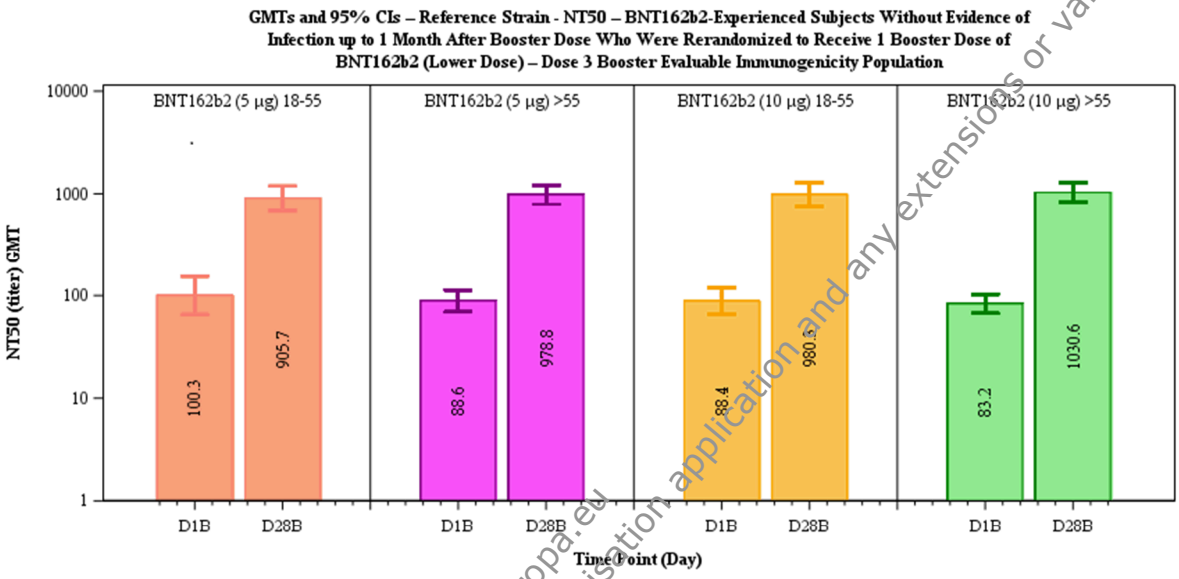
5.2.1.1.1. GMTs

Among participants in the Dose 3 evaluable immunogenicity population without evidence of SARS-CoV-2 infection up to 1 month after the booster dose, SARS-CoV-2 50% neutralizing GMTs increased substantially at 1 month (Day 28) after the booster (Dose 3) for both dose and age groups (Figure 3, Supplemental Figure 14.1, and Supplemental Table 14.33). The SARS-CoV-2 50% neutralizing GMTs were similar, immediately before and 1 month after booster dose across the dose and age groups.

Similar results were observed for participants in the booster (Dose 3) evaluable immunogenicity population regardless of prior infection status (Supplemental Tables 14.34) and for participants in the Dose 3 booster all-available immunogenicity population (Supplemental Table 14.35).

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Figure 3. Geometric Mean Titers and 95% CIs: SARS-CoV2 Neutralizing Titers (NT50) – BNT162b2-Experienced Subjects Without Evidence of Infection up to 1 Month After Booster Dose Who were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Dose 3 Booster Evaluable Immunogenicity Population



Abbreviations: B = booster vaccination; D = day; GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (up to 1 month after receipt of the booster vaccination) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Dose 1 visit, 1-month post–Dose 2 visit, booster dose visit, 1-month post–booster visit and SARS-CoV-2 not detected by NAAT [nasal swab] at Dose 1 visit, Dose 2 visit, booster dose visit) and had a negative NAAT (nasal swab) at any unscheduled visit up to 1 month after booster vaccination were included in the analysis.
Note: Number within each bar denotes geometric mean titer.
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5.2.1.1.2. GMFRs

Among participants in the Dose 3 booster evaluable immunogenicity population without evidence of SARS-CoV-2 infection up to 1 month after the booster (Dose 3), the GMFR of SARS-CoV-2 50% serum neutralizing titers 1 month after Dose 3 ranged from 9.0 to 12.4 (median time 6.8 to 7.2 months from Dose 2 to booster [Dose 3]) in the BNT162b2 (5 or 10 µg) groups (Supplemental Table 14.36). Of note, GMFR of SARS-CoV-2 50% serum neutralizing titer from before Dose 3 to 1 month after Dose 3 of BNT162b2 30 µg was 17.7 (median time 6.8 months from Dose 2 to booster [Dose 3]) (20 May 2022 interim CSR), indicating a higher booster effect of the 30-µg dose than the lower doses (5 or 10 µg).

The GMFRs were similar for participants in the booster (Dose 3) evaluable immunogenicity population regardless of prior infection status and for participants in the booster (Dose 3) all-available immunogenicity population (Supplemental Tables 14.37 and 14.38).

5.2.2. Summary of Immunogenicity

Lower booster doses of BNT162b2 (5 or 10 µg) in BNT162b2-experienced participants substantially increased SARS-CoV-2 neutralizing antibody response 1 month after Dose 3 in participants 18 through 55 and >55 years of age, based on GMTs, GMFRs, and RCDCs.

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Although there is no contemporaneous 30-µg comparator for lower booster doses of BNT162b2 (5 or 10 µg), the GMFR for 30-µg booster (Phase 3), presented in the 20 May 2022 interim CSR, show that, based on GMFR values, a higher booster dose of BNT162b2 elicits a more robust immune response.

5.3. Safety

This final CSR summarizes Phase 1 and Phase 2/3 safety data for study objectives and endpoints that have not been reported previously. It should be noted that the safety narratives in Section 14 are inclusive of the entire study duration and were identified based on the criteria listed in the final safety narrative plan. This text in this final CSR refers to the narratives specific to the safety data presented in Section 5 of this final report.

Refer to the Errata for information regarding missing AEs/SAE that were discovered for 2 participants in Study C4591001.

5.3.1. Phase 1

Summarized below are results for Phase 1 participants, which include but are not limited to the following safety results:

- SAEs from Dose 1 (placebo, BNT162b1 [10, 20, 30, and 100 µg] or BNT162b2 [10, 20, and 30 µg]) to 6 months after Dose 2 (placebo, BNT162b1 or BNT162b2)
- AEs and SAEs from Dose 3 of BNT162b2 (30 µg) to 1 month after Dose 3
- AEs and SAEs from Dose 4 of BNT162b2 (30 µg) to 1 month after Dose 4

5.3.1.1. Local Reactions and Systemic Events

In this study, reactogenicity events after each dose for both BNT162b1 and BNT162b2 were typically mild to moderate and short-lived. Refer to Table 5 for reactogenicity (local reactions and systemic events) previously reported for Phase 1 participants.

5.3.1.2. Adverse Events

5.3.1.2.1. Dose 1 to 6 Months After Dose 2

5.3.1.2.1.1. Serious Adverse Events

There were no Phase 1 participants who reported any SAEs in the placebo group from Dose 1 to 6 months after Dose 2 (Supplemental Table 14.39).

Two SAEs were reported by 1 participant in the BNT162b2 20-µg group and 1 participant in the 30-µg group. In the BNT162b2 20-µg group, 1 SAE of appendicitis was reported in 1 participant (Supplemental Table 14.39) and was assessed by the investigator as not related to study intervention (Appendix 16.2.7.7.1). In the BNT162b2 30-µg group, 1 severe SAE of neuritis was reported by 1 participant and was assessed by the investigator as not related to study intervention (see Table 5 for interim reporting).

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5.3.1.2.2. First Booster Dose to 1 Month After the First Booster Dose

5.3.1.2.2.1. Brief Summary of Adverse Events

An overview of AEs from administration of the first booster dose of BNT162b2 30 µg (Dose 3) to 1 month after the first booster dose for the initial vaccines groups is shown in Table 38.

In the initial BNT162b1 vaccine groups, AEs were reported by 1 to 5 participants (9.5% to 20.8%). Related AEs were reported in the 10, 20, and 30-µg groups by 1 to 3 participants (4.2% to 12.5%), and 2 participants (8.3%) reported a severe AE in the 30-µg dose group. In the 100-µg group, 1 participant (11.1%) reported a life-threatening event that was assessed by the investigator as not related to study intervention.

In the initial BNT162b2 10, 20, and 30-µg groups, 1 to 3 participants (4.2% to 13.6%) reported at least 1 AE from the first booster dose (Dose 3) of BNT162b2 30 µg to 1 month after the first booster dose. Related AEs were reported in the 10-µg group by 3 participants (13.6%). No participants reported life-threatening AEs.

No AEs leading to withdrawal or deaths were reported for participants in either the initial BNT162b1 or BNT162b2 vaccine groups.

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Table 38. Number (%) of Subjects Reporting at Least 1 Adverse Event From the First Booster Dose to 1 Month After the First Booster Dose – Phase 1 – Subjects Who Received the First Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Initial Vaccine Group (as Administered)							
	BNT162b1				BNT162b2			
Adverse Event	10 µg (N^a=21) n^b (%)	20 µg (N^a=24) n^b (%)	30 µg (N^a=24) n^b (%)	100 µg (N^a=9) n^b (%)	10 µg (N^a=22) n^b (%)	20 µg (N^a=23) n^b (%)	30 µg (N^a=24) n^b (%)	Placebo (N^a=28) n^b (%)
Any adverse event	2 (9.5)	5 (20.8)	4 (16.7)	1 (11.1)	3 (13.6)	1 (4.3)	1 (4.2)	0
Related[c]	1 (4.8)	1 (4.2)	3 (12.5)	0	3 (13.6)	0	0	0
Severe	0	0	2 (8.3)	0	0	0	0	0
Life-threatening	0	0	0	1 (11.1)	0	0	0	0
Any serious adverse event	0	0	0	1 (11.1)	0	0	0	0
Related[c]	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Life-threatening	0	0	0	1 (11.1)	0	0	0	0
Any nonserious adverse event	2 (9.5)	5 (20.8)	4 (16.7)	0	3 (13.6)	1 (4.3)	1 (4.2)	0
Related[c]	1 (4.8)	1 (4.2)	3 (12.5)	0	3 (13.6)	0	0	0
Severe	0	0	2 (8.3)	0	0	0	0	0
Life-threatening	0	0	0	0	0	0	0	0
Any adverse event leading to withdrawal	0	0	0	0	0	0	0	0
Related[c]	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Life-threatening	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0

Table 38. Number (%) of Subjects Reporting at Least 1 Adverse Event From the First Booster Dose to 1 Month After the First Booster Dose – Phase 1 – Subjects Who Received the First Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Initial Vaccine Group (as Administered)							
	BNT162b1				BNT162b2			
Adverse Event	10 µg (N[a]=21) n[b] (%)	20 µg (N[a]=24) n[b] (%)	30 µg (N[a]=24) n[b] (%)	100 µg (N[a]=9) n[b] (%)	10 µg (N[a]=22) n[b] (%)	20 µg (N[a]=23) n[b] (%)	30 µg (N[a]=24) n[b] (%)	Placebo (N[a]=28) n[b] (%)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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5.3.1.2.2.2. Analysis of Adverse Events

5.3.1.2.2.2.1. Adverse Events by System Organ Class and Preferred Term

AE by SOC and PT summaries in this section included AEs from the first booster dose to 1 month after the first booster dose for all initial BNT162b1 and BNT162b2 groups.

A limited number of AEs by SOC were reported by Phase 1 participants from the first booster dose to 1 month after the first booster dose (Supplemental Table 14.40). Generally, most PTs were reported by no more than 1 participant per the initial BNT162b1 and BNT162b2 dose groups and included, but not limited to, reports of lymphadenopathy, fatigue, axillary pain, chills, myalgia, muscle spasms, dizziness, headache, paresthesia, and presyncope. One participant (4.2%) reported an AE of deep vein thrombosis in the initial BNT162b1 20-µg group.

5.3.1.2.2.2.2. Related Adverse Events

Related AEs were reported in the initial BNT162b1 10-, 20-, and 30-µg groups and the initial BNT162b2 10-µg group only (Supplemental Table 14.41). Related AEs were reported by no more than 3 participants per group.

From the first booster dose to 1 month after the first booster dose, AEs assessed as related by the investigator in the initial BNT162b1 10- and 20-µg groups were reported by no more than 1 participant per group. Two participants (8.3%) in the initial 30-µg dose group reported a related AE of lymphadenopathy.

In the initial BNT162b2 10-µg group, general disorders and administration site conditions (chills, injection site haemorrhage) and nervous system disorders (paraesthesia and headache) were reported by 2 participants (9.1%) each.

5.3.1.2.2.2.3. Immediate Adverse Events

There were no immediate adverse events reported after the first booster dose in the initial BNT162b1 groups (Supplemental Table 14.42).

In the initial BNT162b2 10-µg group, 1 immediate AE of injection site haemorrhage was reported in 1 participant.

5.3.1.2.2.2.4. Severe or Life-Threatening Adverse Events

From the first booster dose to 1 month after the first booster dose, 2 severe events (axillary pain and headache) were reported by 2 participants (8.3%) in the initial BNT162b1 30-µg group (Supplemental Table 14.43).

One life-threatening (Grade 4) event of colitis was reported in the initial BNT162b1 100-µg group (Supplemental Table 14.44), onset 4 days after booster vaccination, and was assessed by the investigator as unrelated to study vaccine (Appendix 16.2.7.4.1) (see Section 5.3.1.2.2.3.2 for further details).

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5.3.1.2.2.3. Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events

5.3.1.2.2.3.1. Deaths

No deaths were reported in the Phase 1 booster safety population in the initial BNT162b1 and BNT162b2 groups from the first booster dose to 1 month after the first booster dose (Table 38).

5.3.1.2.2.3.2. Serious Adverse Events

From booster dose (Dose 3) to 1 month after booster dose of BNT162b2 30 µg, 1 participant (11.1%) in the initial BNT162b1 100-µg group reported 1 SAE of colitis (Supplemental Table 14.45) which was assessed by the investigator as unrelated to the vaccine (Appendix 16.2.7.7.1). This participant required overnight observation at the emergency room due to symptoms of abdominal pain, diarrhea, and blood in stool, with the diagnosis confirmed by CT scan of the abdomen. Treatment was with oral antibiotics and a follow up sigmoidoscopy was negative with full resolution of symptoms 19 days after onset.

5.3.1.2.2.3.3. Discontinuations From Study Due to Adverse Events

No participants in the Phase 1 BNT162b2 booster safety population in the initial BNT162b1 and BNT162b2 groups were withdrawn due to AEs from the first booster dose of BNT162b2 (30 µg) to 1 month after the first booster dose (Table 38) (Appendix 16.2.7.3.1).

5.3.1.2.2.3.4. Pregnancy

One pregnancy was reported in the Phase 1 BNT162b2 booster safety population in the initial BNT162b1 group from the first booster dose of BNT162b2 (30 µg) to 1 month after the first booster dose (Appendix.16.2.7.8).

5.3.1.2.3. Additional Booster Dose to 1 Month After the Additional Booster Dose

5.3.1.2.3.1. Brief Summary of Adverse Events

An overview of AEs from administration of the additional booster dose (Dose 4) to 1 month after the additional booster dose is shown in Table 39.

From Dose 4 to 1 month after Dose 4, the number (%) of participants with any AE was 3 (3.8%); these AEs were considered by investigators as related to study intervention. No participants reported a severe or life-threatening AE.

No SAEs, AEs leading to withdrawal, or deaths were reported.

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Table 39. Number (%) of Subjects Reporting at Least 1 Adverse Event From the Additional Booster Dose to 1 Month After the Additional Booster Dose – Phase 1 – Subjects Who Received the Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

	Vaccine Group (as Administered)
Adverse Event	**BNT162b2 (30 µg) (N[a]=80) n[b] (%)**
Any adverse event	3 (3.8)
Related[c]	3 (3.8)
Severe	0
Life-threatening	0
Any serious adverse event	0
Related[c]	0
Severe	0
Life-threatening	0
Any nonserious adverse event	3 (3.8)
Related[c]	3 (3.8)
Severe	0
Life-threatening	0
Any adverse event leading to withdrawal	0
Related[c]	0
Severe	0
Life-threatening	0
Death	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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5.3.1.2.3.2. Analysis of Adverse Events

5.3.1.2.3.2.1. Adverse Events by System Organ Class and Preferred Term

AEs reported from the additional booster dose (Dose 4) to 1 month after the additional booster dose by SOC and preferred term are presented in Table 40. The study did not use e-diary to collect reactogenicity events after the additional booster dose (Dose 4). Events related to reactogenicity (eg, injection site pain, fatigue, myalgia, pyrexia, and headache) were collected as AEs. Of the AEs reported during this period, some were reactogenicity events reported as AEs. The number of participants (%) who reported AEs by SOC were as follows:

- general disorders and administration site conditions: 1 (1.3%)
- musculoskeletal and connective tissue disorders: 2 (2.5%)

These events were assessed by the investigator as related to study intervention. See Section 5.3.1.2.3.2.2 for details.

Table 40. Number (%) of Subjects Reporting at Least 1 Adverse Event From the Additional Booster Dose to 1 Month After the Additional Booster Dose, by System Organ Class and Preferred Term – Phase 1 – Subjects Who Received the Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=80) n[b] (%)	(95% CI[c])
Any adverse event	3 (3.8)	(0.8, 10.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (1.3)	(0.0, 6.8)
Injection site pain	1 (1.3)	(0.0, 6.8)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (2.5)	(0.3, 8.7)
Myalgia	1 (1.3)	(0.0, 6.8)
Pain in extremity	1 (1.3)	(0.0, 6.8)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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5.3.1.2.3.2.2. Related Adverse Events

From the additional booster dose to 1 month after the additional booster dose, 3 participants (3.8%) had AEs assessed by the investigator as related to study intervention (Supplemental Table 14.46). These events, which also included reactogenicity events, were reported as AEs (see Section 5.3.1.2.3.2.1). One participant (1.3%) each reported injection site pain, myalgia, and pain in extremity.

5.3.1.2.3.2.3. Immediate Adverse Events

There were no immediate AEs reported after the additional booster dose.

5.3.1.2.3.2.4. Severe or Life-Threatening Adverse Events

There were no severe or life-threatening AEs reported after the additional booster dose (Table 39).

5.3.1.2.3.3. Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events

5.3.1.2.3.3.1. Deaths

No deaths were reported in the Phase 1 booster safety population from the additional booster dose to 1 month after the additional booster dose.

5.3.1.2.3.3.2. Serious Adverse Events

No SAEs were reported in the Phase 1 booster safety population from the additional booster dose to 1 month after the additional booster dose.

5.3.1.2.3.3.3. Discontinuations from Study Due to Adverse Events

No participants in the Phase 1 BNT162b2 booster safety population were withdrawn due to AEs from the additional booster dose of BNT162b2 (30 µg) to 1 month after the additional booster dose (Appendix 16.2.7.3.1).

5.3.1.2.3.3.4. Pregnancy

No pregnancies were reported in the Phase 1 BNT162b2 booster safety population from the additional booster dose of BNT162b2 (30 µg) to 1 month after the additional booster dose (Appendix 16.2.7.8).

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5.3.1.3. Phase 1 Safety Conclusions

- All doses of BNT162b1 and BNT162b2 were safe and well tolerated. BNT162b1 at 100 µg was discontinued due to the reactogenicity profile (previously reported); no participants in either age group received any dose of BNT162b2 at the 100-µg dose level.
- The frequency of participants with any AE after the booster doses (Dose 3 and Dose 4) of BNT162b2 (30 µg) was low, with most participants reporting mild, reactogenicity-type events.
- The frequency of participants reporting SAEs after the first 2 doses of BNT162b1 and BNT162b2, and the booster doses (Dose 3 and Dose 4), was from none to low, and all SAEs reported were assessed by the investigator as not related to study intervention. There were no AEs leading to withdrawal or deaths reported.

5.3.2. Phase 2/3

5.3.2.1. Local Reactions and Systemic Events

In this study, reactogenicity of BNT162b2 was typically mild to moderate and short-lived. Refer to Table 5 for previously reported results.

Local reactions and systemic events for BNT162b2-experienced participants 18 through 55 and >55 years of age who were rerandomized to receive 1 booster dose of BNT162b2 (lower dose of 5 or 10 µg) under protocol amendment 15 are presented in this final CSR.

5.3.2.1.1. Local Reactions for Participants Who Received Lower Dose Booster

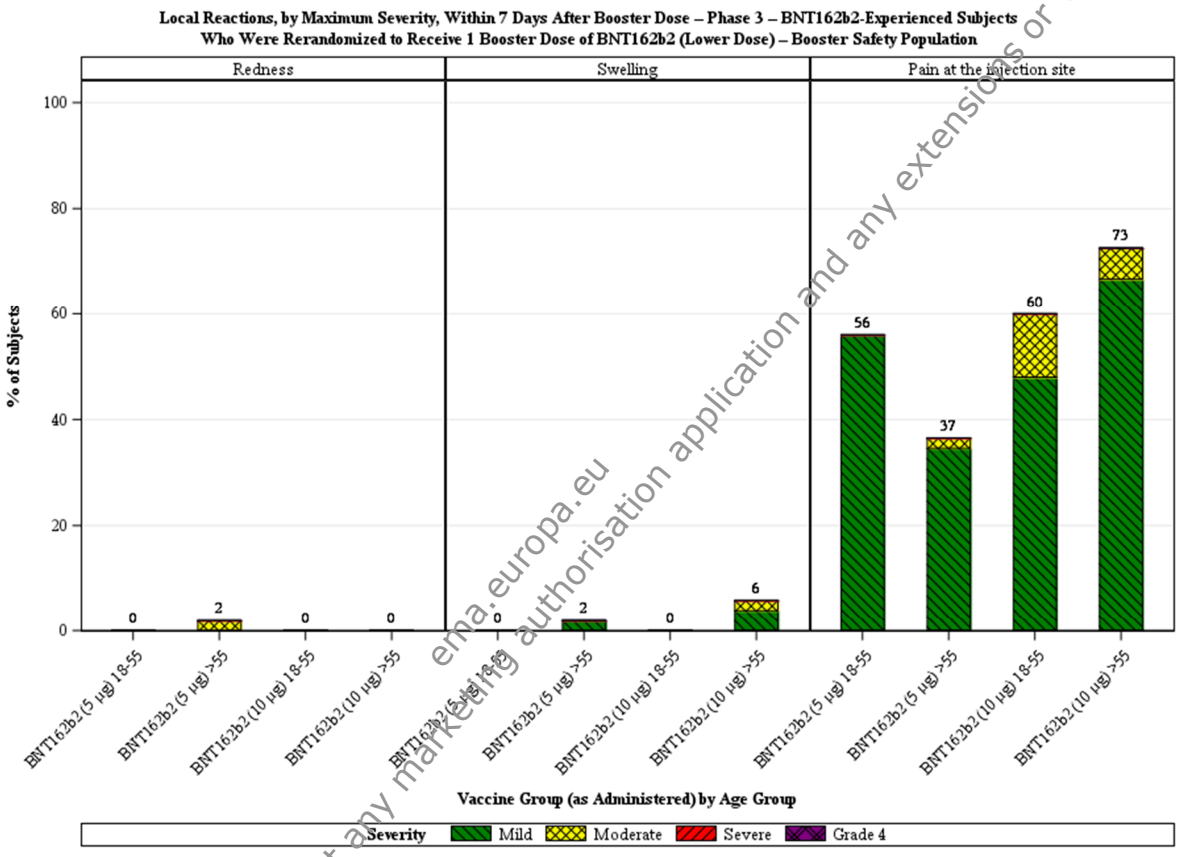
Local reactions in BNT162b2-experienced participants 18 through 55 and >55 years of age who received 1 booster dose of BNT162b2 (5 or 10 µg) were mild to moderate and pain at the injection site was the most frequently reported local reaction (Figure 4 and Supplemental Table 14.47).

In the BNT162b2 (5 µg) groups, the most frequent local reaction was pain at the injection site with a higher percentage of younger (18 through 55 years) than older (>55 years) participants reporting the local reaction (56.0% vs 36.5%). In the BNT162b2 (10 µg) groups, pain at the injection site was also the most common local reaction, with a lower percentage of younger (18 through 55 years) than older (>55 years) participants reporting the local reaction (60.0% vs 72.5%). In the BNT162b2 (5 and 10 µg) groups, redness and swelling were infrequent (≤5.9%) and no severe or Grade 4 local reactions were reported. In both the BNT162b2 5 and 10 µg groups, the frequency of any local reaction was similar in participants 18 through 55 years of age, while in participants >55 years of age, the frequency of any local reaction was higher with increased dose.

Across the age groups, median onset for all local reactions after either dose of BNT162b2 was Day 1 to Day 2 (Day 1 was the day of vaccination) (Supplemental Table 14.48) and resolved with a median duration of 1.0 to 4.0 days (Supplemental Table 14.49).

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Figure 4. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Booster Dose Phase 3 BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) Booster Safety Population



Note: Number above each bar denotes percentage of subjects reporting the reaction with any severity.
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5.3.2.1.2. Systemic Events for Participants Who Received Lower Dose Booster

Systemic events in BNT162b2-experienced participants 18 through 55 and >55 years of age who received 1 booster dose of BNT162b2 (5 or 10 µg) were predominantly mild to moderate and fatigue was the most frequently reported systemic event (Figure 5 and Supplemental Table 14.50). Reporting of fever and vomiting was infrequent (≤4.0% and ≤3.8% respectively), and no Grade 4 systemic events were reported in any of the groups.

In the BNT162b2 (5 µg) groups, systemic events by age (18 through 55 and >55 years of age, respectively), were:

- fatigue: 44.0% and 26.9%
- headache: 24.0% and 23.1%
- new or worsened muscle pain: 24.0% and 13.5%
- chills: 8.0% and 11.5%
- diarrhea: 8.0% and 3.8%
- vomiting: 0.0% and 3.8%
- new or worsened joint pain: 4.0% and 0.0%

In the BNT162b2 (10 µg) groups, systemic events by age (18 through 55 and >55 years of age, respectively), were:

- fatigue: 60.0% and 51.0%
- headache: 40.0% and 37.3%
- new or worsened muscle pain: 28.0% and 13.7%
- chills: 24.0% and 21.6%
- new or worsened joint pain: 20.0% and 13.7%
- diarrhea: 16.0% and 2.0%

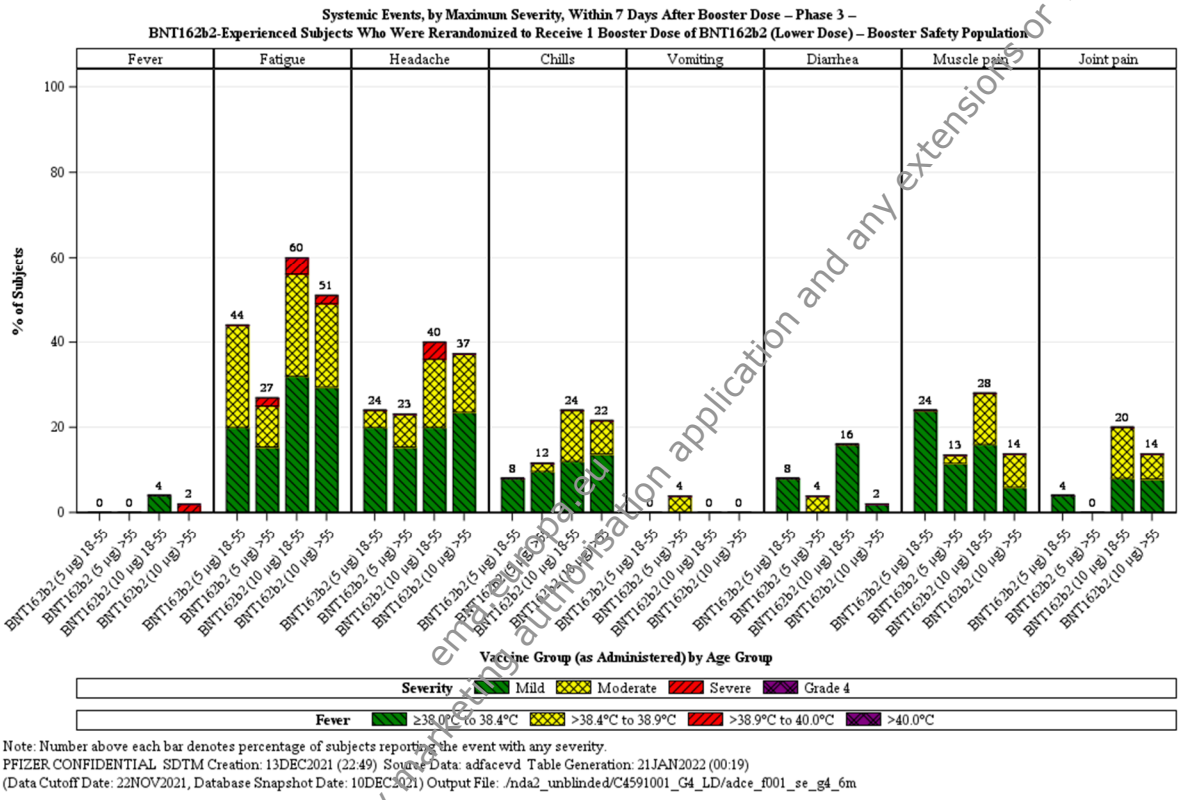
In the BNT162b2 5 and 10 µg groups, systemic events were reported more frequently in the younger age group than the older age group, and there was a higher frequency of systemic events reported in the higher dose groups (10 µg) for participants in both age groups.

Use of antipyretic/pain medication was more frequent in the BNT162b2 (10 µg) groups (28.0% and 23.5% in the 18 through 55 and >55 years of age groups, respectively) compared to the BNT162b2 (5 µg) groups (16.0% and 15.4% in the 18 through 55 and >55 years of age groups, respectively).

Median onset for all systemic events after either dose was Day 1.0 to Day 5.5 (Day 1 was the day of vaccination) (Supplemental Table 14.51). Systemic events resolved after each dose with a median duration of 1.0 to 4.0 days (Supplemental Table 14.52).

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Figure 5. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Booster Dose Phase 3 BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) Booster Safety Population



Note: Number above each bar denotes percentage of subjects reporting the event with any severity.
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5.3.2.2. Adverse Events

5.3.2.2.1. Dose 1 to 6 Months After Dose 2

5.3.2.2.1.1. Serious Adverse Events

Final SAE analyses are reported for adolescents (12 through 15 years of age) and participants ≥16 years of age from Dose 1 to 6 months after Dose 2 during the blinded, placebo-controlled and open label follow-periods. Refer to Table 5 for previously reported results.

Participants 12 Through 15 Years of Age

From Dose 1 to 6 months after Dose 2, 2 participants (0.2%) in the placebo group reported SAEs (Supplemental Table 14.53). Note the follow-up time for the placebo group is less than 6 months after Dose 2 because of unblinding of placebo recipients and administration of BNT162b2 after unblinding.

From Dose 1 to 6 months after Dose 2 of BNT162b2, the proportions of participants who reported at least 1 SAE were similar in the original BNT162b2 group (1.1%) and original placebo/BNT162b2 group (1.3%) (Supplemental Table 14.54).

No participants in the placebo, original BNT162b2, and original placebo/BNT162b2 groups had SAEs assessed by the investigator as related to study intervention (Appendix 16.2.7.7.1).

Participants ≥16 Years of Age

From Dose 1 to 6 months after Dose 2 of BNT162b2, 291 participants (1.3%) in the placebo group reported SAEs after receiving placebo (Supplemental Table 14.55). All SAEs were assessed by the investigator as not related to study intervention (Appendix 16.2.7.7.1).

From Dose 1 to 6 months after Dose 2 of BNT162b2, participants who reported at least 1 SAE were similar in the original BNT162b2 group (428 participants [2.0%]) and original placebo/BNT162b2 group (353 participants [1.7%]) (Supplemental Table 14.56).

In the original BNT162b2 (30 µg) group, there were 3 participants with an SAE each assessed by the investigator as related to study intervention:

- One participant experienced a ventricular arrhythmia that occurred 1 day after Dose 2 of BNT162b2 and resolved within 8 days.
- One participant experienced a shoulder injury related to vaccine administration that resolved 153 days after Dose 2 of BNT162b2 administration.
- One participant experienced paresthesia that occurred 47 days after Dose 2 of BNT162b2, which lasted 221 days and resolved.

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In the original placebo/BNT162b2 (30 µg) group, 3 participants had an SAE assessed by the investigator as related to study intervention (Appendix 16.2.7.7.1):

- One participant experienced an SAE of portal vein thrombosis that occurred 61 days after Dose 2 of BNT162b2, which lasted 8 days and resolved.
- One participant experienced a transient ischemic attack that occurred 5 days after Dose 2 of BNT162b2, which lasted 1 day and resolved.
- One participant experienced myalgia that occurred 59 days after Dose 2 of BNT162b2, which lasted for 51 days and resolved.

There were no clinically meaningful differences in SAEs by age group, race, sex, or ethnicity. These data are presented in the following tables:

Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Age Group, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population	Supplemental Table 14.57 and Supplemental Table 14.58
Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Race, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population	Supplemental Table 14.59 – Supplemental Table 14.61
Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Sex, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population	Supplemental Table 14.62 and Supplemental Table 14.63
Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Ethnicity, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population	Supplemental Table 14.64 – Supplemental Table 14.66
Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Age Group, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population	Supplemental Table 14.67 and Supplemental Table 14.68
Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population	Supplemental Table 14.69 – Supplemental Table 14.71
Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Sex, by System Organ Class and Preferred Term – Blinded and Open	Supplemental Table 14.72 and Supplemental Table 14.73

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Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population	
Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Ethnicity, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population	Supplemental Table 14.74 – Supplemental Table 14.76

Narratives for participants with related SAEs are provided in Section 14 Narratives.

5.3.2.2.2. First Booster Dose to 1 Month After the First Booster Dose of BNT162b2 (30 µg)

Final safety evaluations of a booster dose in Phase 2/3 participants who received a third dose of BNT162b2 (30 µg) as part of protocol amendment 18 are reported. See Table 5 for interim reporting on participants 12 through 15 years of age. Study C4591001 did not use an e-diary for the collection of reactogenicity event data for participants that received a booster dose of BNT162b2 (30 µg) as part of protocol amendment 18. Events related to reactogenicity were reported as AEs.

5.3.2.2.2.1. Brief Summary of Adverse Events

Phase 2/3 Participants 12 Through 15 Years of Age and ≥16 Years of Age Who Received Booster Dose of BNT162b2 (30 µg)

An overview of AEs from administration of Dose 3 to 1 month after Dose 3 in participants 12 through 15 years of age and ≥16 years of age is shown in Table 41.

From Dose 3 to 1 month after Dose 3, the number of participants with any AE was 153 (18.5%) in the 12 through 15 years of age group, and 3818 (17.0%) in the ≥16 years of age group. Events considered by the investigator as related to study intervention were reported by 139 participants (16.8%) in the 12 through 15 years of age group and 3377 participants (15.0%) in the ≥16 years of age group. Two and 40 participants (0.2% and 0.2%) reported a severe AE in the 12 through 15 years of age group and ≥16 years of age group, respectively (see details in Section 5.3.2.2.2.2.4).

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Table 41. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	
Adverse Event	12-15 Years (N[a]=825) n[b] (%)	≥16 Years (N[a]=22470) n[b] (%)
Any adverse event	153 (18.5)	3818 (17.0)
Related[c]	139 (16.8)	3377 (15.0)
Severe	6 (0.7)	90 (0.4)
Life-threatening	1 (0.1)	6 (0.0)
Any serious adverse event	2 (0.2)	65 (0.3)
Related[c]	0	3 (0.0)
Severe	2 (0.2)	40 (0.2)
Life-threatening	1 (0.1)	6 (0.0)
Any nonserious adverse event	153 (18.5)	3779 (16.8)
Related[c]	139 (16.8)	3377 (15.0)
Severe	6 (0.7)	52 (0.2)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	1 (0.0)
Related[c]	0	0
Severe	0	0
Life-threatening	0	1 (0.0)
Death	0	1 (0.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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Subgroup Analyses

There were no clinically important differences regarding the percentage of participants reporting at least 1 AE in the subgroup analyses by age, race, sex, and ethnicity from the administration of Dose 3 of BNT162b2 (30 µg) to 1 month after Dose 3. These data are presented in the following tables:

Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population	Supplemental Table 14.77 - Supplemental Table 14.79
Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population	Supplemental Table 14.80 – Supplemental Table 14.82
Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population	Supplemental Table 14.83 and Supplemental Table 14.84
Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population	Supplemental Table 14.85 – Supplemental Table 14.87

Participants With Confirmed Stable HIV Disease Who Received Booster Dose of BNT162b2 (30 µg)

An overview of AEs from administration of Dose 3 to 1 month after Dose 3 in participants with confirmed stable HIV disease is shown in Supplemental Table 14.88.

From Dose 3 to 1 month after Dose 3, the number of participants with any AE was 11 (11.2%). Events considered by the investigator as related to study intervention were reported by 8 participants (8.2%). No participants reported a severe AE.

No AEs leading to withdrawals or deaths were reported.

BNT162b2-Naïve Participants Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg)

An overview of AEs from administration of Dose 3 to 1 month after Dose 3 in BNT162b2-naïve participants assigned to receive BNT162b2$_{SA}$ who received a booster dose of BNT162b2 (30 µg) is shown in Supplemental Table 14.89.

From Dose 3 to 1 month after Dose 3, the number of participants with any AE was 27 (11.4%). Events considered by the investigator as related to study intervention were reported by 25 participants (10.6%). No participants reported a severe AE.

No AEs leading to withdrawals or deaths were reported.

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5.3.2.2.2.2. Analysis of Adverse Events

5.3.2.2.2.2.1. Adverse Events by System Organ Class and Preferred Term

Participants 12 Through 15 Years of Age and ≥16 Years of Age Who Received Booster Dose of BNT162b2 (30 µg)

AEs reported from Dose 3 to 1 month after Dose 3 by SOC and preferred term are presented in Supplemental Table 14.90 for Phase 2/3 participants in the 12 through 15 years of age and ≥16 years of age groups.

The most commonly reported AE in both age groups was injection site pain, in 66 participants (8.0%) in the 12 through 15 years of age group and 1679 (7.5%) in the ≥16 years of age group. Most AEs reported during this period reflect reactogenicity events reported as AEs. AE frequencies by reactogenicity SOC for both groups (12 through 15 years of age and ≥16 years of age) were:

- general disorders and administration site conditions (130 [15.8%] and 2923 [13.0%)
- nervous system disorders (49 [5.9%] and 632 [2.8%])
- musculoskeletal and connective tissue disorders (19 [2.3%] and 646 [2.9%])
- gastrointestinal disorders (12 [1.5%] and 203 [0.9%]

Lymphadenopathy was reported by 8 and 360 participants (1.0% and 1.6%) in the 12 through 15 years of age and ≥16 years of age groups, respectively.

Subgroup Analyses

There were no clinically important differences regarding the percentage of participants reporting at least 1 AE by SOC and PT in the subgroup analyses by age, race, sex, and ethnicity from the administration of Dose 3 of BNT162b2 (30 µg) to 1 month after Dose 3. These data are presented in the following tables:

Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population	Supplemental Table 14.91 - Supplemental Table 14.93
Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population	Supplemental Table 14.94 – Supplemental Table 14.96
Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population	Supplemental Table 14.97 and Supplemental Table 14.98
Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received	Supplemental Table 14.99 – Supplemental Table 14.101

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Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population	

Participants With Confirmed Stable HIV Disease Who Received Booster Dose of BNT162b2 (30 µg)

AEs reported from Dose 3 to 1 month after Dose 3 by SOC and preferred term are presented in Supplemental Table 14.102 for Phase 2/3 participants with confirmed stable HIV disease.

From Dose 3 to 1 month after Dose 3, AEs were most commonly reported in the SOC of general disorders and administration site conditions (7 participants [7.1%]), followed by gastrointestinal disorders (2 participants [2.0%]).

BNT162b2-Naïve Participants Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg)

AEs reported from Dose 3 to 1 month after Dose 3 by SOC and preferred term are presented in Supplemental Table 14.103.

From Dose 3 to 1 month after Dose 3, AEs were most commonly reported in the SOC of general disorders and administration site conditions (23 participants [9.7%]) followed by musculoskeletal and connective tissue disorders (6 participants [2.5%]).

5.3.2.2.2.2.2. Related Adverse Events

Phase 2/3 Participants 12 Through 15 Years of Age and ≥16 Years of Age Who Received Booster Dose of BNT162b2 (30 µg)

From Dose 3 to 1 month after Dose 3, 139 participants (16.8%) in the 12 through 15 years of age group and 3377 participants (15.0%) in the ≥16 years of age group had AEs assessed by the investigator as related to study intervention (Supplemental Table 14.104). The most common related event for both groups was injection site pain, in 65 participants (7.9%) in the 12 through 15 years of age group and 1678 participants (7.5%) in the ≥16 years of age group. Most of the other related AEs were reactogenicity events in the SOC of general disorders and administration site conditions, reported by 129 participants (15.6%) and 2910 (13.0%) in the 12 through 15 years of age and ≥16 years of age groups respectively. Headache was reported by 47 participants (5.7%) in the 12 through 15 years of age group and 550 participants (2.4%) in the ≥16 years of age group.

BNT162b2-Naïve Participants Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg)

From Dose 3 to 1 month after Dose 3, 25 BNT162b2-naïve participants (10.6%) assigned to receive BNT162b2$_{SA}$ who received the booster dose of BNT162b2 (30 µg) had AEs assessed by the investigators as related to study intervention (Supplemental Table 14.105). The most common related event was injection site pain in 11 participants (4.7%).

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5.3.2.2.2.2.3. Immediate Adverse Events

Phase 2/3 Participants 12 Through 15 Years of Age and ≥16 Years of Age Who Received Booster Dose of BNT162b2 (30 µg)

The frequencies of immediate AEs reported within 30 minutes after the booster dose were low (≤ 0.4%) in the 12 through 15 years of age and ≥16 years of age groups (Supplemental Table 14.106). In the 12 through 15 years of age group, 2 participants reported injection site pain and 1 participant reported fatigue, while 26 participants reported injection site pain and 6 participants reported fatigue in the ≥16 years of age group. In addition, in the ≥16 years of age group, 31 participants (0.1%) reported immediate AEs in the SOC of injury, poisoning and procedural complications with 20 participants (0.1%) reporting exposure during pregnancy.

BNT162b2-Naïve Participants Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg)

There were no immediate AEs reported in the BNT162b2-naïve booster safety population after receiving the booster dose.

5.3.2.2.2.2.4. Severe or Life-Threatening Adverse Events

Phase 2/3 Participants 12 Through 15 Years of Age and ≥16 Years of Age Who Received Booster Dose of BNT162b2 (30 µg)

Refer to Table 5 for previously reported results of severe and life-threatening AEs in adolescents 12 through 15 years of age.

From Dose 3 to 1 month after Dose 3, severe events in participants ≥16 years of age were overall low in number and frequency (90 participants [0.4%]). Severe AEs reported for these participants are presented by SOC and PT in Supplemental Table 14.107.

Life-threatening (or Grade 4) events were rare in participants ≥16 years of age and reported in 6 participants from booster dose to 1 month after booster dose (Supplemental Table 14.108). Of the 6 reported life-threatening events, 1 was considered by the investigator as related to study intervention:

- Angioedema reported in 1 participant, occurred 1 day after Dose 3 with a duration of 2 days. The event was reported as an SAE and resolved, and the participant continued in the study (Appendix 16.2.7.7.1).

BNT162b2-Naïve Participants Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg)

There were no severe or life-threatening AEs reported in BNT162b2-naïve participants who received the booster dose of BNT162b2 (30 µg) (Supplemental Table 14.89).

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5.3.2.2.2.3. Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events

5.3.2.2.2.3.1. Deaths

One death was reported in the booster dose BNT162b2 (30 µg) ≥16 years of age group. The participant died 22 days after Dose 3 with the cause of death provided as adenocarcinoma of the pancreas which was considered unrelated to study intervention (Appendix 16.2.7.7.1 and Appendix 16.2.7.6.1).

A narrative for this participant is provided in Section 14 Narratives.

5.3.2.2.2.3.2. Serious Adverse Events

Phase 2/3 Participants 12 through 15 Years of Age and ≥16 Years of Age Who Received Booster Dose of BNT162b2 (30 µg)

From Dose 3 to 1 month after Dose 3, the proportions of participants in the 12 through 15 years of age group and ≥16 years of age group who reported any SAE after receiving the booster dose of BNT162b2 were ≤0.3% (Supplemental Table 14.109).

Refer to Table 5 for previously reported results of SAEs in adolescents 12 through 15 years of age.

In the ≥16 years age groups, 2 participants had SAEs assessed by the investigator as related to study intervention (Appendix 16.2.7.7.1 and Appendix 16.2.8.7):

- One participant experienced an SAE of spontaneous abortion that occurred 13 days after Dose 3.
- An SAE of myocarditis of Grade 3 severity was reported in 1 PPD participant, 4 days following the booster dose. The SAE lasted for 101 days and the event resolved with sequalae.

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Subgroup Analyses

There were no clinically important differences regarding the percentage of participants reporting at least 1 SAE in the subgroup analyses by age, race, sex, and ethnicity from the administration of Dose 3 of BNT162b2 (30 µg) to 1 month after Dose 3. These data are presented in the following tables:

Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population	Supplemental Table 14.110 – Supplemental 14.112
Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population	Supplemental Table 14.113 – Supplemental Table 14.115
Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population	Supplemental Table 14.116 and Supplemental Table 14.117
Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population	Supplemental Table 14.118 – Supplemental Table 14.120

Participants With Confirmed Stable HIV Disease Who Received Booster Dose of BNT162b2 (30 µg)

From Dose 3 to 1 month after Dose 3, 1 participant (1.0%) reported 2 SAEs, assessed by the investigator as not related to study intervention (Supplemental Table 14.121 and Appendix 16.2.7.7.1).

Narratives for participants with related SAEs are provided in Section 14 Narratives.

BNT162b2-Naïve Participants Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg)

There were no SAEs reported in the booster safety population after receiving the booster dose.

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5.3.2.2.2.3.3. Discontinuations From Study Due to Adverse Events

Phase 2/3 Participants 12 Through 15 Years of Age and ≥16 Years of Age Who Received Booster Dose of BNT162b2 (30 µg)

One participant in the ≥16 years of age group had an AE leading to withdrawal that was considered by the investigator as not related to study intervention (adenocarcinoma of the pancreas) (Supplemental Table 14.122 and Appendix 16.2.7.5.1).

BNT162b2-Naïve Participants Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg)

No participants in the Phase 3 BNT162b2 booster safety population were withdrawn due to AEs from Dose 3 to 1 month after Dose 3 (Appendix 16.2.1.3).

5.3.2.2.2.3.4. Pregnancy

Phase 2/3 Participants 12 Through 15 Years of Age and ≥16 Years of Age Who Received Booster Dose of BNT162b2 (30 µg)

No pregnancies were reported in the Phase 2/3 BNT162b2 booster 12 through 15 years of age group.

Refer to Appendix 16.2.7.8 for participants reporting pregnancy after Dose 1.

BNT162b2-Naïve Participants Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg)

One pregnancy was reported in BNT162b2-Naïve participants assigned to received BNT162b2$_{SA}$ who received booster dose of BNT162b2 (30 µg) (Appendix 16.2.7.8).

5.3.2.2.3. First Booster to 1 and 6 Months after Booster Dose (Lower Doses)

5.3.2.2.3.1. Brief Summary of Adverse Events

Adverse Events from Booster Dose (5 or 10 µg) to 1 Month and 6 Months After Booster Dose

An overview of AEs for administration of a booster dose of BNT162b2 (lower dose of 5 or 10 µg) to BNT162b2-experienced participants rerandomized to receive a booster dose of BNT162b2 (lower dose of 5 or 10 µg) under protocol amendment 15, 1 month and 6 months after the booster, is presented in Table 42 and Table 43, respectively.

BNT162b2 (5 µg) Groups

From the BNT162b2 (5 µg) booster dose to 1 month after the booster dose, the number of BNT162b2-experienced participants with any AE was 3 and 2 participants (11.5% and 3.8%) in the 18 through 55 years of age and >55 years of age groups, respectively. One participant (1.9%) reported a related AE in the >55 years of age group. No participants reported severe AEs, SAEs, AEs leading to withdrawal, or deaths in either age group.

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Through 6 months after the booster dose, AEs were reported by 2 additional participants >55 years of age, with 1 participant (1.9%) reporting an SAE that was assessed by the investigator as not related to study intervention. No AEs leading to withdrawal or deaths were reported in either of the age groups.

BNT162b2 (10 µg) Groups

From the BNT162b2 (10 µg) booster dose to 1 month after the booster dose, 2 (8.0%) participants 18 through 55 years of age reported an AE. No participants in the >55 years of age group reported any AEs. One participant (4.0%) reported a related AE in the 18 through 55 years of age group. No SAEs, AEs leading to withdrawal, or deaths were reported in either of the age groups.

Through 6 months after the booster dose, AEs were reported 6 months after the booster dose by 1 additional participant each in 18 through 55 years of age and >55 years of age. No SAEs, AEs leading to withdrawal, or deaths were reported in either of the age groups.

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Table 42. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
Adverse Event	18-55 Years (N[a]=26) n[b] (%)	>55 Years (N[a]=53) n[b] (%)	18-55 Years (N[a]=25) n[b] (%)	>55 Years (N[a]=51) n[b] (%)
Any adverse event	3 (11.5)	2 (3.8)	2 (8.0)	0
Related[c]	0	1 (1.9)	1 (4.0)	0
Severe	0	0	0	0
Life-threatening	0	0	0	0
Any serious adverse event	0	0	0	0
Related[c]	0	0	0	0
Severe	0	0	0	0
Life-threatening	0	0	0	0
Any nonserious adverse event	3 (11.5)	2 (3.8)	2 (8.0)	0
Related[c]	0	1 (1.9)	1 (4.0)	0
Severe	0	0	0	0
Life-threatening	0	0	0	0
Any adverse event leading to withdrawal	0	0	0	0
Related[c]	0	0	0	0
Severe	0	0	0	0
Life-threatening	0	0	0	0
Death	0	0	0	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational vaccine.
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(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_G4_6MPD_CSR/adae_s091_g4_1m6

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Table 43. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 6 Months After Booster Dose – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
Adverse Event	18-55 Years (N^a=26) n^b (%)	>55 Years (N^a=53) n^b (%)	18-55 Years (N^a=25) n^b (%)	>55 Years (N^a=51) n^b (%)
Any adverse event	3 (11.5)	4 (7.5)	3 (12.0)	1 (2.0)
Related[c]	0	1 (1.9)	1 (4.0)	0
Severe	0	0	0	0
Life-threatening	0	0	0	0
Any serious adverse event	0	1 (1.9)	0	0
Related[c]	0	0	0	0
Severe	0	0	0	0
Life-threatening	0	0	0	0
Any nonserious adverse event	3 (11.5)	3 (5.7)	3 (12.0)	1 (2.0)
Related[c]	0	1 (1.9)	1 (4.0)	0
Severe	0	0	0	0
Life-threatening	0	0	0	0
Any adverse event leading to withdrawal	0	0	0	0
Related[c]	0	0	0	0
Severe	0	0	0	0
Life-threatening	0	0	0	0
Death	0	0	0	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational vaccine.
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(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_G4_6MPD_CSR/adae_s091_g4_6m

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5.3.2.2.3.2. Analysis of Adverse Events

5.3.2.2.3.2.1. Adverse Events by System Organ Class and Preferred Term

Adverse Events from Booster Dose (5 or 10 µg) to 1 Month and 6 Months After Booster Dose

AEs by SOC and preferred term from the administration of a booster dose of BNT162b2 (lower dose of 5 or 10 µg) to BNT162b2-experienced participants rerandomized to receive a booster dose of BNT162b2 (lower dose of 5 or 10 µg), through 1 month and 6 months after the booster dose, are presented in Table 44 and Table 45, respectively.

In the BNT162b2 5 and 10 µg groups for participants 18 through 55 and >55 years of age, the frequency of AEs were low and were mostly reported by no more than 1 participant per AE preferred term.

Table 44. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (5 µg)				BNT162b2 (10 µg)			
	18-55 Years (N^a=26)		>55 Years (N^a=53)		18-55 Years (N^a=25)		>55 Years (N^a=51)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Any adverse event	3 (11.5)	(2.4, 30.2)	2 (3.8)	(0.5, 13.0)	2 (8.0)	(1.0, 26.0)	0	(0.0, 7.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 13.2)	0	(0.0, 6.7)	1 (4.0)	(0.1, 20.4)	0	(0.0, 7.0)
Lymphadenopathy	0	(0.0, 13.2)	0	(0.0, 6.7)	1 (4.0)	(0.1, 20.4)	0	(0.0, 7.0)
GASTROINTESTINAL DISORDERS	1 (3.8)	(0.1, 19.6)	0	(0.0, 6.7)	1 (4.0)	(0.1, 20.4)	0	(0.0, 7.0)
Gastrooesophageal reflux disease	1 (3.8)	(0.1, 19.6)	0	(0.0, 6.7)	1 (4.0)	(0.1, 20.4)	0	(0.0, 7.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
Fatigue	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (3.8)	(0.1, 19.6)	0	(0.0, 6.7)	0	(0.0, 13.7)	0	(0.0, 7.0)
Skin laceration	1 (3.8)	(0.1, 19.6)	0	(0.0, 6.7)	0	(0.0, 13.7)	0	(0.0, 7.0)

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Table 44. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (5 µg)				BNT162b2 (10 µg)			
	18-55 Years (N[a]=26)		>55 Years (N[a]=53)		18-55 Years (N[a]=25)		>55 Years (N[a]=51)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
Dehydration	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (3.8)	(0.1, 19.6)	0	(0.0, 6.7)	0	(0.0, 13.7)	0	(0.0, 7.0)
Pain in extremity	1 (3.8)	(0.1, 19.6)	0	(0.0, 6.7)	0	(0.0, 13.7)	0	(0.0, 7.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 13.2)	2 (3.8)	(0.5, 13.0)	0	(0.0, 13.7)	0	(0.0, 7.0)
Dizziness	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
Dysgeusia	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
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Table 45. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 6 Months After Booster Dose, by System Organ Class and Preferred Term – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (5 µg)				BNT162b2 (10 µg)			
	18-55 Years (N[a]=26)		>55 Years (N[a]=53)		18-55 Years (N[a]=25)		>55 Years (N[a]=51)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	3 (11.5)	(2.4, 30.2)	4 (7.5)	(2.1, 18.2)	3 (12.0)	(2.5, 31.2)	1 (2.0)	(0.0, 10.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 13.2)	0	(0.0, 6.7)	1 (4.0)	(0.1, 20.4)	0	(0.0, 7.0)
Lymphadenopathy	0	(0.0, 13.2)	0	(0.0, 6.7)	1 (4.0)	(0.1, 20.4)	0	(0.0, 7.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 13.2)	0	(0.0, 6.7)	0	(0.0, 13.7)	1 (2.0)	(0.0, 10.4)
Deafness unilateral	0	(0.0, 13.2)	0	(0.0, 6.7)	0	(0.0, 13.7)	1 (2.0)	(0.0, 10.4)
Vertigo	0	(0.0, 13.2)	0	(0.0, 6.7)	0	(0.0, 13.7)	1 (2.0)	(0.0, 10.4)
GASTROINTESTINAL DISORDERS	1 (3.8)	(0.1, 19.6)	0	(0.0, 6.7)	2 (8.0)	(1.0, 26.0)	0	(0.0, 7.0)
Gastrooesophageal reflux disease	1 (3.8)	(0.1, 19.6)	0	(0.0, 6.7)	1 (4.0)	(0.1, 20.4)	0	(0.0, 7.0)
Haemorrhoids	0	(0.0, 13.2)	0	(0.0, 6.7)	1 (4.0)	(0.1, 20.4)	0	(0.0, 7.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
Fatigue	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (3.8)	(0.1, 19.6)	0	(0.0, 6.7)	0	(0.0, 13.7)	0	(0.0, 7.0)
Skin laceration	1 (3.8)	(0.1, 19.6)	0	(0.0, 6.7)	0	(0.0, 13.7)	0	(0.0, 7.0)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
Dehydration	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (3.8)	(0.1, 19.6)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
Back pain	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)

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Table 45. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 6 Months After Booster Dose, by System Organ Class and Preferred Term – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (5 µg)				BNT162b2 (10 µg)			
	18-55 Years (N[a]=26)		>55 Years (N[a]=53)		18-55 Years (N[a]=25)		>55 Years (N[a]=51)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pain in extremity	1 (3.8)	(0.1, 19.6)	0	(0.0, 6.7)	0	(0.0, 13.7)	0	(0.0, 7.0)
Temporomandibular joint syndrome	1 (3.8)	(0.1, 19.6)	0	(0.0, 6.7)	0	(0.0, 13.7)	0	(0.0, 7.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 13.2)	2 (3.8)	(0.5, 13.0)	0	(0.0, 13.7)	0	(0.0, 7.0)
Dizziness	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
Dysgeusia	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
RENAL AND URINARY DISORDERS	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
Nephrolithiasis	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
SURGICAL AND MEDICAL PROCEDURES	1 (3.8)	(0.1, 19.6)	0	(0.0, 6.7)	0	(0.0, 13.7)	0	(0.0, 7.0)
Endodontic procedure	1 (3.8)	(0.1, 19.6)	0	(0.0, 6.7)	0	(0.0, 13.7)	0	(0.0, 7.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
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(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_G4_6MPD_CSR/adae_s130_g4_6m

5.3.2.2.3.2.2. Related Adverse Events

Related AEs were reported by 1 participant (1.9%) in the BNT162b2 (5 µg) >55 years of age group only and included general disorders and administration site conditions (fatigue), metabolism and nutrition disorders (dehydration), and nervous system disorders (dizziness) (Supplemental Table 14.123).

One participant (4.0%) reported a related AE of lymphadenopathy in the BNT162b2 (10 µg) 18 through 55 years of age group.

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5.3.2.2.3.3. Immediate Adverse Events

There were no immediate AEs reported in the BNT162b2-experienced (lower dose) booster safety population after the booster dose.

5.3.2.2.3.4. Severe or Life-Threatening Adverse Events

There were no severe or life-threatening AEs reported in BNT162b2-experienced (lower dose) booster safety population after the booster dose.

5.3.2.2.3.3. Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Event

5.3.2.2.3.3.1. Deaths

No deaths were reported in the BNT162b2-experienced (lower dose) safety population from the booster dose to 6 months after the booster dose (Appendix 16.2.7.6.4).

5.3.2.2.3.3.2. Serious Adverse Events

From booster dose (BNT162b2 5 or 10 µg) to 6 months after booster dose 1 participant (1.9%) in the BNT162b2 (5 µg) >55 years of age group reported 1 SAE of back pain (Supplemental Table 14.124) which was assessed by the investigator as unrelated to the vaccine (Appendix 16.2.7.7.3).

5.3.2.2.3.3.3. Discontinuations from Study Due to Adverse Events

No participants in the Phase 3 BNT162b2 (lower dose) booster safety population were withdrawn due to AEs from booster dose to 6 months after booster dose (Appendix 16.2.1.4).

5.3.2.2.3.3.4. Other Significant Adverse Events

One participant (2.0%) reported a significant AE of unilateral deafness in the BNT162b2 (10 µg) >55 years of age group that began approximately 2 and a half months after receipt of booster vaccination and was assessed by the investigator as not related to study intervention (Supplemental Table 14.125 and Appendix 16.2.7.4.5).

5.3.2.2.4. Additional Booster Dose to 1 Month After Additional Booster Dose of BNT162b2 30 µg

5.3.2.2.4.1. Brief Summary of Adverse Events

An overview of AEs from the administration of the additional booster dose (Dose 4 or Dose 5) to 1 month after the additional booster dose for the participants rerandomized to receive booster dose(s) under protocol amendments 14 and 15 and received the additional booster dose of BNT162b2 30 µg under protocol amendment 19 is shown in Table 46. Study C4591001 did not use an e-diary for the collection of reactogenicity event data for participants that received an additional booster dose of BNT162b2 (30 µg) as part of protocol amendment 19. Events related to reactogenicity were reported as AEs.

In all the vaccine groups except for those who previously received BNT162b2 5-µg booster dose, from the additional booster dose to 1 month after the booster dose, 1 to 17 participants

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(2.6% to 9.3%) reported at least 1 AE. No AEs were reported by the participants who previously received the BNT162b2 5-µg booster dose.

One participant (0.5%) who previously received the BNT162b2$_{SA}$ 30-µg booster dose reported an SAE of muscular weakness. The event was unrelated to study vaccination.

No SAEs, AEs leading to withdrawal, or deaths were reported.

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Table 46. Number (%) of Subjects Reporting at Least 1 Adverse Event From the Additional Booster Dose to 1 Month After the Additional Booster Dose – Phase 3 – BNT162b2-Experienced Subjects Who Were Previously Rerandomized/Assigned to Receive Booster Dose(s), and Received an Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

	Previous Booster Vaccine Group (as Administered)				
	BNT162b2 (30 µg) (N^a=182)	$BNT162b2_{SA}$ (30 µg) (N^a=196)	BNT162b2 (5 µg) (N^a=33)	BNT162b2 (10 µg) (N^a=38)	$BNT162b2_{SA}$ (30 µg, 2 Doses) (N^a=15)
Adverse Event	n^b (%)	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Any adverse event	17 (9.3)	17 (8.7)	0	1 (2.6)	1 (6.7)
Related[c]	14 (7.7)	16 (8.2)	0	1 (2.6)	0
Severe	0	0	0	0	0
Life-threatening	0	0	0	0	0
Any serious adverse event	0	1 (0.5)	0	0	0
Related[c]	0	0	0	0	0
Severe	0	0	0	0	0
Life-threatening	0	0	0	0	0
Any nonserious adverse event	17 (9.3)	17 (8.7)	0	1 (2.6)	1 (6.7)
Related[c]	14 (7.7)	16 (8.2)	0	1 (2.6)	0
Severe	0	0	0	0	0
Life-threatening	0	0	0	0	0
Any adverse event leading to withdrawal	0	0	0	0	0
Related[c]	0	0	0	0	0
Severe	0	0	0	0	0
Life-threatening	0	0	0	0	0
Death	0	0	0	0	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s091_p3_d4

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5.3.2.2.4.2. Analysis of Adverse Events

5.3.2.2.4.2.1. Adverse Events by System Organ Class and Preferred Term

AEs reported from the administration of the additional booster Dose to 1 month after the additional booster dose by SOC and preferred term for the vaccine groups are presented in Table 47. Of the AEs reported during this period, some were reactogenicity events. Most AEs were reported in the BNT162b2 (30 µg) and BNT162b2$_{SA}$ (30 µg) groups. AE frequencies by SOCs for both groups (BNT162b2 (30 µg) and BNT162b2$_{SA}$ (30 µg)) were:

- general disorders and administration site conditions (13 [7.1%] and 14 [7.1%])
- musculoskeletal and connective tissue disorders (5 [2.7%] and 4 [2.0%])
- nervous system disorders (1 [0.5%] and 4 [2.0%])

There were no AEs reported in the BNT162b2 (5 µg) group. There were participants reporting AEs for both BNT162b2 (10 µg) and BNT162b2 (30 µg, 2 doses) groups.

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Table 47. Number (%) of Subjects Reporting at Least 1 Adverse Event From the Additional Booster Dose to 1 Month After the Additional Booster Dose, by System Organ Class and Preferred Term – Phase 3 – BNT162b2-Experienced Subjects Who Were Previously Rerandomized/Assigned to Receive Booster Dose(s), and Received an Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

	Previous Vaccine Group (as Administered)									
	BNT162b2 (30 µg) (N[a]=182)		BNT162b2$_{SA}$ (30 µg) (N[a]=196)		BNT162b2 (5 µg) (N[a]=33)		BNT162b2 (10 µg) (N[a]=38)		BNT162b2$_{SA}$ (30 µg, 2 Doses) (N[a]=15)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	17 (9.3)	(5.5, 14.5)	17 (8.7)	(5.1, 13.5)	0	(0.0, 10.6)	1 (2.6)	(0.1, 13.8)	1 (6.7)	(0.2, 31.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	2 (1.1)	(0.1, 3.9)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Lymphadenopathy	2 (1.1)	(0.1, 3.9)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
CARDIAC DISORDERS	0	(0.0, 2.0)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Atrial fibrillation	0	(0.0, 2.0)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	13 (7.1)	(3.9, 11.9)	14 (7.1)	(4.0, 11.7)	0	(0.0, 10.6)	1 (2.6)	(0.1, 13.8)	0	(0.0, 21.8)
Injection site pain	9 (4.9)	(2.3, 9.2)	8 (4.1)	(1.8, 7.9)	0	(0.0, 10.6)	1 (2.6)	(0.1, 13.8)	0	(0.0, 21.8)
Fatigue	4 (2.2)	(0.6, 5.5)	5 (2.6)	(0.8, 5.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Chills	2 (1.1)	(0.1, 3.9)	2 (1.0)	(0.1, 3.6)	0	(0.0, 10.6)	1 (2.6)	(0.1, 13.8)	0	(0.0, 21.8)
Pyrexia	3 (1.6)	(0.3, 4.7)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	1 (2.6)	(0.1, 13.8)	0	(0.0, 21.8)
Pain	1 (0.5)	(0.0, 3.0)	3 (1.5)	(0.3, 4.4)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Axillary pain	0	(0.0, 2.0)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Injection site swelling	1 (0.5)	(0.0, 3.0)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
INFECTIONS AND INFESTATIONS	1 (0.5)	(0.0, 3.0)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Ear infection	1 (0.5)	(0.0, 3.0)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)

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Table 47. Number (%) of Subjects Reporting at Least 1 Adverse Event From the Additional Booster Dose to 1 Month After the Additional Booster Dose, by System Organ Class and Preferred Term – Phase 3 – BNT162b2-Experienced Subjects Who Were Previously Rerandomized/Assigned to Receive Booster Dose(s), and Received an Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

	Previous Vaccine Group (as Administered)									
	BNT162b2 (30 µg) (N[a]=182)		BNT162b2$_{SA}$ (30 µg) (N[a]=196)		BNT162b2 (5 µg) (N[a]=33)		BNT162b2 (10 µg) (N[a]=38)		BNT162b2$_{SA}$ (30 µg, 2 Doses) (N[a]=15)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.5)	(0.0, 3.0)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Corneal abrasion	1 (0.5)	(0.0, 3.0)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
INVESTIGATIONS	1 (0.5)	(0.0, 3.0)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	0	(0.0, 9.3)	1 (6.7)	(0.2, 31.9)
Blood cholesterol increased	1 (0.5)	(0.0, 3.0)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Blood testosterone decreased	0	(0.0, 2.0)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	1 (6.7)	(0.2, 31.9)
Body temperature increased	0	(0.0, 2.0)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	5 (2.7)	(0.9, 6.3)	4 (2.0)	(0.6, 5.1)	0	(0.0, 10.6)	1 (2.6)	(0.1, 13.8)	0	(0.0, 21.8)
Myalgia	3 (1.6)	(0.3, 4.7)	3 (1.5)	(0.3, 4.4)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Arthralgia	1 (0.5)	(0.0, 3.0)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	1 (2.6)	(0.1, 13.8)	0	(0.0, 21.8)
Back pain	1 (0.5)	(0.0, 3.0)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Intervertebral disc protrusion	0	(0.0, 2.0)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Muscular weakness	0	(0.0, 2.0)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
NERVOUS SYSTEM DISORDERS	1 (0.5)	(0.0, 3.0)	4 (2.0)	(0.6, 5.1)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Headache	1 (0.5)	(0.0, 3.0)	4 (2.0)	(0.6, 5.1)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.5)	(0.0, 3.0)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Erythema	1 (0.5)	(0.0, 3.0)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)

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Table 47. Number (%) of Subjects Reporting at Least 1 Adverse Event From the Additional Booster Dose to 1 Month After the Additional Booster Dose, by System Organ Class and Preferred Term – Phase 3 – BNT162b2-Experienced Subjects Who Were Previously Rerandomized/Assigned to Receive Booster Dose(s), and Received an Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

	Previous Vaccine Group (as Administered)									
	BNT162b2 (30 µg) (N[a]=182)		BNT162b2$_{SA}$ (30 µg) (N[a]=196)		BNT162b2 (5 µg) (N[a]=33)		BNT162b2 (10 µg) (N[a]=38)		BNT162b2$_{SA}$ (30 µg, 2 Doses) (N[a]=15)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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5.3.2.2.4.2.2. Related Adverse Events by System Organ Class and Preferred Term

Related AEs were reported in the BNT162b2 (30 µg), BNT162b2$_{SA}$ (30 µg), and BNT162b2$_{SA}$ (10 µg) groups (Supplemental Table 14.126).

In the BNT162b2 (30 µg) and BNT162b2$_{SA}$ (30 µg) groups, most related AEs reported were reactogenicity-type events and generally included injection site pain, pyrexia, headache, fatigue, myalgia, and chills.

There were no related AEs reported in the BNT162b2 (5 µg) and BNT162b2$_{SA}$ (30 µg, 2 doses) groups. There was 1 participant reported related AE in the BNT162b2 (10 µg) group.

5.3.2.2.4.2.3. Immediate Adverse Events

There were no participants in any of the groups who reported any immediate AEs after the additional booster dose of BNT162b2 (30 µg) (Appendix 16.2.7.7.1).

5.3.2.2.4.2.4. Severe or Life-Threatening Adverse Events

There were no participants in any of the groups who reported any severe or life-threatening AEs after the additional booster dose of BNT162b2 (30 µg).

5.3.2.2.4.3. Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events

5.3.2.2.4.3.1. Deaths

There were no deaths reported in participants after the additional booster dose of BNT162b2 (30 µg) (Appendix 16.2.7.6.1).

5.3.2.2.4.3.2. Serious Adverse Events

From the additional booster dose to 1 month after the booster dose, 1 participant (0.5%) reported an SAE in the BNT162b2$_{SA}$ (30 µg) group that was assessed by the investigator as not related to study intervention (Supplemental Table 14.127 and Appendix 16.2.7.7.1).

5.3.2.2.4.3.3. Discontinuations From Study Due to Adverse Events

No participants in the BNT162b2 were withdrawn due to AEs after the additional booster dose of BNT162b2 (30 µg) (Appendix 16.2.1.1).

5.3.2.2.4.3.4. Pregnancy

Refer to Appendix 16.2.7.8 for participants reporting pregnancy after Dose 1.

5.3.2.3. Phase 2/3 Safety Conclusions

- BNT162b2 was safe and well tolerated.
- Local reactions and systemic events in BNT162b2-experienced participants who received a lower booster dose of BNT162b2 (5 or 10 µg) were predominantly mild to moderate, well-tolerated, and short-lived (median duration of 1.0 to 4.0 days). Reactogenicity was generally lower after the booster dose of BNT162b2 5 µg than after the booster dose of

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BNT162b2 10 µg. For the booster dose of BNT162b2 (5 or 10 µg), the frequency of participants with any AE or SAE was low (≤12.0% and ≤1.9%, respectively).

- The frequency of participants with any AE after booster dose(s) of BNT162b2 (30 µg) was low with most participants reporting mild, reactogenicity-type events. In Phase 2/3 participants 12 through 15 and ≥16 years of age, the frequency of participants with any AE from Dose 3 to 1 month after Dose 3 was ≤18.5%. For all vaccine groups in which participants received an additional booster dose (Dose 4 or Dose 5), the frequency of participants with any AE from the additional booster dose to 1 month after the additional booster dose was ≤9.3%.

- The frequency of participants with any SAEs after the first 2 doses of BNT162b2, and the booster dose(s) of BNT162b2, was low (≤1.9%). One death and 1 AE leading to withdrawal was reported and assessed by the investigator as not related to study intervention.

6. CONCLUSIONS

Data previously presented from this clinical study showed that the primary 2 dose series of BNT162b2 30 µg was highly effective against symptomatic COVID-19, including cases that were severe and/or resulted in hospitalization, prior to the emergence of the Omicron variant. Additional efficacy data presented in this CSR show that BNT162b2 30 µg likely also provides some protection against asymptomatic SARS-CoV-2 infection in an analysis conducted prior to the emergence of Omicron. In addition, the cumulative incidence of confirmed COVID-19 cases increased as multiple SARS-CoV-2 variants circulated, most notably following the emergence of Omicron. This resulted in the development and implementation of variant-adapted vaccines: bivalent vaccines targeting the original/wild type strain and Omicron BA.1 or BA.4/BA.5, and most recently monovalent XBB.1.5.

Overall immunogenicity responses were similar for lower booster doses (Dose 3) of BNT162b2 (5 or 10 µg) in the BNT162b2 5- and 10-µg groups, and SARS-CoV-2 neutralizing GMTs substantially increased at 1 month after the lower booster dose. In addition, administration of lower booster dose of BNT162b2 (5 or 10 µg) was safe and tolerable.

The primary 2-dose series for BNT162b1 and BNT162b2 at doses of 10, 20, and 30 µg was safe and tolerable. Administration of booster dose(s) (Dose 3, 4, or 5) of BNT162b2 30 µg to participants who had completed the 2-dose series shows continued safety and tolerability with most AEs consistent with reactogenicity-type events, and no new safety concerns.

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7. REFERENCES

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14. TABLES AND FIGURES REFERRED TO BUT NOT INCLUDED IN THE TEXT

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SUPPLEMENTAL TABLES

Conduct of Study

14.1. Important Protocol Deviations After the First Booster Dose – Phase 1 – Subjects Who Received the First Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Initial Vaccine Group (as Administered)							
	BNT162b1				BNT162b2			
Protocol Deviation Category Subcategory	10 µg (N[a]=21) n[b] (%)	20 µg (N[a]=24) n[b] (%)	30 µg (N[a]=24) n[b] (%)	100 µg (N[a]=9) n[b] (%)	10 µg (N[a]=22) n[b] (%)	20 µg (N[a]=23) n[b] (%)	30 µg (N[a]=24) n[b] (%)	Placebo (N[a]=28) n[b] (%)
Concomitant Medications	6 (28.6)	5 (20.8)	8 (33.3)	0	2 (9.1)	1 (4.3)	4 (16.7)	5 (17.9)
Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	6 (28.6)	5 (20.8)	8 (33.3)	0	2 (9.1)	1 (4.3)	4 (16.7)	5 (17.9)

Note: A subject with multiple deviations is counted only once in each of the specified categories and subcategories.
a. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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14.2. Important Protocol Deviations After the Additional Booster Dose – Phase 1 – Subjects Who Received the Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

Protocol Deviation Category Subcategory	Vaccine Group (as Administered) BNT162b2 (30 µg) (N^a=80) n^b (%)
Concomitant Medications	5 (6.3)
Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	5 (6.3)

Note: A subject with multiple deviations is counted only once in each of the specified categories and subcategories.
a. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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14.3. Demographic Characteristics – Phase 1 – Subjects Who Received the Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=80) n[b] (%)
Sex	
Male	34 (42.5)
Female	46 (57.5)
Race	
White	70 (87.5)
Black or African American	2 (2.5)
Asian	8 (10.0)
Ethnicity	
Hispanic/Latino	1 (1.3)
Non-Hispanic/non-Latino	78 (97.5)
Not reported	1 (1.3)
Country	
USA	80 (100.0)
Age at the additional booster dose of BNT162b2 (30 µg) (years)	
Mean (SD)	54.7 (17.77)
Median	54.5
Min, max	(23, 83)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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14.4. Nonstudy Vaccines Received After the First Booster Dose – Phase 1 – Subjects Who Received the First Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

Vaccine[b] Preferred Term	Initial Vaccine Group (as Administered)							
	BNT162b1				BNT162b2			
	10 µg (N[a]=21) n[c] (%)	20 µg (N[a]=24) n[c] (%)	30 µg (N[a]=24) n[c] (%)	100 µg (N[a]=9) n[c] (%)	10 µg (N[a]=22) n[c] (%)	20 µg (N[a]=23) n[c] (%)	30 µg (N[a]=24) n[c] (%)	Placebo (N[a]=28) n[c] (%)
Any nonstudy vaccine	7 (33.3)	5 (20.8)	9 (37.5)	1 (11.1)	6 (27.3)	4 (17.4)	5 (20.8)	8 (28.6)
COVID-19 VACCINE	1 (4.8)	0	1 (4.2)	0	0	0	1 (4.2)	1 (3.6)
ELASOMERAN	2 (9.5)	1 (4.2)	2 (8.3)	0	0	0	2 (8.3)	1 (3.6)
HEPATITIS B VACCINE	0	0	0	0	0	1 (4.3)	0	0
INFLUENZA VACCINE	0	0	0	1 (11.1)	4 (18.2)	1 (4.3)	1 (4.2)	4 (14.3)
PNEUMOCOCCAL VACCINE	0	0	0	0	0	0	1 (4.2)	0
TETANUS VACCINE	1 (4.8)	0	0	0	0	0	1 (4.2)	0
TETANUS VACCINE TOXOID	1 (4.8)	0	0	0	0	0	0	0
TOZINAMERAN	3 (14.3)	4 (16.7)	5 (20.8)	0	2 (9.1)	1 (4.3)	1 (4.2)	3 (10.7)
VARICELLA ZOSTER VACCINE	0	1 (4.2)	1 (4.2)	0	1 (4.5)	1 (4.3)	0	0
VARICELLA ZOSTER VACCINE RGE (CHO)	0	0	0	0	0	1 (4.3)	0	0

Note: WHODDG B3 v202203 coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. Subjects are counted only once for each preferred term.
c. n = Number of subjects with the specified characteristic.
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14.5. Nonstudy Vaccines Received After the Additional Booster Dose – Phase 1 – Subjects Who Received the Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

Vaccine[b] Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=80) n[c] (%)
Any nonstudy vaccine	10 (12.5)
BNT162B2;BNT162B2 OMI BA.4-5	3 (3.8)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	1 (1.3)
INFLUENZA VACCINE	6 (7.5)
PNEUMOCOCCAL VACCINE	1 (1.3)
TOZINAMERAN	3 (3.8)
VARICELLA ZOSTER VACCINE	1 (1.3)

Note: WHODDG B3 v202203 coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. Subjects are counted only once for each preferred term.
c. n = Number of subjects with the specified characteristic.
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14.6. Disposition of All Randomized Subjects – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose)

	Vaccine Group (as Randomized)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N[a]=26) n[b] (%)	>55 Years (N[a]=53) n[b] (%)	18-55 Years (N[a]=25) n[b] (%)	>55 Years (N[a]=51) n[b] (%)
Rerandomized	26 (100.0)	53 (100.0)	25 (100.0)	51 (100.0)
Did not receive booster vaccination	0	0	0	0
Vaccinated	26 (100.0)	53 (100.0)	25 (100.0)	51 (100.0)
Booster vaccination	26 (100.0)	53 (100.0)	25 (100.0)	51 (100.0)
Completed booster vaccination period[c]	26 (100.0)	53 (100.0)	25 (100.0)	51 (100.0)
Completed 6-month post–booster visit	26 (100.0)	52 (98.1)	25 (100.0)	50 (98.0)
Withdrawn from the study	9 (34.6)	25 (47.2)	9 (36.0)	24 (47.1)
Withdrawn after booster vaccination and before 1-month post–booster visit	0	0	0	0
Withdrawn after 1-month and before 6-month post–booster visit	0	1 (1.9)	0	1 (2.0)
Withdrawn after 6-month post–booster visit	9 (34.6)	24 (45.3)	9 (36.0)	23 (45.1)
Reason for withdrawal				
No longer meets eligibility criteria	5 (19.2)	12 (22.6)	5 (20.0)	14 (27.5)
Withdrawal by subject	3 (11.5)	8 (15.1)	4 (16.0)	8 (15.7)
Protocol deviation	1 (3.8)	2 (3.8)	0	2 (3.9)
Lost to follow-up	0	1 (1.9)	0	0
Other	0	2 (3.8)	0	0

a. N = number of randomized subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Booster vaccination period: from booster vaccination to the 1-month follow-up visit after the booster vaccination.
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14.7. Important Protocol Deviations After Booster Dose – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	
Protocol Deviation Category Subcategory	12-15 Years (N[a]=825) n[b] (%)	≥16 Years (N[a]=22470) n[b] (%)
Concomitant Medications	21 (2.5)	2538 (11.3)
Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	21 (2.5)	2486 (11.1)
Receipt of blood/plasma products or immunoglobulins within 60 days before enrollment through conclusion of the study.	0	24 (0.1)
Subject received chronic systemic treatment with known immunosuppressant medication, or radiotherapy, within 60 days before enrollment through conclusion of the study.	0	41 (0.2)
Subject received systemic corticosteroids (>=20mg/day of prednisone or equivalent) for >=14 days is prohibited from 28 days prior to enrollment to specified visits/cohorts per protocol.	0	1 (0.0)
Inclusion/Exclusion	0	5 (0.0)
Participant met exclusion criterion #11 (women who are pregnant or breastfeeding)	0	2 (0.0)
Participant met exclusion criterion #12 (previous vaccination of any coronavirus vaccine).	0	2 (0.0)
Participant met exclusion criterion #16 (Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation)	0	1 (0.0)
Investigational Product	2 (0.2)	30 (0.1)
Dosing/administration error, subject did not receive correct dose of vaccine	0	1 (0.0)
IP administered that was deemed not suitable for use by Almac	2 (0.2)	28 (0.1)
Subject was vaccinated despite being ineligible	0	1 (0.0)
Laboratory	0	2 (0.0)
Nasal swab can't be analyzed due to incorrect shipping procedure	0	2 (0.0)

Note: A subject with multiple deviations is counted only once in each of the specified categories and subcategories.
a. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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14.8. Important Protocol Deviations After Booster Dose – Phase 3 – BNT162b2-Naïve Subjects Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

Protocol Deviation Category Subcategory	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=236) n[b] (%)
Concomitant Medications	1 (0.4)
Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	1 (0.4)

Note: A subject with multiple deviations is counted only once in each of the specified categories and subcategories.
a. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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14.9. Important Protocol Deviations – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose)

	Vaccine Group (as Randomized)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
Protocol Deviation Category/Subcategory	18-55 Years (N^a=26) n^b (%)	>55 Years (N^a=53) n^b (%)	18-55 Years (N^a=25) n^b (%)	>55 Years (N^a=51) n^b (%)
CONCOMITANT MEDICATIONS	5 (19.2)	15 (28.3)	5 (20.0)	15 (29.4)
Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	5 (19.2)	15 (28.3)	5 (20.0)	15 (29.4)
INCLUSION/EXCLUSION	0	1 (1.9)	0	0
Participant failed to meet inclusion criterion #05 (Boostability subset only: Participants who provided a serum sample at Visit 3, with Visit 3 occurring within the protocol-specified window)	0	1 (1.9)	0	0
VISIT SCHEDULE	0	1 (1.9)	0	0
Visit 301 was conducted outside of the protocol specified window	0	1 (1.9)	0	0

Note: A subject with multiple deviations is counted only once in each of the specified categories and subcategories.
a. These values are the denominators for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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14.10. Important Protocol Deviations After the Additional Booster Dose – Phase 3 – BNT162b2-Experienced Subjects Who Were Previously Rerandomized/Assigned to Receive Booster Dose(s), and Received an Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

	Vaccine Group (as Administered)				
Protocol Deviation Category Subcategory	BNT162b2 (30 µg) (N[a]=182) n[b] (%)	BNT162b2$_{SA}$ (30 µg) (N[a]=196) n[b] (%)	BNT162b2 (5 µg) (N[a]=33) n[b] (%)	BNT162b2 (10 µg) (N[a]=38) n[b] (%)	BNT162b2$_{SA}$ (30 µg, 2 Doses) (N[a]=15) n[b] (%)
Concomitant Medications	2 (1.1)	3 (1.5)	0	0	0
Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	2 (1.1)	3 (1.5)	0	0	0

Note: A subject with multiple deviations is counted only once in each of the specified categories and subcategories.
a. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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14.11. Demographic Characteristics – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg)		
	12-15 Years (N^a=825) n^b (%)	≥16 Years (N^a=22568) n^b (%)	Total (N^a=23393) n^b (%)
Sex			
Male	407 (49.3)	11328 (50.2)	11735 (50.2)
Female	418 (50.7)	11240 (49.8)	11658 (49.8)
Race			
White	689 (83.5)	18905 (83.8)	19594 (83.8)
Black or African American	38 (4.6)	2020 (9.0)	2058 (8.8)
American Indian or Alaska Native	3 (0.4)	164 (0.7)	167 (0.7)
Asian	62 (7.5)	815 (3.6)	877 (3.7)
Native Hawaiian or other Pacific Islander	1 (0.1)	32 (0.1)	33 (0.1)
Multiracial	26 (3.2)	554 (2.5)	580 (2.5)
Not reported	6 (0.7)	78 (0.3)	84 (0.4)
Racial designation			
Japanese	3 (0.4)	72 (0.3)	75 (0.3)
Ethnicity			
Hispanic/Latino	89 (10.8)	7507 (33.3)	7596 (32.5)
Non-Hispanic/non-Latino	734 (89.0)	14979 (66.4)	15713 (67.2)
Not reported	2 (0.2)	82 (0.4)	84 (0.4)
Country			
Argentina	0	5195 (23.0)	5195 (22.2)
Brazil	0	1329 (5.9)	1329 (5.7)
Germany	0	336 (1.5)	336 (1.4)
South Africa	0	325 (1.4)	325 (1.4)
Turkey	0	244 (1.1)	244 (1.0)
USA	825 (100.0)	15139 (67.1)	15964 (68.2)
Age group (at booster vaccination)			
12-15 Years	825 (100.0)	0	825 (3.5)
16-55 Years	0	12902 (57.2)	12902 (55.2)
>55 Years	0	9666 (42.8)	9666 (41.3)
Age at booster vaccination (years)			
Mean (SD)	14.1 (0.80)	50.1 (16.60)	48.8 (17.60)
Median	14.0	52.0	51.0
Min, max	(13, 15)	(16, 92)	(13, 92)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)		361 (1.6)	361 (1.5)

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14.11. Demographic Characteristics – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg)		
	12-15 Years (N^a=825) n^b (%)	≥16 Years (N^a=22568) n^b (%)	Total (N^a=23393) n^b (%)
Normal weight (≥18.5-24.9 kg/m^2)		6765 (30.0)	6765 (28.9)
Overweight (≥25.0-29.9 kg/m^2)		7739 (34.3)	7739 (33.1)
Obese (≥30.0 kg/m^2)		7696 (34.1)	7696 (32.9)
Missing		7 (0.0)	7 (0.0)
Body mass index (BMI) 12-15 years of age/obese[c]			
Yes	100 (12.1)		100 (0.4)
No	725 (87.9)		725 (3.1)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Obese is defined as BMI ≥95th percentile from the growth chart. The obese status is based on data collected at Visit 1. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.
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14.12. Demographic Characteristics – Phase 2/3 – HIV-Positive Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg)
	≥16 Years (N[a]=98) n[b] (%)
Sex	
Male	61 (62.2)
Female	37 (37.8)
Race	
White	36 (36.7)
Black or African American	58 (59.2)
American Indian or Alaska Native	1 (1.0)
Asian	1 (1.0)
Multiracial	2 (2.0)
Ethnicity	
Hispanic/Latino	18 (18.4)
Non-Hispanic/non-Latino	80 (81.6)
Country	
Argentina	4 (4.1)
Brazil	2 (2.0)
South Africa	32 (32.7)
Turkey	4 (4.1)
USA	56 (57.1)
Age group (at booster vaccination)	
16-55 Years	68 (69.4)
>55 Years	30 (30.6)
Age at booster vaccination (years)	
Mean (SD)	49.7 (11.22)
Median	49.5
Min, max	(27, 76)
Body mass index (BMI)	
Underweight (<18.5 kg/m^2)	2 (2.0)
Normal weight (≥18.5-24.9 kg/m^2)	26 (26.5)
Overweight (≥25.0-29.9 kg/m^2)	33 (33.7)
Obese (≥30.0 kg/m^2)	37 (37.8)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adsl Table Generation: 05MAY2023 (11:39)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adsl_s005_p23_d3_hiv

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14.13. Demographic Characteristics – Phase 3 – BNT162b2-Naïve Subjects Assigned to Receive BNT162b2SA Who Received Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=242) n[b] (%)
Sex	
Male	123 (50.8)
Female	119 (49.2)
Race	
White	184 (76.0)
Black or African American	34 (14.0)
Asian	19 (7.9)
Multiracial	4 (1.7)
Not reported	1 (0.4)
Racial designation	
Japanese	1 (0.4)
Ethnicity	
Hispanic/Latino	30 (12.4)
Non-Hispanic/non-Latino	211 (87.2)
Not reported	1 (0.4)
Country	
USA	242 (100.0)
Age at booster vaccination (years)	
Mean (SD)	37.3 (10.60)
Median	38.0
Min, max	(18, 56)
Body mass index (BMI)	
Underweight (<18.5 kg/m^2)	2 (0.8)
Normal weight (≥18.5-24.9 kg/m^2)	83 (34.3)
Overweight (≥25.0-29.9 kg/m^2)	85 (35.1)
Obese (≥30.0 kg/m^2)	72 (29.8)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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14.14. Demographic Characteristics – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N[a]=26) n[b] (%)	>55 Years (N[a]=53) n[b] (%)	18-55 Years (N[a]=25) n[b] (%)	>55 Years (N[a]=51) n[b] (%)
Sex				
Male	13 (50.0)	30 (56.6)	16 (64.0)	21 (41.2)
Female	13 (50.0)	23 (43.4)	9 (36.0)	30 (58.8)
Race				
White	16 (61.5)	40 (75.5)	17 (68.0)	39 (76.5)
Black or African American	3 (11.5)	3 (5.7)	3 (12.0)	2 (3.9)
Asian	4 (15.4)	10 (18.9)	4 (16.0)	7 (13.7)
Native Hawaiian or other Pacific Islander	1 (3.8)	0	1 (4.0)	0
Multiracial	2 (7.7)	0	0	2 (3.9)
Not reported	0	0	0	1 (2.0)
Racial designation				
Japanese	0	1 (1.9)	0	3 (5.9)
Ethnicity				
Hispanic/Latino	6 (23.1)	4 (7.5)	3 (12.0)	4 (7.8)
Non-Hispanic/non-Latino	20 (76.9)	49 (92.5)	22 (88.0)	47 (92.2)
Country				
USA	26 (100.0)	53 (100.0)	25 (100.0)	51 (100.0)
Age at booster vaccination (years)				
Mean (SD)	40.2 (8.63)	64.5 (6.16)	40.8 (10.98)	64.0 (5.80)
Median	40.0	63.0	44.0	63.0
Min, max	(25, 55)	(56, 83)	(19, 55)	(56, 79)
Body mass index (BMI)				
Underweight (<18.5 kg/m^2)	0	0	0	1 (2.0)
Normal weight (≥18.5-24.9 kg/m^2)	8 (30.8)	12 (22.6)	9 (36.0)	19 (37.3)
Overweight (≥25.0-29.9 kg/m^2)	10 (38.5)	26 (49.1)	6 (24.0)	19 (37.3)
Obese (≥30.0 kg/m^2)	8 (30.8)	15 (28.3)	10 (40.0)	12 (23.5)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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14.15. Demographic Characteristics – Subjects Without Evidence of Infection Prior to the Start of the Asymptomatic Surveillance Period – Evaluable Efficacy (Asymptomatic Surveillance) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=2092) n[b] (%)	Placebo (N[a]=1829) n[b] (%)	Total (N[a]=3921) n[b] (%)
Sex			
Male	1118 (53.4)	978 (53.5)	2096 (53.5)
Female	974 (46.6)	851 (46.5)	1825 (46.5)
Race			
White	1926 (92.1)	1666 (91.1)	3592 (91.6)
Black or African American	69 (3.3)	66 (3.6)	135 (3.4)
American Indian or Alaska Native	10 (0.5)	2 (0.1)	12 (0.3)
Asian	57 (2.7)	60 (3.3)	117 (3.0)
Native Hawaiian or other Pacific Islander	2 (0.1)	0	2 (0.1)
Multiracial	22 (1.1)	25 (1.4)	47 (1.2)
Not reported	6 (0.3)	10 (0.5)	16 (0.4)
All others[c]	97 (4.6)	97 (5.3)	194 (4.9)
Ethnicity			
Hispanic/Latino	1102 (52.7)	1053 (57.6)	2155 (55.0)
Non-Hispanic/non-Latino	988 (47.2)	774 (42.3)	1762 (44.9)
Not reported	2 (0.1)	2 (0.1)	4 (0.1)
Country			
Argentina	912 (43.6)	916 (50.1)	1828 (46.6)
USA	1180 (56.4)	913 (49.9)	2093 (53.4)
Age group (years)			
12 to 15	717 (34.3)	658 (36.0)	1375 (35.1)
16 to 55	1140 (54.5)	991 (54.2)	2131 (54.3)
>55	235 (11.2)	180 (9.8)	415 (10.6)
≥65	52 (2.5)	2 (0.1)	54 (1.4)
16 to 17	53 (2.5)	35 (1.9)	88 (2.2)
16 to 25	223 (10.7)	173 (9.5)	396 (10.1)
16 to 64	1323 (63.2)	1169 (63.9)	2492 (63.6)
18 to 64	1270 (60.7)	1134 (62.0)	2404 (61.3)
55 to 64	216 (10.3)	205 (11.2)	421 (10.7)
65 to 74	43 (2.1)	2 (0.1)	45 (1.1)
≥75	9 (0.4)	0	9 (0.2)
75 to 85	9 (0.4)	0	9 (0.2)
Age at vaccination (years)			
Mean (SD)	32.0 (17.42)	31.2 (16.65)	31.6 (17.07)
Median	30.0	30.0	30.0
Min, max	(12, 82)	(12, 72)	(12, 82)

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14.15. Demographic Characteristics – Subjects Without Evidence of Infection Prior to the Start of the Asymptomatic Surveillance Period – Evaluable Efficacy (Asymptomatic Surveillance) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=2092) n[b] (%)	Placebo (N[a]=1829) n[b] (%)	Total (N[a]=3921) n[b] (%)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence of past SARS-CoV-2 infection (i.e, negative N-binding antibody [serum] result at Visits 1 and 201, SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2, and negative NAAT [nasal swab] result at any unscheduled visits) prior to the start of the asymptomatic surveillance period were included in the analysis.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
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14.16. Demographic Characteristics – Subjects Without Evidence of Infection Prior to the First Post–Dose 2 N-Binding Test – Evaluable Efficacy (Seroconversion) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=20872) n[b] (%)	Placebo (N[a]=20692) n[b] (%)	Total (N[a]=41564) n[b] (%)
Sex			
Male	10697 (51.3)	10421 (50.4)	21118 (50.8)
Female	10175 (48.7)	10271 (49.6)	20446 (49.2)
Race			
White	17314 (83.0)	17221 (83.2)	34535 (83.1)
Black or African American	1733 (8.3)	1729 (8.4)	3462 (8.3)
American Indian or Alaska Native	198 (0.9)	177 (0.9)	375 (0.9)
Asian	955 (4.6)	951 (4.6)	1906 (4.6)
Native Hawaiian or other Pacific Islander	50 (0.2)	28 (0.1)	78 (0.2)
Multiracial	547 (2.6)	484 (2.3)	1031 (2.5)
Not reported	75 (0.4)	102 (0.5)	177 (0.4)
All others[c]	1825 (8.7)	1742 (8.4)	3567 (8.6)
Racial Designation			
Japanese	81 (0.4)	75 (0.4)	156 (0.4)
Ethnicity			
Hispanic/Latino	5184 (24.8)	5094 (24.6)	10278 (24.7)
Non-Hispanic/non-Latino	15618 (74.8)	15503 (74.9)	31121 (74.9)
Not reported	70 (0.3)	95 (0.5)	165 (0.4)
Country			
Argentina	2592 (12.4)	2558 (12.4)	5150 (12.4)
Brazil	1313 (6.3)	1288 (6.2)	2601 (6.3)
Germany	236 (1.1)	242 (1.2)	478 (1.2)
South Africa	291 (1.4)	273 (1.3)	564 (1.4)
Turkey	228 (1.1)	216 (1.0)	444 (1.1)
USA	16212 (77.7)	16115 (77.9)	32327 (77.8)
Age group (years)			
12 to 15	1050 (5.0)	1008 (4.9)	2058 (5.0)
16 to 55	11575 (55.5)	11470 (55.4)	23045 (55.4)
>55	8247 (39.5)	8214 (39.7)	16461 (39.6)
≥65	4221 (20.2)	4232 (20.5)	8453 (20.3)
16 to 17	347 (1.7)	328 (1.6)	675 (1.6)
16 to 25	1639 (7.9)	1618 (7.8)	3257 (7.8)
16 to 64	15601 (74.7)	15452 (74.7)	31053 (74.7)
18 to 64	15254 (73.1)	15124 (73.1)	30378 (73.1)
55 to 64	4455 (21.3)	4385 (21.2)	8840 (21.3)
65 to 74	3374 (16.2)	3390 (16.4)	6764 (16.3)
≥75	847 (4.1)	842 (4.1)	1689 (4.1)

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14.16. Demographic Characteristics – Subjects Without Evidence of Infection Prior to the First Post–Dose 2 N-Binding Test – Evaluable Efficacy (Seroconversion) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=20872) n[b] (%)	Placebo (N[a]=20692) n[b] (%)	Total (N[a]=41564) n[b] (%)
75 to 85	842 (4.0)	836 (4.0)	1678 (4.0)
>85	5 (0.0)	6 (0.0)	11 (0.0)
Age at vaccination (years)			
Mean (SD)	48.2 (17.50)	48.2 (17.49)	48.2 (17.49)
Median	50.0	50.0	50.0
Min, max	(12, 89)	(12, 91)	(12, 91)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence of past SARS-CoV-2 infection before Dose 2 (ie, negative N-binding antibody [serum] result at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2) and had a negative NAAT (nasal swab) result at any unscheduled visit and without any important protocol deviation prior to the first post–Dose 2 N-binding test result were included in the analysis.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
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14.17. Demographic Characteristics – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Dose 3 Booster Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N[a]=26) n[b] (%)	>55 Years (N[a]=51) n[b] (%)	18-55 Years (N[a]=24) n[b] (%)	>55 Years (N[a]=50) n[b] (%)
Sex				
Male	13 (50.0)	29 (56.9)	15 (62.5)	20 (40.0)
Female	13 (50.0)	22 (43.1)	9 (37.5)	30 (60.0)
Race				
White	16 (61.5)	38 (74.5)	16 (66.7)	38 (76.0)
Black or African American	3 (11.5)	3 (5.9)	3 (12.5)	2 (4.0)
Asian	4 (15.4)	10 (19.6)	4 (16.7)	7 (14.0)
Native Hawaiian or other Pacific Islander	1 (3.8)	0	1 (4.2)	0
Multiracial	2 (7.7)	0	0	2 (4.0)
Not reported	0	0	0	1 (2.0)
Racial designation				
Japanese	0	1 (2.0)	0	3 (6.0)
Ethnicity				
Hispanic/Latino	6 (23.1)	4 (7.8)	3 (12.5)	4 (8.0)
Non-Hispanic/non-Latino	20 (76.9)	47 (92.2)	21 (87.5)	46 (92.0)
Country				
USA	26 (100.0)	51 (100.0)	24 (100.0)	50 (100.0)
Age at booster vaccination (years)				
Mean (SD)	40.2 (8.63)	64.5 (6.27)	40.3 (10.86)	64.0 (5.86)
Median	40.0	63.0	42.0	62.5
Min, max	(25, 55)	(56, 83)	(19, 55)	(56, 79)
Body mass index (BMI)				
Underweight (<18.5 kg/m^2)	0	0	0	1 (2.0)
Normal weight (≥18.5-24.9 kg/m^2)	8 (30.8)	11 (21.6)	9 (37.5)	18 (36.0)
Overweight (≥25.0-29.9 kg/m^2)	10 (38.5)	25 (49.0)	6 (25.0)	19 (38.0)
Obese (≥30.0 kg/m^2)	8 (30.8)	15 (29.4)	9 (37.5)	12 (24.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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14.18. Demographic Characteristics – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Dose 3 Booster All-Available Immunogenicity Population

	Vaccine Group (as Randomized)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N[a]=26) n[b] (%)	>55 Years (N[a]=53) n[b] (%)	18-55 Years (N[a]=25) n[b] (%)	>55 Years (N[a]=51) n[b] (%)
Sex				
Male	13 (50.0)	30 (56.6)	16 (64.0)	21 (41.2)
Female	13 (50.0)	23 (43.4)	9 (36.0)	30 (58.8)
Race				
White	16 (61.5)	40 (75.5)	17 (68.0)	39 (76.5)
Black or African American	3 (11.5)	3 (5.7)	3 (12.0)	2 (3.9)
Asian	4 (15.4)	10 (18.9)	4 (16.0)	7 (13.7)
Native Hawaiian or other Pacific Islander	1 (3.8)	0	1 (4.0)	0
Multiracial	2 (7.7)	0	0	2 (3.9)
Not reported	0	0	0	1 (2.0)
Racial designation				
Japanese	0	1 (1.9)	0	3 (5.9)
Ethnicity				
Hispanic/Latino	6 (23.1)	4 (7.5)	3 (12.0)	4 (7.8)
Non-Hispanic/non-Latino	20 (76.9)	49 (92.5)	22 (88.0)	47 (92.2)
Country				
USA	26 (100.0)	53 (100.0)	25 (100.0)	51 (100.0)
Age at booster vaccination (years)				
Mean (SD)	40.2 (8.63)	64.5 (6.16)	40.8 (10.98)	64.0 (5.80)
Median	40.0	63.0	44.0	63.0
Min, max	(25, 55)	(56, 83)	(19, 55)	(56, 79)
Body mass index (BMI)				
Underweight (<18.5 kg/m^2)	0	0	0	1 (2.0)
Normal weight (≥18.5-24.9 kg/m^2)	8 (30.8)	12 (22.6)	9 (36.0)	19 (37.3)
Overweight (≥25.0-29.9 kg/m^2)	10 (38.5)	26 (49.1)	6 (24.0)	19 (37.3)
Obese (≥30.0 kg/m^2)	8 (30.8)	15 (28.3)	10 (40.0)	12 (23.5)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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14.19. Demographic Characteristics – Phase 3 – BNT162b2-Experienced Subjects Who Were Previously Rerandomized/Assigned to Receive Booster Dose(s), and Received an Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

	Previous Booster Vaccine Group (as Administered)				
	Vaccine Group (as Administered)				
	BNT162b2 (30 µg) (N[a]=182) n[b] (%)	BNT162b2$_{SA}$ (30 µg) (N[a]=199) n[b] (%)	BNT162b2 (5 µg) (N[a]=33) n[b] (%)	BNT162b2 (10 µg) (N[a]=38) n[b] (%)	BNT162b2$_{SA}$ (30 µg, 2 Doses) (N[a]=15) n[b] (%)
Sex					
Male	79 (43.4)	96 (48.2)	21 (63.6)	17 (44.7)	11 (73.3)
Female	103 (56.6)	103 (51.8)	12 (36.4)	21 (55.3)	4 (26.7)
Race					
White	148 (81.3)	161 (80.9)	24 (72.7)	31 (81.6)	13 (86.7)
Black or African American	19 (10.4)	22 (11.1)	3 (9.1)	1 (2.6)	2 (13.3)
American Indian or Alaska Native	2 (1.1)	1 (0.5)	0	0	0
Asian	7 (3.8)	13 (6.5)	5 (15.2)	6 (15.8)	0
Native Hawaiian or other Pacific Islander	0	0	1 (3.0)	0	0
Multiracial	4 (2.2)	0	0	0	0
Not reported	2 (1.1)	2 (1.0)	0	0	0
Racial designation					
Japanese	0	0	0	1 (2.6)	0
Ethnicity					
Hispanic/Latino	56 (30.8)	52 (26.1)	2 (6.1)	5 (13.2)	2 (13.3)
Non-Hispanic/non-Latino	126 (69.2)	142 (71.4)	31 (93.9)	33 (86.8)	12 (80.0)
Not reported	0	5 (2.5)	0	0	1 (6.7)
Country					
USA	182 (100.0)	199 (100.0)	33 (100.0)	38 (100.0)	15 (100.0)
Age at the additional booster dose of BNT162b2 (30 µg) (years)					
Mean (SD)	42.0 (9.28)	41.3 (9.83)	56.1 (14.25)	56.5 (15.46)	46.1 (9.52)
Median	43.0	42.0	61.0	60.5	47.0
Min, max	(22, 56)	(20, 63)	(26, 82)	(20, 80)	(23, 57)
Body mass index (BMI)					
Underweight (<18.5 kg/m^2)	1 (0.5)	3 (1.5)	0	0	0
Normal weight (≥18.5-24.9 kg/m^2)	47 (25.8)	44 (22.1)	11 (33.3)	16 (42.1)	2 (13.3)
Overweight (≥25.0-29.9 kg/m^2)	62 (34.1)	75 (37.7)	14 (42.4)	14 (36.8)	8 (53.3)
Obese (≥30.0 kg/m^2)	72 (39.6)	77 (38.7)	8 (24.2)	8 (21.1)	5 (33.3)

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14.19. Demographic Characteristics – Phase 3 – BNT162b2-Experienced Subjects Who Were Previously Rerandomized/Assigned to Receive Booster Dose(s), and Received an Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

	Previous Booster Vaccine Group (as Administered)				
	Vaccine Group (as Administered)				
	BNT162b2 (30 µg) (N[a]=182) n[b] (%)	BNT162b2$_{SA}$ (30 µg) (N[a]=199) n[b] (%)	BNT162b2 (5 µg) (N[a]=33) n[b] (%)	BNT162b2 (10 µg) (N[a]=38) n[b] (%)	BNT162b2$_{SA}$ (30 µg, 2 Doses) (N[a]=15) n[b] (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adsl Table Generation: 05MAY2023 (11:39)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adsl_s005_p3_d4

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14.20. Medical History – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N[a]=26)	>55 Years (N[a]=53)	18-55 Years (N[a]=25)	>55 Years (N[a]=51)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Any medical history	24 (92.3)	53 (100.0)	23 (92.0)	50 (98.0)
Blood and lymphatic system disorders	0	0	0	1 (2.0)
Anaemia	0	0	0	1 (2.0)
Cardiac disorders	1 (3.8)	10 (18.9)	0	3 (5.9)
Atrial fibrillation	0	4 (7.5)	0	2 (3.9)
Cardiac failure congestive	0	0	0	1 (2.0)
Coronary artery disease	0	2 (3.8)	0	0
Mitral valve prolapse	0	2 (3.8)	0	0
Myocardial infarction	0	2 (3.8)	0	0
Supraventricular tachycardia	1 (3.8)	1 (1.9)	0	1 (2.0)
Ventricular extrasystoles	0	1 (1.9)	0	0
Congenital, familial and genetic disorders	0	1 (1.9)	1 (4.0)	0
Arnold-Chiari malformation	0	1 (1.9)	0	0
Congenital aortic stenosis	0	0	1 (4.0)	0
Ear and labyrinth disorders	2 (7.7)	5 (9.4)	0	1 (2.0)
Deafness	0	1 (1.9)	0	0
Deafness unilateral	0	0	0	1 (2.0)
Hypoacusis	0	1 (1.9)	0	0
Tinnitus	2 (7.7)	1 (1.9)	0	0
Vertigo	0	2 (3.8)	0	0
Endocrine disorders	1 (3.8)	12 (22.6)	2 (8.0)	12 (23.5)
Autoimmune thyroiditis	0	1 (1.9)	0	0
Goitre	0	1 (1.9)	0	1 (2.0)
Growth hormone deficiency	0	0	0	1 (2.0)
Hypogonadism	1 (3.8)	1 (1.9)	0	2 (3.9)
Hypoparathyroidism	0	0	0	1 (2.0)
Hypothyroidism	0	9 (17.0)	2 (8.0)	8 (15.7)
Eye disorders	6 (23.1)	14 (26.4)	7 (28.0)	6 (11.8)
Cataract	0	2 (3.8)	1 (4.0)	2 (3.9)

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14.20. Medical History – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N^a=26)	>55 Years (N^a=53)	18-55 Years (N^a=25)	>55 Years (N^a=51)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Cataract nuclear	0	1 (1.9)	0	0
Diabetic retinopathy	0	0	0	1 (2.0)
Dry age-related macular degeneration	0	0	0	1 (2.0)
Dry eye	0	2 (3.8)	0	1 (2.0)
Eyelid ptosis	0	1 (1.9)	0	1 (2.0)
Glaucoma	0	1 (1.9)	0	0
Hypermetropia	0	5 (9.4)	1 (4.0)	0
Myopia	5 (19.2)	1 (1.9)	5 (20.0)	1 (2.0)
Ocular discomfort	0	1 (1.9)	0	0
Presbyopia	1 (3.8)	1 (1.9)	1 (4.0)	0
Pterygium	0	2 (3.8)	0	0
Retinal drusen	0	1 (1.9)	0	0
Retinal tear	0	0	0	1 (2.0)
Vitreous degeneration	0	1 (1.9)	0	0
Gastrointestinal disorders	4 (15.4)	18 (34.0)	9 (36.0)	12 (23.5)
Abdominal hernia	0	0	0	1 (2.0)
Abdominal pain	0	0	0	1 (2.0)
Anal fistula	0	0	1 (4.0)	0
Colitis ulcerative	0	1 (1.9)	0	0
Constipation	1 (3.8)	0	0	0
Dyspepsia	0	1 (1.9)	1 (4.0)	1 (2.0)
Gastrointestinal ulcer	0	1 (1.9)	0	0
Gastrooesophageal reflux disease	1 (3.8)	12 (22.6)	5 (20.0)	7 (13.7)
Haemorrhoids	1 (3.8)	0	0	1 (2.0)
Hiatus hernia	0	1 (1.9)	0	0
Inguinal hernia	0	3 (5.7)	0	1 (2.0)
Intestinal obstruction	0	0	0	1 (2.0)
Intestinal polyp	0	1 (1.9)	0	0
Irritable bowel syndrome	1 (3.8)	0	0	0
Leukoplakia oral	0	1 (1.9)	0	0
Mouth ulceration	0	1 (1.9)	0	0
Peptic ulcer	0	0	0	1 (2.0)
Tooth impacted	1 (3.8)	0	2 (8.0)	0
Toothache	1 (3.8)	0	0	0
Umbilical hernia	0	0	1 (4.0)	1 (2.0)

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14.20. Medical History – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N^a=26)	>55 Years (N^a=53)	18-55 Years (N^a=25)	>55 Years (N^a=51)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
General disorders and administration site conditions	1 (3.8)	3 (5.7)	0	1 (2.0)
Chest pain	1 (3.8)	0	0	0
Drug intolerance	0	1 (1.9)	0	1 (2.0)
Fatigue	0	1 (1.9)	0	0
Pain	1 (3.8)	1 (1.9)	0	0
Hepatobiliary disorders	1 (3.8)	0	1 (4.0)	3 (5.9)
Cholelithiasis	0	0	1 (4.0)	1 (2.0)
Hepatic steatosis	1 (3.8)	0	0	1 (2.0)
Non-alcoholic steatohepatitis	0	0	0	1 (2.0)
Immune system disorders	13 (50.0)	23 (43.4)	12 (48.0)	29 (56.9)
Allergy to animal	1 (3.8)	1 (1.9)	1 (4.0)	1 (2.0)
Allergy to arthropod sting	0	0	0	1 (2.0)
Contrast media allergy	0	0	0	1 (2.0)
Drug hypersensitivity	5 (19.2)	11 (20.8)	3 (12.0)	17 (33.3)
Dust allergy	0	1 (1.9)	0	0
Food allergy	1 (3.8)	3 (5.7)	1 (4.0)	3 (5.9)
Iodine allergy	0	1 (1.9)	1 (4.0)	0
Mite allergy	0	1 (1.9)	0	0
Rubber sensitivity	1 (3.8)	0	0	2 (3.9)
Seasonal allergy	10 (38.5)	13 (24.5)	9 (36.0)	11 (21.6)
Infections and infestations	4 (15.4)	11 (20.8)	2 (8.0)	7 (13.7)
Appendicitis	1 (3.8)	3 (5.7)	0	3 (5.9)
Diverticulitis	0	1 (1.9)	0	0
Encephalitis	0	1 (1.9)	0	0
Genital herpes simplex	0	1 (1.9)	0	0
Herpes simplex	2 (7.7)	1 (1.9)	0	1 (2.0)
Herpes zoster	0	0	1 (4.0)	1 (2.0)
Pneumonia	1 (3.8)	1 (1.9)	0	0
Sepsis	0	1 (1.9)	0	0
Sinusitis	0	0	0	2 (3.9)
Tinea capitis	0	1 (1.9)	0	0
Tonsillitis	1 (3.8)	1 (1.9)	0	0
Urinary tract infection	0	1 (1.9)	0	0
Vaginal infection	0	0	1 (4.0)	0

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14.20. Medical History – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N^a=26)	>55 Years (N^a=53)	18-55 Years (N^a=25)	>55 Years (N^a=51)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Injury, poisoning and procedural complications	3 (11.5)	8 (15.1)	2 (8.0)	2 (3.9)
Epicondylitis	0	0	1 (4.0)	0
Hand fracture	1 (3.8)	0	0	0
Ligament injury	0	2 (3.8)	0	0
Ligament rupture	0	0	0	1 (2.0)
Ligament sprain	0	1 (1.9)	0	0
Meniscus injury	1 (3.8)	1 (1.9)	0	1 (2.0)
Muscle rupture	0	1 (1.9)	0	0
Sciatic nerve injury	1 (3.8)	0	0	0
Tendon rupture	0	1 (1.9)	1 (4.0)	0
Ulna fracture	0	1 (1.9)	0	0
Vascular pseudoaneurysm	0	1 (1.9)	0	0
Investigations	1 (3.8)	6 (11.3)	4 (16.0)	1 (2.0)
Arthroscopy	1 (3.8)	0	0	0
Biopsy breast	0	1 (1.9)	0	0
Blood cholesterol increased	0	1 (1.9)	0	0
Blood testosterone decreased	0	0	3 (12.0)	1 (2.0)
Bronchoscopy	0	0	1 (4.0)	0
Colonoscopy	0	3 (5.7)	0	0
Nasoendoscopy	0	0	0	1 (2.0)
Prostatic specific antigen increased	0	1 (1.9)	0	0
Metabolism and nutrition disorders	7 (26.9)	30 (56.6)	10 (40.0)	29 (56.9)
Dyslipidaemia	1 (3.8)	10 (18.9)	1 (4.0)	8 (15.7)
Glucose tolerance impaired	1 (3.8)	2 (3.8)	0	1 (2.0)
Gout	0	2 (3.8)	0	6 (11.8)
Hypercholesterolaemia	0	5 (9.4)	1 (4.0)	7 (13.7)
Hyperlipidaemia	1 (3.8)	12 (22.6)	1 (4.0)	9 (17.6)
Hypertriglyceridaemia	0	0	1 (4.0)	0
Iron deficiency	0	0	0	1 (2.0)
Obesity	5 (19.2)	7 (13.2)	6 (24.0)	4 (7.8)
Overweight	3 (11.5)	2 (3.8)	3 (12.0)	0
Type 1 diabetes mellitus	0	0	1 (4.0)	1 (2.0)
Type 2 diabetes mellitus	2 (7.7)	3 (5.7)	0	5 (9.8)
Vitamin B12 deficiency	0	0	0	1 (2.0)

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14.20. Medical History – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N^a=26)	>55 Years (N^a=53)	18-55 Years (N^a=25)	>55 Years (N^a=51)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Vitamin D deficiency	0	1 (1.9)	0	2 (3.9)
Musculoskeletal and connective tissue disorders	3 (11.5)	24 (45.3)	1 (4.0)	11 (21.6)
Arthralgia	0	1 (1.9)	0	1 (2.0)
Arthritis	0	2 (3.8)	0	1 (2.0)
Back pain	2 (7.7)	3 (5.7)	0	1 (2.0)
Cervical spinal stenosis	0	1 (1.9)	0	0
Fibromyalgia	0	1 (1.9)	0	0
Foot deformity	0	0	0	1 (2.0)
Intervertebral disc degeneration	0	1 (1.9)	0	0
Intervertebral disc protrusion	0	2 (3.8)	0	2 (3.9)
Muscle tightness	0	1 (1.9)	0	0
Neck pain	0	1 (1.9)	0	0
Osteoarthritis	1 (3.8)	7 (13.2)	1 (4.0)	5 (9.8)
Osteopenia	0	5 (9.4)	0	2 (3.9)
Osteoporosis	0	4 (7.5)	0	1 (2.0)
Plantar fascial fibromatosis	0	1 (1.9)	0	0
Plantar fasciitis	0	0	1 (4.0)	0
Rotator cuff syndrome	0	4 (7.5)	0	1 (2.0)
Spinal stenosis	0	1 (1.9)	0	0
Spondylolisthesis	0	0	0	1 (2.0)
Tendonitis	0	1 (1.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (3.8)	13 (24.5)	2 (8.0)	12 (23.5)
Adenocarcinoma of appendix	0	1 (1.9)	0	0
Adenoma benign	0	1 (1.9)	0	0
Basal cell carcinoma	0	4 (7.5)	1 (4.0)	0
Basosquamous carcinoma	0	0	0	1 (2.0)
Benign breast neoplasm	0	1 (1.9)	0	1 (2.0)
Benign neoplasm of testis	0	0	0	1 (2.0)
Breast cancer	0	1 (1.9)	0	2 (3.9)
Breast fibroma	0	0	0	1 (2.0)
Chronic lymphocytic leukaemia	0	0	0	1 (2.0)
Intraductal proliferative breast lesion	0	0	0	1 (2.0)
Lipoma	0	1 (1.9)	0	0
Lobular breast carcinoma in situ	0	0	0	1 (2.0)

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14.20. Medical History – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N^a=26)	>55 Years (N^a=53)	18-55 Years (N^a=25)	>55 Years (N^a=51)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Lymphoma	0	1 (1.9)	0	0
Malignant melanoma	0	0	0	1 (2.0)
Non-Hodgkin's lymphoma	0	1 (1.9)	0	0
Parathyroid tumour	0	0	0	1 (2.0)
Prostate cancer	0	2 (3.8)	0	2 (3.9)
Renal cell carcinoma	0	1 (1.9)	0	0
Uterine leiomyoma	1 (3.8)	4 (7.5)	1 (4.0)	1 (2.0)
Nervous system disorders	5 (19.2)	14 (26.4)	4 (16.0)	8 (15.7)
Autonomic neuropathy	0	1 (1.9)	0	0
Carpal tunnel syndrome	0	0	0	1 (2.0)
Cerebrovascular accident	0	2 (3.8)	0	0
Diabetic neuropathy	0	0	0	1 (2.0)
Headache	4 (15.4)	1 (1.9)	3 (12.0)	1 (2.0)
Memory impairment	0	1 (1.9)	0	0
Migraine	0	3 (5.7)	1 (4.0)	3 (5.9)
Nerve compression	0	1 (1.9)	0	0
Neuropathy peripheral	0	3 (5.7)	0	1 (2.0)
Parkinson's disease	0	1 (1.9)	0	0
Restless legs syndrome	1 (3.8)	0	0	0
Sciatica	0	1 (1.9)	0	1 (2.0)
Seizure	0	1 (1.9)	0	0
Transient global amnesia	0	1 (1.9)	0	1 (2.0)
Transient ischaemic attack	0	1 (1.9)	0	0
Tremor	0	0	0	1 (2.0)
Psychiatric disorders	8 (30.8)	14 (26.4)	11 (44.0)	12 (23.5)
Anxiety	5 (19.2)	5 (9.4)	4 (16.0)	4 (7.8)
Attention deficit hyperactivity disorder	1 (3.8)	1 (1.9)	4 (16.0)	1 (2.0)
Depression	4 (15.4)	8 (15.1)	3 (12.0)	6 (11.8)
Insomnia	1 (3.8)	5 (9.4)	2 (8.0)	4 (7.8)
Obsessive-compulsive disorder	0	1 (1.9)	0	0
Panic attack	1 (3.8)	0	1 (4.0)	0
Persistent depressive disorder	0	0	0	1 (2.0)
Renal and urinary disorders	0	4 (7.5)	1 (4.0)	8 (15.7)
Chronic kidney disease	0	2 (3.8)	0	2 (3.9)

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14.20. Medical History – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N^a=26)	>55 Years (N^a=53)	18-55 Years (N^a=25)	>55 Years (N^a=51)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Cystitis interstitial	0	1 (1.9)	0	0
Diabetic nephropathy	0	0	0	1 (2.0)
Haematuria	0	0	1 (4.0)	0
Hypertonic bladder	0	1 (1.9)	0	0
Nephrolithiasis	0	1 (1.9)	0	3 (5.9)
Pelvi-ureteric obstruction	0	0	0	1 (2.0)
Urinary incontinence	0	0	0	1 (2.0)
Urinary retention	0	1 (1.9)	0	0
Reproductive system and breast disorders	0	10 (18.9)	3 (12.0)	10 (19.6)
Abnormal uterine bleeding	0	0	0	1 (2.0)
Benign prostatic hyperplasia	0	6 (11.3)	0	3 (5.9)
Breast calcifications	0	0	0	1 (2.0)
Endometriosis	0	1 (1.9)	0	1 (2.0)
Erectile dysfunction	0	2 (3.8)	1 (4.0)	1 (2.0)
Heavy menstrual bleeding	0	1 (1.9)	0	1 (2.0)
Infertility	0	2 (3.8)	0	1 (2.0)
Ovarian cyst	0	0	0	1 (2.0)
Prostatic disorder	0	0	0	1 (2.0)
Prostatomegaly	0	0	1 (4.0)	0
Uterine haemorrhage	0	0	0	1 (2.0)
Uterine prolapse	0	0	0	1 (2.0)
Varicocele	0	0	1 (4.0)	0
Respiratory, thoracic and mediastinal disorders	4 (15.4)	10 (18.9)	10 (40.0)	7 (13.7)
Adenoidal hypertrophy	0	0	1 (4.0)	0
Asthma	2 (7.7)	2 (3.8)	3 (12.0)	3 (5.9)
Asthma exercise induced	0	1 (1.9)	0	0
Bronchiectasis	0	1 (1.9)	0	0
Bronchitis chronic	0	1 (1.9)	0	0
Nasal septum deviation	0	0	1 (4.0)	1 (2.0)
Obstructive sleep apnoea syndrome	0	0	1 (4.0)	1 (2.0)
Rhinitis allergic	1 (3.8)	6 (11.3)	3 (12.0)	4 (7.8)
Rhinitis perennial	1 (3.8)	1 (1.9)	1 (4.0)	0
Sleep apnoea syndrome	1 (3.8)	2 (3.8)	3 (12.0)	1 (2.0)
Skin and subcutaneous tissue disorders	6 (23.1)	3 (5.7)	8 (32.0)	7 (13.7)

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14.20. Medical History – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N^a=26)	>55 Years (N^a=53)	18-55 Years (N^a=25)	>55 Years (N^a=51)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Acne	1 (3.8)	0	3 (12.0)	2 (3.9)
Actinic keratosis	0	0	1 (4.0)	0
Alopecia	0	0	1 (4.0)	0
Dermatitis contact	3 (11.5)	0	1 (4.0)	2 (3.9)
Diabetic foot	0	0	0	1 (2.0)
Eczema	3 (11.5)	0	2 (8.0)	0
Hand dermatitis	0	0	0	1 (2.0)
Parapsoriasis	0	0	0	1 (2.0)
Perioral dermatitis	0	0	1 (4.0)	0
Seborrhoeic dermatitis	0	1 (1.9)	0	0
Vitiligo	0	2 (3.8)	0	0
Social circumstances	4 (15.4)	12 (22.6)	1 (4.0)	20 (39.2)
Corrective lens user	1 (3.8)	0	1 (4.0)	0
Menopause	1 (3.8)	0	0	3 (5.9)
Organ donor	0	1 (1.9)	0	0
Postmenopause	2 (7.7)	11 (20.8)	0	17 (33.3)
Tobacco user	0	1 (1.9)	0	0
Surgical and medical procedures	8 (30.8)	35 (66.0)	15 (60.0)	35 (68.6)
Abdominal hernia repair	0	1 (1.9)	0	1 (2.0)
Abdominoplasty	0	0	0	1 (2.0)
Adenoidectomy	0	0	1 (4.0)	0
Anal fistula repair	0	0	1 (4.0)	0
Angioplasty	0	1 (1.9)	0	0
Ankle arthroplasty	0	1 (1.9)	0	0
Ankle operation	0	1 (1.9)	0	0
Appendicectomy	1 (3.8)	4 (7.5)	0	3 (5.9)
Blepharoplasty	0	1 (1.9)	0	0
Bone cyst excision	0	0	0	1 (2.0)
Bone lesion excision	0	0	0	1 (2.0)
Bone operation	0	1 (1.9)	0	0
Brachytherapy	0	0	0	1 (2.0)
Breast conserving surgery	0	2 (3.8)	0	2 (3.9)
Breast cyst excision	0	0	0	1 (2.0)
Caesarean section	0	2 (3.8)	0	2 (3.9)
Cancer surgery	0	1 (1.9)	0	0

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14.20. Medical History – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N^a=26)	>55 Years (N^a=53)	18-55 Years (N^a=25)	>55 Years (N^a=51)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Cardiac ablation	0	2 (3.8)	0	1 (2.0)
Carpal tunnel decompression	0	1 (1.9)	0	0
Cataract operation	0	1 (1.9)	1 (4.0)	2 (3.9)
Chemotherapy	0	1 (1.9)	0	0
Cholecystectomy	0	1 (1.9)	1 (4.0)	3 (5.9)
Colectomy	0	1 (1.9)	0	0
Cytoreductive surgery	0	1 (1.9)	0	0
Debridement	0	0	0	1 (2.0)
Deep brain stimulation	0	1 (1.9)	0	0
Diplopia correction	0	0	1 (4.0)	0
Endometriosis ablation	0	0	0	1 (2.0)
Eyelid operation	0	0	0	1 (2.0)
Female sterilisation	0	0	1 (4.0)	3 (5.9)
Fracture treatment	0	0	0	1 (2.0)
Functional endoscopic sinus surgery	0	0	0	1 (2.0)
Gastrectomy	1 (3.8)	0	1 (4.0)	1 (2.0)
Gastric banding	1 (3.8)	0	0	0
Gastric banding reversal	1 (3.8)	0	0	0
Gastric bypass	0	1 (1.9)	0	0
Haemorrhoid operation	1 (3.8)	0	0	1 (2.0)
Hip arthroplasty	0	2 (3.8)	0	0
Hip surgery	0	1 (1.9)	0	0
Hysterectomy	2 (7.7)	8 (15.1)	2 (8.0)	6 (11.8)
Inguinal hernia repair	0	3 (5.7)	0	1 (2.0)
Keratomileusis	0	0	1 (4.0)	0
Knee arthroplasty	0	1 (1.9)	0	2 (3.9)
Knee operation	0	2 (3.8)	0	1 (2.0)
Ligament operation	0	3 (5.7)	0	2 (3.9)
Limb operation	1 (3.8)	0	0	0
Liposuction	1 (3.8)	0	0	0
Lithotripsy	0	0	0	1 (2.0)
Mammoplasty	1 (3.8)	2 (3.8)	0	1 (2.0)
Mastectomy	0	0	0	1 (2.0)
Meniscus operation	0	1 (1.9)	0	1 (2.0)
Micrographic skin surgery	0	1 (1.9)	0	0
Myomectomy	0	1 (1.9)	0	0
Nasal operation	0	0	1 (4.0)	0

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14.20. Medical History – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N^a=26)	>55 Years (N^a=53)	18-55 Years (N^a=25)	>55 Years (N^a=51)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Nasal septal operation	0	0	1 (4.0)	1 (2.0)
Nephrectomy	0	2 (3.8)	0	0
Oophorectomy	0	0	0	1 (2.0)
Oophorectomy bilateral	0	0	0	1 (2.0)
Orchidectomy	0	0	0	1 (2.0)
Parathyroidectomy	0	0	0	1 (2.0)
Peripheral nerve decompression	0	1 (1.9)	0	0
Pilonidal sinus repair	0	0	0	1 (2.0)
Prostatectomy	0	1 (1.9)	0	0
Pterygium operation	0	1 (1.9)	0	0
Ptosis repair	0	1 (1.9)	0	0
Pyeloplasty	0	0	0	1 (2.0)
Radical prostatectomy	0	1 (1.9)	0	1 (2.0)
Radiotherapy	0	0	0	1 (2.0)
Renal stone removal	0	2 (3.8)	0	0
Rotator cuff repair	0	1 (1.9)	0	2 (3.9)
Salpingo-oophorectomy bilateral	0	1 (1.9)	0	0
Shoulder arthroplasty	0	0	0	1 (2.0)
Shoulder operation	0	1 (1.9)	0	1 (2.0)
Sigmoidectomy	0	1 (1.9)	0	0
Skin neoplasm excision	0	1 (1.9)	0	0
Spinal fusion surgery	0	1 (1.9)	0	1 (2.0)
Spinal laminectomy	0	1 (1.9)	0	0
Spinal nerve stimulator implantation	0	2 (3.8)	0	0
Strabismus correction	0	1 (1.9)	0	0
Tenoplasty	0	1 (1.9)	1 (4.0)	0
Therapeutic procedure	0	0	0	1 (2.0)
Toe operation	0	1 (1.9)	0	1 (2.0)
Tonsillectomy	1 (3.8)	1 (1.9)	1 (4.0)	2 (3.9)
Tympanoplasty	1 (3.8)	0	0	0
Umbilical hernia repair	0	0	2 (8.0)	1 (2.0)
Urinary bladder suspension	0	1 (1.9)	0	0
Uterine cystectomy	0	0	0	1 (2.0)
Uterine dilation and curettage	0	0	0	1 (2.0)
Uvulopalatopharyngoplasty	0	0	1 (4.0)	0
Varicocele repair	0	0	1 (4.0)	0
Vasectomy	0	1 (1.9)	3 (12.0)	0

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14.20. Medical History – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N^a=26)	>55 Years (N^a=53)	18-55 Years (N^a=25)	>55 Years (N^a=51)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Vitrectomy	0	0	0	1 (2.0)
Wisdom teeth removal	1 (3.8)	0	3 (12.0)	0
Vascular disorders	6 (23.1)	22 (41.5)	7 (28.0)	18 (35.3)
Aortic aneurysm	0	0	0	1 (2.0)
Essential hypertension	0	1 (1.9)	1 (4.0)	0
Hot flush	1 (3.8)	0	0	0
Hypertension	5 (19.2)	20 (37.7)	6 (24.0)	17 (33.3)
Hypotension	0	1 (1.9)	0	1 (2.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic. Subjects with multiple occurrences of the same preferred term are counted only once.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:41) Source Data: admh Table Generation: 28JUN2023 (00:21)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_G4_6MPD_CSR/admh_s002_g4_6m

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14.21. Nonstudy Vaccines Received After Booster Dose – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

Vaccine[b] Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) 12-15 Years (N[a]=825) n[c] (%)	Vaccine Group (as Administered) BNT162b2 (30 µg) ≥16 Years (N[a]=22470) n[c] (%)
Any nonstudy vaccine	62 (7.5)	5259 (23.4)
BACTERIAL VACCINES	0	3 (0.0)
BNT162B2;BNT162B2 OMI BA.4-5	1 (0.1)	10 (0.0)
COVID-19 VACCINE	2 (0.2)	133 (0.6)
COVID-19 VACCINE INACT (VERO) CZ02	0	16 (0.1)
COVID-19 VACCINE INACT (VERO) HB02	0	3 (0.0)
COVID-19 VACCINE MRNA	2 (0.2)	3 (0.0)
COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)	0	201 (0.9)
COVID-19 VACCINE NRVV AD26 (GAM-COVID-VAC)	0	59 (0.3)
COVID-19 VACCINE NRVV AD26 (GAM-COVID-VAC);COVID-19 VACCINE NRVV AD5 (GAM-COVID-VAC)	0	4 (0.0)
COVID-19 VACCINE NRVV AD26 (JNJ 78436735)	0	63 (0.3)
COVID-19 VACCINE NRVV AD5 (AD5-NCOV)	0	2 (0.0)
DAVESOMERAN;ELASOMERAN	0	1 (0.0)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID	0	1 (0.0)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 5-COMPONENT;POLIO VACCINE INACT 3V (VERO);TETANUS VACCINE TOXOID	0	2 (0.0)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 5-COMPONENT;TETANUS VACCINE TOXOID	0	5 (0.0)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	0	45 (0.2)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE;TETANUS VACCINE TOXOID	0	2 (0.0)
DIPHTHERIA VACCINE TOXOID;TETANUS VACCINE TOXOID	0	21 (0.1)
DIPHTHERIA VACCINE;PERTUSSIS VACCINE;POLIO VACCINE;TETANUS VACCINE	0	1 (0.0)
DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE	0	5 (0.0)
DIPHTHERIA VACCINE;TETANUS VACCINE	0	24 (0.1)
ELASOMERAN	0	784 (3.5)
HEPATITIS A VACCINE	1 (0.1)	9 (0.0)
HEPATITIS A VACCINE INACT	0	1 (0.0)
HEPATITIS A VACCINE;HEPATITIS B VACCINE	0	1 (0.0)
HEPATITIS B VACCINE	0	66 (0.3)
HEPATITIS B VACCINE R	0	1 (0.0)
HEPATITIS B VACCINE RHBSAG	0	1 (0.0)
HEPATITIS B VACCINE RHBSAG (YEAST)	1 (0.1)	1 (0.0)

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14.21. Nonstudy Vaccines Received After Booster Dose – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

Vaccine[b] Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	
	12-15 Years (N[a]=825) n[c] (%)	≥16 Years (N[a]=22470) n[c] (%)
HEPATITIS VACCINES	0	1 (0.0)
HPV VACCINE	2 (0.2)	10 (0.0)
HPV VACCINE VLP RL1 4V (YEAST)	5 (0.6)	6 (0.0)
HPV VACCINE VLP RL1 9V (YEAST)	1 (0.1)	0
INFLUENZA VACCINE	16 (1.9)	2736 (12.2)
INFLUENZA VACCINE INACT SAG 3V	0	72 (0.3)
INFLUENZA VACCINE INACT SAG 4V	0	19 (0.1)
INFLUENZA VACCINE INACT SPLIT 3V	4 (0.5)	130 (0.6)
INFLUENZA VACCINE INACT SPLIT 4V	1 (0.1)	118 (0.5)
INFLUENZA VACCINE LIVE REASSORT 3V	0	1 (0.0)
INFLUENZA VACCINE RHA 3V (BACULOVIRUS)	0	1 (0.0)
INFLUENZA VACCINE RHA 4V (BACULOVIRUS)	0	1 (0.0)
MEASLES VACCINE	0	13 (0.1)
MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE	0	42 (0.2)
MEASLES VACCINE;RUBELLA VACCINE	0	6 (0.0)
MENINGOCOCCAL VACCINE	3 (0.4)	10 (0.0)
MENINGOCOCCAL VACCINE A/C/Y/W	1 (0.1)	7 (0.0)
MENINGOCOCCAL VACCINE A/C/Y/W CONJ (CRM197)	5 (0.6)	11 (0.0)
MENINGOCOCCAL VACCINE A/C/Y/W CONJ (DIP TOX)	1 (0.1)	1 (0.0)
MENINGOCOCCAL VACCINE A/C/Y/W CONJ (TET TOX)	0	3 (0.0)
MENINGOCOCCAL VACCINE B	2 (0.2)	6 (0.0)
MENINGOCOCCAL VACCINE B OMV	0	1 (0.0)
MENINGOCOCCAL VACCINE B RFHBP/NADA/NHBA OMV	0	2 (0.0)
MENINGOCOCCAL VACCINE B RFHBPA/FHBPB	0	2 (0.0)
MENINGOCOCCAL VACCINE C	0	1 (0.0)
MENINGOCOCCAL VACCINE C CONJ	0	4 (0.0)
MENINGOCOCCAL VACCINE CONJ	0	1 (0.0)
OTHER VIRAL VACCINES	0	15 (0.1)
PNEUMOCOCCAL VACCINE	0	162 (0.7)
PNEUMOCOCCAL VACCINE 13V	0	1 (0.0)
PNEUMOCOCCAL VACCINE CONJ 13V (CRM197)	0	13 (0.1)
PNEUMOCOCCAL VACCINE CONJ 20V (CRM197)	0	2 (0.0)
PNEUMOCOCCAL VACCINE CONJ 7V (CRM197)	0	2 (0.0)
PNEUMOCOCCAL VACCINE POLYSACCH	0	2 (0.0)
PNEUMOCOCCAL VACCINE POLYSACCH 23V	0	39 (0.2)
POLIO VACCINE	0	1 (0.0)

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14.21. Nonstudy Vaccines Received After Booster Dose – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

Vaccine[b] Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	
	12-15 Years (N[a]=825) n[c] (%)	≥16 Years (N[a]=22470) n[c] (%)
RABIES VACCINE	1 (0.1)	7 (0.0)
RILTOZINAMERAN	0	1 (0.0)
RSV VACCINE	0	3 (0.0)
SMALLPOX VACCINE	0	1 (0.0)
SMALLPOX VACCINE LIVE (MAV-BN)	0	6 (0.0)
TETANUS VACCINE	0	48 (0.2)
TETANUS VACCINE TOXOID	1 (0.1)	3 (0.0)
TICK-BORNE ENCEPHALITIS VACCINE INACT (NEUV)	0	1 (0.0)
TOZINAMERAN	17 (2.1)	1314 (5.8)
TUBERCULOSIS VACCINES	0	1 (0.0)
TYPHOID VACCINE	4 (0.5)	7 (0.0)
TYPHOID VACCINE INACT	0	1 (0.0)
TYPHOID VACCINE LIVE ORAL (TY21A)	1 (0.1)	0
VACCINES	0	4 (0.0)
VARICELLA ZOSTER VACCINE	0	91 (0.4)
VARICELLA ZOSTER VACCINE LIVE (OKA/MERCK)	0	1 (0.0)
VARICELLA ZOSTER VACCINE RGE (CHO)	0	99 (0.4)
YELLOW FEVER VACCINE	1 (0.1)	10 (0.0)

Note: WHODDG B3 v202203 coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. Subjects are counted only once for each preferred term.
c. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adcm Table Generation: 05MAY2023 (11:37)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adcm_s001_p23_d3

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14.22. Nonstudy Vaccines Received After Booster Dose – Phase 3 – BNT162b2-Naïve Subjects Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

Vaccine[b] Preferred Term	Vaccine Group (as Administered) BNT162b2(30 µg) (N[a]=236) n[c] (%)
Any nonstudy vaccine	16 (6.8)
COVID-19 VACCINE	1 (0.4)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	1 (0.4)
INFLUENZA VACCINE	12 (5.1)
INFLUENZA VACCINE INACT SPLIT 3V	2 (0.8)
INFLUENZA VACCINE INACT SPLIT 4V	1 (0.4)
PNEUMOCOCCAL VACCINE	1 (0.4)
PNEUMOCOCCAL VACCINE POLYSACCH 23V	1 (0.4)
VARICELLA ZOSTER VACCINE	1 (0.4)

Note: WHODDG B3 v202203 coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. Subjects are counted only once for each preferred term.
c. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adcm Table Generation: 05MAY2023 (11:37)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adcm_s001_na_d3

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14.23. Concomitant Vaccines Received After Booster Dose – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
Vaccine[b] Preferred Term	18-55 Years (N[a]=26) n[c] (%)	>55 Years (N[a]=53) n[c] (%)	18-55 Years (N[a]=25) n[c] (%)	>55 Years (N[a]=51) n[c] (%)
Any concomitant vaccine	7 (26.9)	27 (50.9)	10 (40.0)	24 (47.1)
COVID-19 VACCINE	0	1 (1.9)	0	0
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	1 (3.8)	0	0	0
DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE	0	1 (1.9)	0	1 (2.0)
ELASOMERAN	3 (11.5)	4 (7.5)	1 (4.0)	3 (5.9)
INFLUENZA VACCINE	4 (15.4)	15 (28.3)	6 (24.0)	14 (27.5)
PNEUMOCOCCAL VACCINE	0	0	0	1 (2.0)
TETANUS VACCINE	1 (3.8)	0	0	0
TOZINAMERAN	2 (7.7)	11 (20.8)	5 (20.0)	13 (25.5)
VARICELLA ZOSTER VACCINE	0	1 (1.9)	0	1 (2.0)
VARICELLA ZOSTER VACCINE RGE (CHO)	0	1 (1.9)	0	0

Note: WHODDG B3 v202203 coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. Subjects are counted only once for each preferred term.
c. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adcm Table Generation: 29JUN2023 (06:35)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_G4_6MPD_CSR/adcm_s001_g4_6m

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14.24. Nonstudy Vaccines Received After the Additional Booster Dose – Phase 3 – BNT162b2-Experienced Subjects Who Were Previously Rerandomized/Assigned to Receive Booster Dose(s), and Received an Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

Vaccine[b] Preferred Term	Previous Booster Vaccine Group (as Administered)				
	BNT162b2 (30 µg) (N[a]=182) n[c] (%)	BNT162b2$_{SA}$ (30 µg) (N[a]=196) n[c] (%)	BNT162b2 (5 µg) (N[a]=33) n[c] (%)	BNT162b2 (10 µg) (N[a]=38) n[c] (%)	BNT162b2$_{SA}$ (30 µg, 2 Doses) (N[a]=15) n[c] (%)
Any nonstudy vaccine	7 (3.8)	10 (5.1)	1 (3.0)	6 (15.8)	0
BNT162B2;BNT162B2 OMI BA.4-5	0	1 (0.5)	0	0	0
COVID-19 VACCINE	1 (0.5)	0	0	0	0
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	1 (0.5)	0	0	0	0
ELASOMERAN	0	1 (0.5)	0	0	0
INFLUENZA VACCINE	4 (2.2)	5 (2.6)	1 (3.0)	5 (13.2)	0
OTHER VIRAL VACCINES	0	1 (0.5)	0	0	0
PNEUMOCOCCAL VACCINE CONJ 13V (CRM197)	0	0	0	1 (2.6)	0
SMALLPOX VACCINE LIVE (MAV-BN)	1 (0.5)	1 (0.5)	0	0	0
TOZINAMERAN	1 (0.5)	1 (0.5)	0	1 (2.6)	0
VARICELLA ZOSTER VACCINE RGE (CHO)	0	1 (0.5)	0	0	0

Note: WHODDG B3 v202203 coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. Subjects are counted only once for each preferred term.
c. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adcm Table Generation: 05MAY2023 (11:37)
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14.25. Immunogenicity Blood Samples Drawn – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose)

	Vaccine Group (as Randomized)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years (N[a]=26) n[b] (%)	>55 Years (N[a]=53) n[b] (%)	18-55 Years (N[a]=25) n[b] (%)	>55 Years (N[a]=51) n[b] (%)
Rerandomized	26 (100.0)	53 (100.0)	25 (100.0)	51 (100.0)
Did not receive booster vaccination	0	0	0	0
Blood sample drawn	26 (100.0)	53 (100.0)	25 (100.0)	51 (100.0)
Received booster vaccination	26 (100.0)	53 (100.0)	25 (100.0)	51 (100.0)
Blood sample drawn before booster vaccination[c]	26 (100.0)	53 (100.0)	25 (100.0)	51 (100.0)
Blood sample drawn 7 days after booster vaccination[c]				
<6 Days	0	1 (1.9)	0	0
6-8 Days	26 (100.0)	50 (94.3)	25 (100.0)	49 (96.1)
>8 Days	0	2 (3.8)	0	1 (2.0)
Not obtained	0	0	0	1 (2.0)
Blood sample drawn 1 month after booster vaccination[c]				
<28 Days	0	1 (1.9)	0	1 (2.0)
28-35 Days	25 (96.2)	50 (94.3)	24 (96.0)	49 (96.1)
>35 Days	1 (3.8)	2 (3.8)	1 (4.0)	1 (2.0)
Not obtained	0	0	0	0
Blood sample drawn 6 months after booster vaccination[c]				
<175 Days	0	1 (1.9)	0	0
175-189 Days	24 (92.3)	51 (96.2)	24 (96.0)	46 (90.2)
>189 Days	1 (3.8)	0	1 (4.0)	4 (7.8)
Not obtained	1 (3.8)	1 (1.9)	0	1 (2.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Protocol-specified time frame.

PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adsl Table Generation: 29JUN2023 (07:28)
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14.26. E-Diary Transmission – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose)

	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
	18-55 Years n[a] (%)	>55 Years n[a] (%)	18-55 Years n[a] (%)	>55 Years n[a] (%)
Received booster vaccination[b]	26	53	25	51
E-diary				
Not transmitted[c]	1 (3.8)	1 (1.9)	0	0
Transmitted[d]				
Day 1	17 (65.4)	43 (81.1)	19 (76.0)	44 (86.3)
Day 2	22 (84.6)	49 (92.5)	20 (80.0)	48 (94.1)
Day 3	20 (76.9)	50 (94.3)	20 (80.0)	48 (94.1)
Day 4	23 (88.5)	48 (90.6)	23 (92.0)	50 (98.0)
Day 5	23 (88.5)	50 (94.3)	24 (96.0)	47 (92.2)
Day 6	24 (92.3)	48 (90.6)	22 (88.0)	48 (94.1)
Day 7	23 (88.5)	51 (96.2)	22 (88.0)	46 (90.2)
All 7 days[e]	13 (50.0)	40 (75.5)	12 (48.0)	31 (60.8)

a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. If no data for temperature, local reactions, fever/pain medication, or systemic events are reported for the entire electronic diary (e-diary) collection period (Day 1 through Day 7), the e-diary is considered not transmitted.
d. If any data for temperature, local reactions, fever/pain medication, or systemic events are reported for the specified day or set of days (i.e., "all 7 days"), the e-diary is considered transmitted.
e. "All 7 days" includes Day 1 through Day 7 after vaccination. Day 1 is the day of vaccination.
PFIZER CONFIDENTIAL SDTM Creation: 13DEC2021 (22:49) Source Data: adfacevd Table Generation: 13JAN2022 (21:59)
(Data Cutoff Date: 22NOV2021, Database Snapshot Date: 10DEC2021) Output File: ./nda2_unblinded/C4591001_G4_LD/adce_s200_g4_6m

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Efficacy

14.27. Vaccine Efficacy – Asymptomatic SARS-CoV-2 Infection Based on Central Laboratory–Confirmed NAAT Result – Subjects Without Evidence of Infection Prior to the Start of the Asymptomatic Surveillance Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=2130)		Placebo (N[a]=1871)			
Efficacy Endpoint	n[b]	Surveillance Time[c]	n[b]	Surveillance Time[c]	VE (%)	(95% CI[d])
Asymptomatic SARS-CoV-2 infection based on central laboratory–confirmed NAAT result during asymptomatic surveillance period	25	0.390	22	0.205	40.4	(-10.8, 67.8)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence of past SARS-CoV-2 infection (i.e, negative N-binding antibody [serum] result at Visits 1 and 201, SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2, and negative NAAT [nasal swab] result at any unscheduled visits) prior to the start of the asymptomatic surveillance period were included in the analysis.
a. N = number of subjects in the specified group.
b. n = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group. Time period for case accrual is from the start of the asymptomatic surveillance period to the end of the surveillance period.
d. Two-sided confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adc19nat Table Generation: 18JUL2023 (22:33)
(Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_ASYMP_CSR/adc19nat_ve_as_nat_wo_pd1_aai

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14.28. Vaccine Efficacy – Asymptomatic SARS-CoV-2 Infection Based on Central Laboratory–Confirmed NAAT Result – Subjects Without Evidence of Infection Prior to the Start of the Asymptomatic Surveillance Period – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=2130)		Placebo (N[a]=1871)			
Efficacy Endpoint	n[b]	Surveillance Time[c]	n[b]	Surveillance Time[c]	VE (%)	(95% CI[d])
Asymptomatic SARS-CoV-2 infection based on central laboratory–confirmed NAAT result during asymptomatic surveillance period	25	0.390	22	0.205	40.4	(-10.8, 67.8)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence of past SARS-CoV-2 infection (i.e, negative N-binding antibody [serum] result at Visits 1 and 201, SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2, and negative NAAT [nasal swab] result at any unscheduled visits) prior to the start of the asymptomatic surveillance period were included in the analysis.
a. N = number of subjects in the specified group.
b. n = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group. Time period for case accrual is from the start of the asymptomatic surveillance period to the end of the surveillance period.
d. Two-sided confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adc19nat Table Generation: 18JUL2023 (22:33)
(Snapshot Date: 28APR2023) Output File: /nda2_unblinded/C4591001_ASYMP_CSR/adc19nat_ve_as_nat_wo_pd2_aai

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14.29. Vaccine Efficacy – Asymptomatic SARS-CoV-2 Infection Based on Central Laboratory–Confirmed NAAT Result – Subjects With Evidence of Infection Prior to the Start of the Asymptomatic Surveillance Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=83)		Placebo (N[a]=144)			
Efficacy Endpoint	n[b]	Surveillance Time[c]	n[b]	Surveillance Time[c]	VE (%)	(95% CI[d])
Asymptomatic SARS-CoV-2 infection based on central laboratory–confirmed NAAT result during asymptomatic surveillance period	12	0.014	39	0.015	67.4	(36.4, 84.4)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had serological or virological evidence of past SARS-CoV-2 infection (i.e, N-binding antibody [serum] positive at either Visit 1 or asymptomatic surveillance consent visit, or SARS-CoV-2 positive detected by NAAT [nasal swab] at Visits 1 or 2, or had positive NAAT [nasal swab] at any unscheduled visit) prior to the start of the asymptomatic surveillance period were included in the analysis.
a. N = number of subjects in the specified group.
b. n = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group. Time period for case accrual is from the start of the asymptomatic surveillance period to the end of the surveillance period.
d. Two-sided confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adc19nat Table Generation: 18JUL2023 (22:33)
(Snapshot Date: 28APR2023) Output File: /nda2_unblinded/C4591001_ASYMP_CSR/adc19nat_ve_as_nat_pd1_aai

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14.30. Vaccine Efficacy – Asymptomatic SARS-CoV-2 Infection Based on Central Laboratory–Confirmed NAAT Result – Subjects With Evidence of Infection Prior to the Start of the Asymptomatic Surveillance Period – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=83)		Placebo (N[a]=139)			
Efficacy Endpoint	n[b]	Surveillance Time[c]	n[b]	Surveillance Time[c]	VE (%)	(95% CI[d])
Asymptomatic SARS-CoV-2 infection based on central laboratory–confirmed NAAT result during asymptomatic surveillance period	12	0.014	36	0.014	65.6	(32.3, 83.7)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had serological or virological evidence of past SARS-CoV-2 infection (i.e, N-binding antibody [serum] positive at either Visit 1 or asymptomatic surveillance consent visit, or SARS-CoV-2 positive detected by NAAT [nasal swab] at Visits 1 or 2, or had positive NAAT [nasal swab] at any unscheduled visit) prior to the start of the asymptomatic surveillance period were included in the analysis.
a. N = number of subjects in the specified group.
b. n = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group. Time period for case accrual is from the start of the asymptomatic surveillance period to the end of the surveillance period.
d. Two-sided confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adc19nat Table Generation: 18JUL2023 (22:33)
(Snapshot Date: 28APR2023) Output File: /nda2_unblinded/C4591001_ASYMP_CSR/adc19nat_ve_as_nat_pd2_aai

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14.31. Vaccine Efficacy – Asymptomatic Infection Based on N-Binding Antibody Seroconversion – Subjects Without Evidence of Infection Prior to the First Post–Dose 1 N-Binding Test – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21565)		Placebo (N[a]=21201)			
Efficacy Endpoint	n[b]	Surveillance Time[c]	n[b]	Surveillance Time[c]	VE (%)	(95% CI[d])
Asymptomatic infection based on N-binding antibody seroconversion after Dose 1	680	15.706	681	7.904	49.7	(44.0, 54.9)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding;SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence of past SARS-CoV-2 infection before Dose 1 (ie, negative N-binding antibody [serum] result at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visit 1) and had a negative NAAT (nasal swab) result at any unscheduled visit prior to the first post–Dose 1 N-binding test result were included in the analysis.
a. N = number of subjects in the specified group.
b. n = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group. Time period for case accrual is from Dose 1 to the end of the surveillance period.
d. Two-sided confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adc19asm Table Generation: 18JUL2023 (22:33)
(Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_ASYMP_CSR/adc19asm_ve_as_nig_pd1_aai

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14.32. Vaccine Efficacy – Asymptomatic Infection Based on N-Binding Antibody Seroconversion – Subjects Without Evidence of Infection Prior to the First Post–Dose 2 N-Binding Test – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21376)		Placebo (N[a]=21032)			
Efficacy Endpoint	n[b]	Surveillance Time[c]	n[b]	Surveillance Time[c]	VE (%)	(95% CI[d])
Asymptomatic infection based on N-binding antibody seroconversion after Dose 2	644	14.336	625	6.635	52.3	(46.7, 57.3)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding;SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence of past SARS-CoV-2 infection before Dose 2 (ie, negative N-binding antibody [serum] result at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2) and had a negative NAAT (nasal swab) result at any unscheduled visit prior to the first post–Dose 2 N-binding test result were included in the analysis.
a. N = number of subjects in the specified group.
b. n = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group. Time period for case accrual is from Dose 2 to the end of the surveillance period.
d. Two-sided confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
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Immunogenicity

14.33. Geometric Mean Titers – Phase 3 – BNT162b2-Experienced Subjects Without Evidence of Infection up to 1 Month After Booster Dose Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Dose 3 Booster Evaluable Immunogenicity Population

Assay	Dose/ Sampling Time Point[a]	Vaccine Group (as Randomized)							
		BNT162b2 (5 µg)				BNT162b2 (10 µg)			
		18-55 Years		>55 Years		18-55 Years		>55 Years	
		n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
SARS-CoV-2 neutralization assay - reference strain - NT50 (titer)	3/Prevax	24	100.3 (64.9, 155.1)	47	88.6 (69.1, 113.5)	24	88.4 (65.6, 119.1)	48	83.2 (66.9, 103.3)
	3/1 Month	24	905.7 (689.7, 1189.4)	47	978.8 (790.9, 1211.3)	24	980.3 (749.6, 1282.1)	48	1030.6 (830.3, 1279.2)

Abbreviations: GMT = geometric mean titer; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; Prevax = prevaccination; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (up to 1 month after receipt of the booster vaccination) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Dose 1 visit, 1-month post–Dose 2 visit, booster dose visit, 1-month post–booster visit and SARS-CoV-2 not detected by NAAT [nasal swab] at Dose 1 visit, Dose 2 visit, booster dose visit) and had a negative NAAT (nasal swab) at any unscheduled visit up to 1 month after booster vaccination were included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
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(Data Cutoff Date: 22NOV2021, Database Snapshot Date: 10DEC2021) Output File: ./nda3_unblinded/C4591001_G4_IMM/adva_s001_gm_g4_6mcf_evl

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14.34. Geometric Mean Titers – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Dose 3 Booster Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (5 µg)				BNT162b2 (10 µg)			
		18-55 Years		>55 Years		18-55 Years		>55 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
SARS-CoV-2 neutralization assay - reference strain - NT50 (titer)	3/Prevax	26	98.2 (65.6, 146.9)	51	91.2 (69.5, 119.8)	24	88.4 (65.6, 119.1)	50	91.6 (70.5, 119.0)
	3/1 Month	26	902.0 (695.9, 1169.1)	51	1013.9 (828.2, 1241.1)	24	980.3 (749.6, 1282.1)	50	1066.4 (860.2, 1322.1)

Abbreviations: GMT = geometric mean titer; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; Prevax = prevaccination; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
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14.35. Geometric Mean Titers – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Dose 3 Booster All-Available Immunogenicity Population

Assay	Dose/ Sampling Time Point[a]	Vaccine Group (as Randomized)							
		BNT162b2 (5 µg)				BNT162b2 (10 µg)			
		18-55 Years		>55 Years		18-55 Years		>55 Years	
		n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
SARS-CoV-2 neutralization assay - reference strain - NT50 (titer)	3/Prevax	26	98.2 (65.6, 146.9)	53	89.2 (68.3, 116.7)	25	83.4 (61.2, 113.6)	51	91.9 (71.1, 118.9)
	3/1 Month	26	902.0 (695.9, 1169.1)	53	992.3 (812.5, 1211.9)	25	938.7 (715.2, 1232.1)	51	1047.7 (846.2, 1297.0)

Abbreviations: GMT = geometric mean titer; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; Prevax = prevaccination; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 16FEB2022 (11:21) Source Data: adva Table Generation: 17FEB2022 (20:53)
(Data Cutoff Date: 22NOV2021, Database Snapshot Date: 10DEC2021) Output File: ./nda3_unblinded/C4591001_G4_IMM/adva_s001_gm_g4_6m_aai

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14.36. Geometric Mean Fold Rise From Before Booster Dose to Each Subsequent Time Point – Phase 3 – BNT162b2-Experienced Subjects Without Evidence of Infection up to 1 Month After Booster Dose Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Dose 3 Booster Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (5 µg)				BNT162b2 (10 µg)			
		18-55 Years		>55 Years		18-55 Years		>55 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - reference strain - NT50 (titer)	3/1 Month	24	9.0 (6.0, 13.6)	47	11.0 (8.4, 14.6)	24	11.1 (8.2, 15.0)	48	12.4 (9.2, 16.7)

Abbreviations: GMFR = geometric mean fold rise; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (up to 1 month after receipt of the booster vaccination) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Dose 1 visit, 1-month post–Dose 2 visit, booster dose visit, 1-month post–booster visit and SARS-CoV-2 not detected by NAAT [nasal swab] at Dose 1 visit, Dose 2 visit, booster dose visit) and had a negative NAAT (nasal swab) at any unscheduled visit up to 1 month after booster vaccination were included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination time point and the given dose/sampling time point.
c. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 16FEB2022 (11:21) Source Data: adva Table Generation: 17FEB2022 (20:53)
(Data Cutoff Date: 22NOV2021, Database Snapshot Date: 10DEC2021) Output File: ./nda3_unblinded/C4591001_G4_IMM/adva_s002_gmfr_g4_6mcf_evl

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14.37. Geometric Mean Fold Rise From Before Booster Dose to Each Subsequent Time Point – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Dose 3 Booster Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (5 µg)				BNT162b2 (10 µg)			
		18-55 Years		>55 Years		18-55 Years		>55 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - reference strain - NT50 (titer)	3/1 Month	26	9.2 (6.3, 13.4)	51	11.1 (8.4, 14.7)	24	11.1 (8.2, 15.0)	50	11.6 (8.6, 15.7)

Abbreviations: GMFR = geometric mean fold rise; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination time point and the given dose/sampling time point.
c. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 16FEB2022 (11:21) Source Data: adva Table Generation: 17FEB2022 (20:53)
(Data Cutoff Date: 22NOV2021, Database Snapshot Date: 10DEC2021) Output File: ./nda3_unblinded/C4591001_G4_IMM/adva_s002_gmfr_g4_6m_evl

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14.38. Geometric Mean Fold Rise From Before Booster Dose to Each Subsequent Time Point – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Dose 3 Booster All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (5 µg)				BNT162b2 (10 µg)			
		18-55 Years		>55 Years		18-55 Years		>55 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - reference strain - NT50 (titer)	3/1 Month	26	9.2 (6.3, 13.4)	53	11.1 (8.5, 14.6)	25	11.3 (8.4, 15.1)	51	11.4 (8.5, 15.4)

Abbreviations: GMFR = geometric mean fold rise; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination time point and the given dose/sampling time point.
c. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 16FEB2022 (11:21) Source Data: adva Table Generation: 17FEB2022 (20:53)
(Data Cutoff Date: 22NOV2021, Database Snapshot Date: 10DEC2021) Output File: ./nda3_unblinded/C4591001_G4_IMM/adva_s002_gmfr_g4_6m_aai

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Adverse Events Phase 1

14.39. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b1 or BNT162b2) to 6 Months After Dose 2 (BNT162b1 or BNT162b2), by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 1 – Safety Population

	Vaccine Group (as Administered)																	
	Original BNT162b1 10 µg (N[a]=24)		Original BNT162b1 20 µg (N[a]=24)		Original BNT162b1 30 µg (N[a]=24)		Original BNT162b1 100 µg (N[a]=12)		Original BNT162b2 10 µg (N[a]=24)		Original BNT162b2 20 µg (N[a]=24)		Original BNT162b2 30 µg (N[a]=24)		Original Placebo/BNT162b2 30 µg (N[a]=35)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 26.5)	0	(0.0, 14.2)	1 (4.2)	(0.1, 21.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 10.0)
INFECTIONS AND INFESTATIONS	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 26.5)	0	(0.0, 14.2)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 10.0)
Appendicitis	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 26.5)	0	(0.0, 14.2)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 10.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 26.5)	0	(0.0, 14.2)	0	(0.0, 14.2)	1 (4.2)	(0.1, 21.1)	0	(0.0, 10.0)
Neuritis	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 26.5)	0	(0.0, 14.2)	0	(0.0, 14.2)	1 (4.2)	(0.1, 21.1)	0	(0.0, 10.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:05)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p1_d2b

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14.40. Number (%) of Subjects Reporting at Least 1 Adverse Event From the First Booster Dose to 1 Month After the First Booster Dose, by System Organ Class and Preferred Term – Phase 1 – Subjects Who Received the First Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Initial Vaccine Group (as Administered)															
	BNT162b1								BNT162b2							
	10 µg (N[a]=21)		20 µg (N[a]=24)		30 µg (N[a]=24)		100 µg (N[a]=9)		10 µg (N[a]=22)		20 µg (N[a]=23)		30 µg (N[a]=24)		Placebo (N[a]=28)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	2 (9.5)	(1.2, 30.4)	5 (20.8)	(7.1, 42.2)	4 (16.7)	(4.7, 37.4)	1 (11.1)	(0.3, 48.2)	3 (13.6)	(2.9, 34.9)	1 (4.3)	(0.1, 21.9)	1 (4.2)	(0.1, 21.1)	0	(0.0, 12.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 16.1)	1 (4.2)	(0.1, 21.1)	2 (8.3)	(1.0, 27.0)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Lymphadenopathy	0	(0.0, 16.1)	1 (4.2)	(0.1, 21.1)	2 (8.3)	(1.0, 27.0)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
GASTROINTESTINAL DISORDERS	0	(0.0, 16.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	1 (11.1)	(0.3, 48.2)	0	(0.0, 15.4)	0	(0.0, 14.8)	1 (4.2)	(0.1, 21.1)	0	(0.0, 12.3)
Abdominal pain	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	1 (4.2)	(0.1, 21.1)	0	(0.0, 12.3)
Colitis	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	1 (11.1)	(0.3, 48.2)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Diarrhoea	0	(0.0, 16.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (4.8)	(0.1, 23.8)	1 (4.2)	(0.1, 21.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 33.6)	2 (9.1)	(1.1, 29.2)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Fatigue	1 (4.8)	(0.1, 23.8)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Axillary pain	0	(0.0, 16.1)	0	(0.0, 14.2)	1 (4.2)	(0.1, 21.1)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Chills	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Injection site haemorrhage	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)

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14.40. Number (%) of Subjects Reporting at Least 1 Adverse Event From the First Booster Dose to 1 Month After the First Booster Dose, by System Organ Class and Preferred Term – Phase 1 – Subjects Who Received the First Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Initial Vaccine Group (as Administered)															
	BNT162b1								BNT162b2							
	10 µg (N[a]=21)		20 µg (N[a]=24)		30 µg (N[a]=24)		100 µg (N[a]=9)		10 µg (N[a]=22)		20 µg (N[a]=23)		30 µg (N[a]=24)		Placebo (N[a]=28)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INFECTIONS AND INFESTATIONS	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Urinary tract infection	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (4.8)	(0.1, 23.8)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Exposure during pregnancy	1 (4.8)	(0.1, 23.8)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 16.1)	3 (12.5)	(2.7, 32.4)	0	(0.0, 14.2)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	1 (4.2)	(0.1, 21.1)	0	(0.0, 12.3)
Myalgia	0	(0.0, 16.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Osteoarthritis	0	(0.0, 16.1)	2 (8.3)	(1.0, 27.0)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Diastasis recti abdominis	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	1 (4.2)	(0.1, 21.1)	0	(0.0, 12.3)
Muscle spasms	0	(0.0, 16.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
NERVOUS SYSTEM DISORDERS	1 (4.8)	(0.1, 23.8)	1 (4.2)	(0.1, 21.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 33.6)	2 (9.1)	(1.1, 29.2)	1 (4.3)	(0.1, 21.9)	0	(0.0, 14.2)	0	(0.0, 12.3)
Dizziness	1 (4.8)	(0.1, 23.8)	0	(0.0, 14.2)	1 (4.2)	(0.1, 21.1)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Headache	0	(0.0, 16.1)	0	(0.0, 14.2)	1 (4.2)	(0.1, 21.1)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Paraesthesia	0	(0.0, 16.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)

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14.40. Number (%) of Subjects Reporting at Least 1 Adverse Event From the First Booster Dose to 1 Month After the First Booster Dose, by System Organ Class and Preferred Term – Phase 1 – Subjects Who Received the First Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Initial Vaccine Group (as Administered)															
	BNT162b1								BNT162b2							
	10 µg (N[a]=21)		20 µg (N[a]=24)		30 µg (N[a]=24)		100 µg (N[a]=9)		10 µg (N[a]=22)		20 µg (N[a]=23)		30 µg (N[a]=24)		Placebo (N[a]=28)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Presyncope	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	1 (4.3)	(0.1, 21.9)	0	(0.0, 14.2)	0	(0.0, 12.3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	1 (4.3)	(0.1, 21.9)	0	(0.0, 14.2)	0	(0.0, 12.3)
Upper-airway cough syndrome	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	1 (4.3)	(0.1, 21.9)	0	(0.0, 14.2)	0	(0.0, 12.3)
VASCULAR DISORDERS	0	(0.0, 16.1)	2 (8.3)	(1.0, 27.0)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Deep vein thrombosis	0	(0.0, 16.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Superficial vein thrombosis	0	(0.0, 16.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:03)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_p1_d3

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14.41. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From the First Booster Dose to 1 Month After the First Booster Dose, by System Organ Class and Preferred Term – Phase 1 – Subjects Who Received the First Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Initial Vaccine Group (as Administered)															
	BNT162b1								BNT162b2							
	10 µg (N[a]=21)		20 µg (N[a]=24)		30 µg (N[a]=24)		100 µg (N[a]=9)		10 µg (N[a]=22)		20 µg (N[a]=23)		30 µg (N[a]=24)		Placebo (N[a]=28)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	1 (4.8)	(0.1, 23.8)	1 (4.2)	(0.1, 21.1)	3 (12.5)	(2.7, 32.4)	0	(0.0, 33.6)	3 (13.6)	(2.9, 34.9)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 16.1)	0	(0.0, 14.2)	2 (8.3)	(1.0, 27.0)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Lymphadenopathy	0	(0.0, 16.1)	0	(0.0, 14.2)	2 (8.3)	(1.0, 27.0)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
GASTROINTESTINAL DISORDERS	0	(0.0, 16.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Diarrhoea	0	(0.0, 16.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (4.8)	(0.1, 23.8)	1 (4.2)	(0.1, 21.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 33.6)	2 (9.1)	(1.1, 29.2)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Fatigue	1 (4.8)	(0.1, 23.8)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Axillary pain	0	(0.0, 16.1)	0	(0.0, 14.2)	1 (4.2)	(0.1, 21.1)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Chills	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Injection site haemorrhage	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 16.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Myalgia	0	(0.0, 16.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Muscle spasms	0	(0.0, 16.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)

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14.41. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From the First Booster Dose to 1 Month After the First Booster Dose, by System Organ Class and Preferred Term – Phase 1 – Subjects Who Received the First Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Initial Vaccine Group (as Administered)															
	BNT162b1								BNT162b2							
	10 µg (N[a]=21)		20 µg (N[a]=24)		30 µg (N[a]=24)		100 µg (N[a]=9)		10 µg (N[a]=22)		20 µg (N[a]=23)		30 µg (N[a]=24)		Placebo (N[a]=28)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
NERVOUS SYSTEM DISORDERS	0	(0.0, 16.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 33.6)	2 (9.1)	(1.1, 29.2)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Paraesthesia	0	(0.0, 16.1)	1 (4.2)	(0.1, 21.1)	0	(0.0, 14.2)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Headache	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.42. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After the First Booster Dose, by System Organ Class and Preferred Term – Phase 1 – Subjects Who Received the First Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Initial Vaccine Group (as Administered)															
	BNT162b1								BNT162b2							
	10 µg (N[a]=21)		20 µg (N[a]=24)		30 µg (N[a]=24)		100 µg (N[a]=9)		10 µg (N[a]=22)		20 µg (N[a]=23)		30 µg (N[a]=24)		Placebo (N[a]=28)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Injection site haemorrhage	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	0	(0.0, 33.6)	1 (4.5)	(0.1, 22.8)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.43. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From the First Booster Dose to 1 Month After the First Booster Dose, by System Organ Class and Preferred Term – Phase 1 – Subjects Who Received the First Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Initial Vaccine Group (as Administered)															
	BNT162b1								BNT162b2							
	10 µg (N[a]=21)		20 µg (N[a]=24)		30 µg (N[a]=24)		100 µg (N[a]=9)		10 µg (N[a]=22)		20 µg (N[a]=23)		30 µg (N[a]=24)		Placebo (N[a]=28)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	0	(0.0, 16.1)	0	(0.0, 14.2)	2 (8.3)	(1.0, 27.0)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 16.1)	0	(0.0, 14.2)	1 (4.2)	(0.1, 21.1)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Axillary pain	0	(0.0, 16.1)	0	(0.0, 14.2)	1 (4.2)	(0.1, 21.1)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
NERVOUS SYSTEM DISORDERS	0	(0.0, 16.1)	0	(0.0, 14.2)	1 (4.2)	(0.1, 21.1)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Headache	0	(0.0, 16.1)	0	(0.0, 14.2)	1 (4.2)	(0.1, 21.1)	0	(0.0, 33.6)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.44. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From the First Booster Dose to 1 Month After the First Booster Dose, by System Organ Class and Preferred Term – Phase 1 – Subjects Who Received the First Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Initial Vaccine Group (as Administered)															
	BNT162b1								BNT162b2							
	10 µg (N[a]=21)		20 µg (N[a]=24)		30 µg (N[a]=24)		100 µg (N[a]=9)		10 µg (N[a]=22)		20 µg (N[a]=23)		30 µg (N[a]=24)		Placebo (N[a]=28)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	1 (11.1)	(0.3, 48.2)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
GASTROINTESTINAL DISORDERS	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	1 (11.1)	(0.3, 48.2)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Colitis	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	1 (11.1)	(0.3, 48.2)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.45. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From the First Booster Dose to 1 Month After the First Booster Dose, by System Organ Class and Preferred Term – Phase 1 – Subjects Who Received the First Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Initial Vaccine Group (as Administered)															
	BNT162b1								BNT162b2							
	10 µg (N[a]=21)		20 µg (N[a]=24)		30 µg (N[a]=24)		100 µg (N[a]=9)		10 µg (N[a]=22)		20 µg (N[a]=23)		30 µg (N[a]=24)		Placebo (N[a]=28)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	1 (11.1)	(0.3, 48.2)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
GASTROINTESTINAL DISORDERS	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	1 (11.1)	(0.3, 48.2)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)
Colitis	0	(0.0, 16.1)	0	(0.0, 14.2)	0	(0.0, 14.2)	1 (11.1)	(0.3, 48.2)	0	(0.0, 15.4)	0	(0.0, 14.8)	0	(0.0, 14.2)	0	(0.0, 12.3)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.46. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From the Additional Booster Dose to 1 Month After the Additional Booster Dose, by System Organ Class and Preferred Term – Phase 1 – Subjects Who Received the Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=80) n[b] (%)	(95% CI[c])
Any adverse event	3 (3.8)	(0.8, 10.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (1.3)	(0.0, 6.8)
Injection site pain	1 (1.3)	(0.0, 6.8)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (2.5)	(0.3, 8.7)
Myalgia	1 (1.3)	(0.0, 6.8)
Pain in extremity	1 (1.3)	(0.0, 6.8)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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Adverse Events Phase 2/3

14.47. Local Reactions, by Maximum Severity, Within 7 Days After Booster Dose – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)											
	BNT162b2 (5 µg)						BNT162b2 (10 µg)					
	18-55 Years			>55 Years			18-55 Years			>55 Years		
Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Redness[d]												
Any	25	0	(0.0, 13.7)	52	1 (1.9)	(0.0, 10.3)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Mild	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Moderate	25	0	(0.0, 13.7)	52	1 (1.9)	(0.0, 10.3)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Severe	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Grade 4	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Swelling[d]												
Any	25	0	(0.0, 13.7)	52	1 (1.9)	(0.0, 10.3)	25	0	(0.0, 13.7)	51	3 (5.9)	(1.2, 16.2)
Mild	25	0	(0.0, 13.7)	52	1 (1.9)	(0.0, 10.3)	25	0	(0.0, 13.7)	51	2 (3.9)	(0.5, 13.5)
Moderate	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	1 (2.0)	(0.0, 10.4)
Severe	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Grade 4	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Pain at the injection site[e]												
Any	25	14 (56.0)	(34.9, 75.6)	52	19 (36.5)	(23.6, 51.0)	25	15 (60.0)	(38.7, 78.9)	51	37 (72.5)	(58.3, 84.1)
Mild	25	14 (56.0)	(34.9, 75.6)	52	18 (34.6)	(22.0, 49.1)	25	12 (48.0)	(27.8, 68.7)	51	34 (66.7)	(52.1, 79.2)
Moderate	25	0	(0.0, 13.7)	52	1 (1.9)	(0.0, 10.3)	25	3 (12.0)	(2.5, 31.2)	51	3 (5.9)	(1.2, 16.2)
Severe	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Grade 4	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Any local reaction[f]	25	14 (56.0)	(34.9, 75.6)	52	19 (36.5)	(23.6, 51.0)	25	15 (60.0)	(38.7, 78.9)	51	38 (74.5)	(60.4, 85.7)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 through Day 7 after the booster dose.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
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14.48. Onset Days for Local Reactions – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
Local Reaction	**18-55 Years**	**>55 Years**	**18-55 Years**	**>55 Years**
Redness				
n[a]	0	1	0	0
Mean (SD)	NE (NE)	1.0 (NE)	NE (NE)	NE (NE)
Median	NE	1.0	NE	NE
Min, max	(NE, NE)	(1, 1)	(NE, NE)	(NE, NE)
Swelling				
n[a]	0	1	0	3
Mean (SD)	NE (NE)	2.0 (NE)	NE (NE)	1.3 (0.58)
Median	NE	2.0	NE	1.0
Min, max	(NE, NE)	(2, 2)	(NE, NE)	(1, 2)
Pain at the injection site				
n[a]	14	19	15	37
Mean (SD)	1.6 (0.94)	1.8 (0.90)	1.9 (0.99)	1.7 (0.57)
Median	1.0	2.0	2.0	2.0
Min, max	(1, 4)	(1, 5)	(1, 4)	(1, 3)
Any local reaction[b]				
n[a]	14	19	15	38
Mean (SD)	1.6 (0.94)	1.8 (0.90)	1.9 (0.99)	1.7 (0.58)
Median	1.0	2.0	2.0	2.0
Min, max	(1, 4)	(1, 5)	(1, 4)	(1, 3)

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified reaction was reported.
a. n = Number of subjects reporting the specified reaction, with each subject counted only once per reaction.
b. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 13DEC2021 (22:49) Source Data: adfacevd Table Generation: 13JAN2022 (22:02)
(Data Cutoff Date: 22NOV2021, Database Snapshot Date: 10DEC2021) Output File: ./nda2_unblinded/C4591001_G4_LD/adce_s050_g4_6m

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14.49. Duration (Days) From First to Last Day of Local Reactions – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
Local Reaction	**18-55 Years**	**>55 Years**	**18-55 Years**	**>55 Years**
Redness				
n[a]	0	1	0	0
Mean (SD)	NE (NE)	4.0 (NE)	NE (NE)	NE (NE)
Median	NE	4.0	NE	NE
Min, max	(NE, NE)	(4, 4)	(NE, NE)	(NE, NE)
Swelling				
n[a]	0	1	0	3
Mean (SD)	NE (NE)	2.0 (NE)	NE (NE)	1.3 (0.58)
Median	NE	2.0	NE	1.0
Min, max	(NE, NE)	(2, 2)	(NE, NE)	(1, 2)
Pain at the injection site				
n[a]	14	19	15	37
Mean (SD)	2.3 (0.99)	2.4 (1.86)	2.3 (1.54)	2.3 (1.54)
Median	2.0	2.0	2.0	2.0
Min, max	(1, 4)	(1, 9)	(1, 6)	(1, 8)

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported reaction to the resolution of the last reported reaction, inclusive.
Note: Reactions were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after the booster dose. The resolution date for reactions lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified reaction on any of the 7 days, including subjects with reactions of unknown duration.
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14.50. Systemic Events, by Maximum Severity, Within 7 Days After Booster Dose – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)											
	BNT162b2 (5 µg)						BNT162b2 (10 µg)					
	18-55 Years			>55 Years			18-55 Years			>55 Years		
Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Fever												
≥38.0°C	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	1 (4.0)	(0.1, 20.4)	51	1 (2.0)	(0.0, 10.4)
≥38.0°C to 38.4°C	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	1 (4.0)	(0.1, 20.4)	51	0	(0.0, 7.0)
>38.4°C to 38.9°C	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
>38.9°C to 40.0°C	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	1 (2.0)	(0.0, 10.4)
>40.0°C	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Fatigue[d]												
Any	25	11 (44.0)	(24.4, 65.1)	52	14 (26.9)	(15.6, 41.0)	25	15 (60.0)	(38.7, 78.9)	51	26 (51.0)	(36.6, 65.2)
Mild	25	5 (20.0)	(6.8, 40.7)	52	8 (15.4)	(6.9, 28.1)	25	8 (32.0)	(14.9, 53.5)	51	15 (29.4)	(17.5, 43.8)
Moderate	25	6 (24.0)	(9.4, 45.1)	52	5 (9.6)	(3.2, 21.0)	25	6 (24.0)	(9.4, 45.1)	51	10 (19.6)	(9.8, 33.1)
Severe	25	0	(0.0, 13.7)	52	1 (1.9)	(0.0, 10.3)	25	1 (4.0)	(0.1, 20.4)	51	1 (2.0)	(0.0, 10.4)
Grade 4	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Headache[d]												
Any	25	6 (24.0)	(9.4, 45.1)	52	12 (23.1)	(12.5, 36.8)	25	10 (40.0)	(21.1, 61.3)	51	19 (37.3)	(24.1, 51.9)
Mild	25	5 (20.0)	(6.8, 40.7)	52	8 (15.4)	(6.9, 28.1)	25	5 (20.0)	(6.8, 40.7)	51	12 (23.5)	(12.8, 37.5)
Moderate	25	1 (4.0)	(0.1, 20.4)	52	4 (7.7)	(2.1, 18.5)	25	4 (16.0)	(4.5, 36.1)	51	7 (13.7)	(5.7, 26.3)
Severe	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	1 (4.0)	(0.1, 20.4)	51	0	(0.0, 7.0)
Grade 4	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Chills[d]												
Any	25	2 (8.0)	(1.0, 26.0)	52	6 (11.5)	(4.4, 23.4)	25	6 (24.0)	(9.4, 45.1)	51	11 (21.6)	(11.3, 35.3)
Mild	25	2 (8.0)	(1.0, 26.0)	52	5 (9.6)	(3.2, 21.0)	25	3 (12.0)	(2.5, 31.2)	51	7 (13.7)	(5.7, 26.3)
Moderate	25	0	(0.0, 13.7)	52	1 (1.9)	(0.0, 10.3)	25	3 (12.0)	(2.5, 31.2)	51	4 (7.8)	(2.2, 18.9)
Severe	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Grade 4	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Vomiting[e]												
Any	25	0	(0.0, 13.7)	52	2 (3.8)	(0.5, 13.2)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Mild	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Moderate	25	0	(0.0, 13.7)	52	2 (3.8)	(0.5, 13.2)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Severe	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Grade 4	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Diarrhea[f]												
Any	25	2 (8.0)	(1.0, 26.0)	52	2 (3.8)	(0.5, 13.2)	25	4 (16.0)	(4.5, 36.1)	51	1 (2.0)	(0.0, 10.4)
Mild	25	2 (8.0)	(1.0, 26.0)	52	0	(0.0, 6.8)	25	4 (16.0)	(4.5, 36.1)	51	1 (2.0)	(0.0, 10.4)

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14.50. Systemic Events, by Maximum Severity, Within 7 Days After Booster Dose – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)											
	BNT162b2 (5 µg)						BNT162b2 (10 µg)					
	18-55 Years			>55 Years			18-55 Years			>55 Years		
Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Moderate	25	0	(0.0, 13.7)	52	2 (3.8)	(0.5, 13.2)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Severe	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Grade 4	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
New or worsened muscle pain[d]												
Any	25	6 (24.0)	(9.4, 45.1)	52	7 (13.5)	(5.6, 25.8)	25	7 (28.0)	(12.1, 49.4)	51	7 (13.7)	(5.7, 26.3)
Mild	25	6 (24.0)	(9.4, 45.1)	52	6 (11.5)	(4.4, 23.4)	25	4 (16.0)	(4.5, 36.1)	51	3 (5.9)	(1.2, 16.2)
Moderate	25	0	(0.0, 13.7)	52	1 (1.9)	(0.0, 10.3)	25	3 (12.0)	(2.5, 31.2)	51	4 (7.8)	(2.2, 18.9)
Severe	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Grade 4	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
New or worsened joint pain[d]												
Any	25	1 (4.0)	(0.1, 20.4)	52	0	(0.0, 6.8)	25	5 (20.0)	(6.8, 40.7)	51	7 (13.7)	(5.7, 26.3)
Mild	25	1 (4.0)	(0.1, 20.4)	52	0	(0.0, 6.8)	25	2 (8.0)	(1.0, 26.0)	51	4 (7.8)	(2.2, 18.9)
Moderate	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	3 (12.0)	(2.5, 31.2)	51	3 (5.9)	(1.2, 16.2)
Severe	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Grade 4	25	0	(0.0, 13.7)	52	0	(0.0, 6.8)	25	0	(0.0, 13.7)	51	0	(0.0, 7.0)
Any systemic event[g]	25	16 (64.0)	(42.5, 82.0)	52	18 (34.6)	(22.0, 49.1)	25	18 (72.0)	(50.6, 87.9)	51	32 (62.7)	(48.1, 75.9)
Use of antipyretic or pain medication[h]	25	4 (16.0)	(4.5, 36.1)	52	8 (15.4)	(6.9, 28.1)	25	7 (28.0)	(12.1, 49.4)	51	12 (23.5)	(12.8, 37.5)

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14.50. Systemic Events, by Maximum Severity, Within 7 Days After Booster Dose – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)											
	BNT162b2 (5 µg)						BNT162b2 (10 µg)					
	18-55 Years			>55 Years			18-55 Years			>55 Years		
Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 through Day 7 after the booster dose.
Note: Grade 4 events were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe chills, severe muscle pain, or severe joint pain.
e. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
f. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
g. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
h. Severity was not collected for use of antipyretic or pain medication.
PFIZER CONFIDENTIAL SDTM Creation: 13DEC2021 (22:49) Source Data: adfacevd Table Generation: 16JAN2022 (21:42)
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14.51. Onset Days for Systemic Events – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
Systemic Event	18-55 Years	>55 Years	18-55 Years	>55 Years
Fever (≥38.0°C)				
n[a]	0	0	1	1
Mean (SD)	NE (NE)	NE (NE)	2.0 (NE)	2.0 (NE)
Median	NE	NE	2.0	2.0
Min, max	(NE, NE)	(NE, NE)	(2, 2)	(2, 2)
Fatigue				
n[a]	11	14	15	26
Mean (SD)	1.9 (0.94)	2.4 (1.65)	2.1 (1.03)	2.1 (1.13)
Median	2.0	2.0	2.0	2.0
Min, max	(1, 4)	(1, 7)	(1, 4)	(1, 5)
Headache				
n[a]	6	12	10	19
Mean (SD)	2.5 (1.76)	2.0 (0.85)	2.3 (1.49)	1.8 (0.50)
Median	2.0	2.0	2.0	2.0
Min, max	(1, 6)	(1, 4)	(1, 6)	(1, 3)
Chills				
n[a]	2	6	6	11
Mean (SD)	1.0 (0.00)	3.0 (1.26)	2.0 (0.63)	2.1 (0.54)
Median	1.0	2.5	2.0	2.0
Min, max	(1, 1)	(2, 5)	(1, 3)	(1, 3)
Vomiting				
n[a]	0	2	0	0
Mean (SD)	NE (NE)	3.5 (0.71)	NE (NE)	NE (NE)
Median	NE	3.5	NE	NE
Min, max	(NE, NE)	(3, 4)	(NE, NE)	(NE, NE)
Diarrhea				
n[a]	2	2	4	1
Mean (SD)	2.0 (1.41)	5.5 (0.71)	4.3 (2.50)	3.0 (NE)
Median	2.0	5.5	4.5	3.0
Min, max	(1, 3)	(5, 6)	(1, 7)	(3, 3)
New or worsened muscle pain				
n[a]	6	7	7	7
Mean (SD)	2.0 (0.00)	2.1 (0.90)	2.0 (0.58)	2.3 (0.95)
Median	2.0	2.0	2.0	2.0
Min, max	(2, 2)	(1, 4)	(1, 3)	(1, 4)
New or worsened joint pain				

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14.51. Onset Days for Systemic Events – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
Systemic Event	**18-55 Years**	**>55 Years**	**18-55 Years**	**>55 Years**
n[a]	1	0	5	7
Mean (SD)	2.0 (NE)	NE (NE)	1.8 (0.45)	2.7 (1.11)
Median	2.0	NE	2.0	2.0
Min, max	(2, 2)	(NE, NE)	(1, 2)	(2, 5)
Any systemic event[b]				
n[a]	16	18	18	32
Mean (SD)	2.1 (1.34)	2.1 (1.02)	1.9 (1.02)	2.1 (1.19)
Median	2.0	2.0	2.0	2.0
Min, max	(1, 6)	(1, 5)	(1, 4)	(1, 5)
Use of antipyretic or pain medication				
n[a]	4	8	7	12
Mean (SD)	3.5 (1.91)	2.4 (1.19)	2.6 (1.40)	2.5 (1.45)
Median	3.0	2.0	2.0	2.0
Min, max	(2, 6)	(1, 5)	(1, 5)	(1, 5)

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified event was reported.
a. n = Number of subjects reporting the specified event, with each subject counted only once per event.
b. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
PFIZER CONFIDENTIAL SDTM Creation: 13DEC2021 (22:49) Source Data: adfacevd Table Generation: 13JAN2022 (22:02)
(Data Cutoff Date: 22NOV2021, Database Snapshot Date: 10DEC2021) Output File: ./nda2_unblinded/C4591001_G4_KD/adce_s060_g4_6m

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14.52. Duration (Days) From First to Last Day of Systemic Events – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
Systemic Event	18-55 Years	>55 Years	18-55 Years	>55 Years
Fever (≥38.0°C)				
n[a]	0	0	1	1
Mean (SD)	NE (NE)	NE (NE)	1.0 (NE)	2.0 (NE)
Median	NE	NE	1.0	2.0
Min, max	(NE, NE)	(NE, NE)	(1, 1)	(2, 2)
Fatigue				
n[a]	11	14	15	26
Mean (SD)	2.3 (2.00)	3.4 (5.09)	2.3 (2.19)	2.7 (2.23)
Median	1.0	1.5	1.0	2.0
Min, max	(1, 7)	(1, 20)	(1, 7)	(1, 8)
Headache				
n[a]	6	12	10	19
Mean (SD)	2.7 (1.86)	3.8 (5.32)	2.0 (1.15)	1.9 (1.15)
Median	2.0	2.0	1.5	2.0
Min, max	(1, 5)	(1, 20)	(1, 4)	(1, 5)
Chills				
n[a]	2	6	6	11
Mean (SD)	1.5 (0.71)	1.0 (0.00)	1.5 (0.84)	1.8 (1.83)
Median	1.5	1.0	1.0	1.0
Min, max	(1, 2)	(1, 1)	(1, 3)	(1, 7)
Vomiting				
n[a]	0	2	0	0
Mean (SD)	NE (NE)	3.5 (2.12)	NE (NE)	NE (NE)
Median	NE	3.5	NE	NE
Min, max	(NE, NE)	(2, 5)	(NE, NE)	(NE, NE)
Diarrhea				
n[a]	2	2	4	1
Mean (SD)	1.0 (0.00)	1.0 (0.00)	1.3 (0.50)	1.0 (NE)
Median	1.0	1.0	1.0	1.0
Min, max	(1, 1)	(1, 1)	(1, 2)	(1, 1)
New or worsened muscle pain				
n[a]	6	7	7	7
Mean (SD)	1.3 (0.52)	1.4 (0.79)	1.7 (0.49)	1.6 (0.79)
Median	1.0	1.0	2.0	1.0
Min, max	(1, 2)	(1, 3)	(1, 2)	(1, 3)
New or worsened joint pain				

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14.52. Duration (Days) From First to Last Day of Systemic Events – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (5 µg)		BNT162b2 (10 µg)	
Systemic Event	**18-55 Years**	**>55 Years**	**18-55 Years**	**>55 Years**
n[a]	1	0	5	7
Mean (SD)	4.0 (NE)	NE (NE)	1.4 (0.55)	1.1 (0.38)
Median	4.0	NE	1.0	1.0
Min, max	(4, 4)	(NE, NE)	(1, 2)	(1, 2)
Use of antipyretic or pain medication				
n[a]	4	8	7	12
Mean (SD)	1.0 (0.00)	2.0 (1.85)	1.4 (0.53)	2.0 (1.76)
Median	1.0	1.0	1.0	1.0
Min, max	(1, 1)	(1, 5)	(1, 2)	(1, 7)

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported event to the resolution of the last reported event, inclusive.
Note: Events and use of antipyretic or pain medication were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after the booster dose. The resolution date for events lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified event on any of the 7 days, including subjects with events of unknown duration.
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14.53. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects 12 Through 15 Years of Age (Subjects Who Originally Received Placebo) – Safety Population

	Vaccine Group (as Administered)	
	Placebo (N[a]=1129)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any adverse event	2 (0.2)	(0.0, 0.6)
INFECTIONS AND INFESTATIONS	2 (0.2)	(0.0, 0.6)
Appendicitis	2 (0.2)	(0.0, 0.6)
Focal peritonitis	1 (0.1)	(0.0, 0.5)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:03)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2p_12

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14.54. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=1131)		Original Placebo/BNT162b2 (30 µg) (N[a]=1014)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	13 (1.1)	(0.6, 2.0)	13 (1.3)	(0.7, 2.2)
CARDIAC DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Myopericarditis	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.4)
Syringomyelia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.4)
GASTROINTESTINAL DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.4)
Abdominal pain	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.4)
Constipation	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.4)
INFECTIONS AND INFESTATIONS	2 (0.2)	(0.0, 0.6)	3 (0.3)	(0.1, 0.9)
Appendicitis	1 (0.1)	(0.0, 0.5)	2 (0.2)	(0.0, 0.7)
Anal abscess	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.4)
Toxic shock syndrome	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.1)	(0.0, 0.5)	3 (0.3)	(0.1, 0.9)
Femur fracture	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.4)
Radius fracture	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Traumatic renal injury	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Ulna fracture	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Upper limb fracture	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.7)
Epilepsy	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Somnolence	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
PSYCHIATRIC DISORDERS	9 (0.8)	(0.4, 1.5)	4 (0.4)	(0.1, 1.0)
Suicidal ideation	4 (0.4)	(0.1, 0.9)	1 (0.1)	(0.0, 0.5)
Depression	3 (0.3)	(0.1, 0.8)	0	(0.0, 0.4)
Suicide attempt	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Anorexia nervosa	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Anxiety	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.4)
Conversion disorder	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.4)
Major depression	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Psychotic disorder	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)

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14.54. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=1131)		Original Placebo/BNT162b2 (30 µg) (N[a]=1014)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.55. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=21911) n[b] (%)	(95% CI[c])
Any adverse event	291 (1.3)	(1.2, 1.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	4 (0.0)	(0.0, 0.0)
Thrombocytopenia	2 (0.0)	(0.0, 0.0)
Anaemia	1 (0.0)	(0.0, 0.0)
Microcytic anaemia	1 (0.0)	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	42 (0.2)	(0.1, 0.3)
Atrial fibrillation	9 (0.0)	(0.0, 0.1)
Myocardial infarction	7 (0.0)	(0.0, 0.1)
Acute coronary syndrome	3 (0.0)	(0.0, 0.0)
Acute myocardial infarction	3 (0.0)	(0.0, 0.0)
Coronary artery disease	3 (0.0)	(0.0, 0.0)
Aortic valve incompetence	2 (0.0)	(0.0, 0.0)
Cardiac arrest	2 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)
Arteriosclerosis coronary artery	1 (0.0)	(0.0, 0.0)
Arteriospasm coronary	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)
Cardiac failure acute	1 (0.0)	(0.0, 0.0)
Cardiac failure chronic	1 (0.0)	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.0)
Cardio-respiratory arrest	1 (0.0)	(0.0, 0.0)
Coronary artery occlusion	1 (0.0)	(0.0, 0.0)
Junctional ectopic tachycardia	1 (0.0)	(0.0, 0.0)
Mitral valve prolapse	1 (0.0)	(0.0, 0.0)
Pericardial haemorrhage	1 (0.0)	(0.0, 0.0)
Tachyarrhythmia	1 (0.0)	(0.0, 0.0)
Tachycardia	1 (0.0)	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2 (0.0)	(0.0, 0.0)
Congenital bladder neck obstruction	1 (0.0)	(0.0, 0.0)
Congenital ureteropelvic junction obstruction	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	3 (0.0)	(0.0, 0.0)

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14.55. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=21911) n[b] (%)	 (95% CI[c])
Eye haemorrhage	1 (0.0)	(0.0, 0.0)
Retinal artery occlusion	1 (0.0)	(0.0, 0.0)
Visual impairment	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	22 (0.1)	(0.1, 0.2)
Pancreatitis acute	3 (0.0)	(0.0, 0.0)
Small intestinal obstruction	2 (0.0)	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)
Anal fistula	1 (0.0)	(0.0, 0.0)
Colitis ischaemic	1 (0.0)	(0.0, 0.0)
Constipation	1 (0.0)	(0.0, 0.0)
Diverticular perforation	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)
Gastrointestinal mucosa hyperaemia	1 (0.0)	(0.0, 0.0)
Hiatus hernia	1 (0.0)	(0.0, 0.0)
Ileus	1 (0.0)	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	1 (0.0)	(0.0, 0.0)
Large intestine perforation	1 (0.0)	(0.0, 0.0)
Oesophageal food impaction	1 (0.0)	(0.0, 0.0)
Oesophageal varices haemorrhage	1 (0.0)	(0.0, 0.0)
Pancreatic cyst	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)
Retroperitoneal haematoma	1 (0.0)	(0.0, 0.0)
Salivary gland calculus	1 (0.0)	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)
Volvulus	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4 (0.0)	(0.0, 0.0)
Chest pain	1 (0.0)	(0.0, 0.0)
Death	1 (0.0)	(0.0, 0.0)
Influenza like illness	1 (0.0)	(0.0, 0.0)
Multiple organ dysfunction syndrome	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	7 (0.0)	(0.0, 0.1)
Cholecystitis acute	3 (0.0)	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)
Cholecystitis chronic	1 (0.0)	(0.0, 0.0)

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14.55. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population

	Vaccine Group (as Administered)	
	Placebo (N[a]=21911)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Cholelithiasis	1 (0.0)	(0.0, 0.0)
Hepatocellular injury	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)
Anaphylactic shock	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	61 (0.3)	(0.2, 0.4)
COVID-19	13 (0.1)	(0.0, 0.1)
Appendicitis	9 (0.0)	(0.0, 0.1)
Pneumonia	8 (0.0)	(0.0, 0.1)
Urinary tract infection	5 (0.0)	(0.0, 0.1)
COVID-19 pneumonia	2 (0.0)	(0.0, 0.0)
Cellulitis	2 (0.0)	(0.0, 0.0)
Complicated appendicitis	2 (0.0)	(0.0, 0.0)
Meningitis bacterial	2 (0.0)	(0.0, 0.0)
Upper respiratory tract infection	2 (0.0)	(0.0, 0.0)
Abdominal abscess	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)
Brain abscess	1 (0.0)	(0.0, 0.0)
Diabetic foot infection	1 (0.0)	(0.0, 0.0)
Diverticulitis	1 (0.0)	(0.0, 0.0)
Extradural abscess	1 (0.0)	(0.0, 0.0)
Gastroenteritis	1 (0.0)	(0.0, 0.0)
Gastroenteritis bacterial	1 (0.0)	(0.0, 0.0)
Osteomyelitis	1 (0.0)	(0.0, 0.0)
Peritonitis	1 (0.0)	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)
Post procedural infection	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)
Renal abscess	1 (0.0)	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)
Septic shock	1 (0.0)	(0.0, 0.0)
Staphylococcal sepsis	1 (0.0)	(0.0, 0.0)
Subacute endocarditis	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.0)
Tooth infection	1 (0.0)	(0.0, 0.0)
Urosepsis	1 (0.0)	(0.0, 0.0)

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14.55. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population

	Vaccine Group (as Administered)	
	Placebo (N[a]=21911)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	26 (0.1)	(0.1, 0.2)
Road traffic accident	3 (0.0)	(0.0, 0.0)
Foot fracture	2 (0.0)	(0.0, 0.0)
Humerus fracture	2 (0.0)	(0.0, 0.0)
Lower limb fracture	2 (0.0)	(0.0, 0.0)
Brain contusion	1 (0.0)	(0.0, 0.0)
Colon injury	1 (0.0)	(0.0, 0.0)
Concussion	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	1 (0.0)	(0.0, 0.0)
Delayed recovery from anaesthesia	1 (0.0)	(0.0, 0.0)
Fall	1 (0.0)	(0.0, 0.0)
Femur fracture	1 (0.0)	(0.0, 0.0)
Flail chest	1 (0.0)	(0.0, 0.0)
Forearm fracture	1 (0.0)	(0.0, 0.0)
Head injury	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)
Ligament rupture	1 (0.0)	(0.0, 0.0)
Meniscus injury	1 (0.0)	(0.0, 0.0)
Multiple injuries	1 (0.0)	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.0)
Post procedural haematoma	1 (0.0)	(0.0, 0.0)
Post-traumatic pain	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	1 (0.0)	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.0)
Rib fracture	1 (0.0)	(0.0, 0.0)
Spinal column injury	1 (0.0)	(0.0, 0.0)
Subdural haematoma	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	1 (0.0)	(0.0, 0.0)
Traumatic haemothorax	1 (0.0)	(0.0, 0.0)
Ulna fracture	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	4 (0.0)	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)
Blood pressure increased	1 (0.0)	(0.0, 0.0)
Hepatic enzyme increased	1 (0.0)	(0.0, 0.0)
Red blood cell morphology abnormal	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	11 (0.1)	(0.0, 0.1)

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14.55. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population

	Vaccine Group (as Administered)	
	Placebo (N[a]=21911)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Hyperglycaemia	2 (0.0)	(0.0, 0.0)
Hypoglycaemia	2 (0.0)	(0.0, 0.0)
Type 2 diabetes mellitus	2 (0.0)	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.0)
Hypokalaemia	1 (0.0)	(0.0, 0.0)
Hyponatraemia	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	15 (0.1)	(0.0, 0.1)
Osteoarthritis	6 (0.0)	(0.0, 0.1)
Arthralgia	2 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	2 (0.0)	(0.0, 0.0)
Cervical spinal stenosis	1 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)
Lumbar spinal stenosis	1 (0.0)	(0.0, 0.0)
Muscular weakness	1 (0.0)	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.0)
Spondylolisthesis	1 (0.0)	(0.0, 0.0)
Thoracic spinal stenosis	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	46 (0.2)	(0.2, 0.3)
Malignant melanoma	5 (0.0)	(0.0, 0.1)
Breast cancer	4 (0.0)	(0.0, 0.0)
Uterine leiomyoma	4 (0.0)	(0.0, 0.0)
Basal cell carcinoma	2 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	2 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	2 (0.0)	(0.0, 0.0)
Lung adenocarcinoma	2 (0.0)	(0.0, 0.0)
Metastases to lymph nodes	2 (0.0)	(0.0, 0.0)
Pancreatic carcinoma	2 (0.0)	(0.0, 0.0)
Papillary thyroid cancer	2 (0.0)	(0.0, 0.0)
Prostate cancer	2 (0.0)	(0.0, 0.0)
B-cell lymphoma	1 (0.0)	(0.0, 0.0)
Biliary cancer metastatic	1 (0.0)	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.0)
Breast cancer stage I	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	1 (0.0)	(0.0, 0.0)

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14.55. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=21911) n[b] (%)	 (95% CI[c])
Clear cell renal cell carcinoma	1 (0.0)	(0.0, 0.0)
Endometrial adenocarcinoma	1 (0.0)	(0.0, 0.0)
Lobular breast carcinoma in situ	1 (0.0)	(0.0, 0.0)
Metastases to liver	1 (0.0)	(0.0, 0.0)
Neuroendocrine tumour	1 (0.0)	(0.0, 0.0)
Non-Hodgkin's lymphoma recurrent	1 (0.0)	(0.0, 0.0)
Oropharyngeal cancer recurrent	1 (0.0)	(0.0, 0.0)
Pancreatic neuroendocrine tumour	1 (0.0)	(0.0, 0.0)
Papillary serous endometrial carcinoma	1 (0.0)	(0.0, 0.0)
Parathyroid tumour benign	1 (0.0)	(0.0, 0.0)
Pituitary tumour benign	1 (0.0)	(0.0, 0.0)
Polycythaemia vera	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma of head and neck	1 (0.0)	(0.0, 0.0)
Teratoma	1 (0.0)	(0.0, 0.0)
Transitional cell carcinoma	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	25 (0.1)	(0.1, 0.2)
Syncope	5 (0.0)	(0.0, 0.1)
Transient ischaemic attack	3 (0.0)	(0.0, 0.0)
Ischaemic stroke	2 (0.0)	(0.0, 0.0)
Spinal cord compression	2 (0.0)	(0.0, 0.0)
Amnesia	1 (0.0)	(0.0, 0.0)
Amyotrophic lateral sclerosis	1 (0.0)	(0.0, 0.0)
Cerebral infarction	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	1 (0.0)	(0.0, 0.0)
Cervicogenic headache	1 (0.0)	(0.0, 0.0)
Dementia Alzheimer's type	1 (0.0)	(0.0, 0.0)
Dizziness	1 (0.0)	(0.0, 0.0)
Guillain-Barre syndrome	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	1 (0.0)	(0.0, 0.0)
Intraventricular haemorrhage	1 (0.0)	(0.0, 0.0)
Paraesthesia	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	6 (0.0)	(0.0, 0.1)
Abortion spontaneous	3 (0.0)	(0.0, 0.0)
Abortion incomplete	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	1 (0.0)	(0.0, 0.0)

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14.55. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population

	Vaccine Group (as Administered)	
	Placebo (N[a]=21911)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Retained products of conception	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	10 (0.0)	(0.0, 0.1)
Bipolar disorder	2 (0.0)	(0.0, 0.0)
Major depression	2 (0.0)	(0.0, 0.0)
Suicidal ideation	2 (0.0)	(0.0, 0.0)
Affective disorder	1 (0.0)	(0.0, 0.0)
Alcohol abuse	1 (0.0)	(0.0, 0.0)
Alcohol withdrawal syndrome	1 (0.0)	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.0)
Depression suicidal	1 (0.0)	(0.0, 0.0)
Drug dependence	1 (0.0)	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)
Suicide attempt	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	7 (0.0)	(0.0, 0.1)
Nephrolithiasis	6 (0.0)	(0.0, 0.1)
Hydronephrosis	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	8 (0.0)	(0.0, 0.1)
Adnexal torsion	2 (0.0)	(0.0, 0.0)
Adenomyosis	1 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)
Endometriosis	1 (0.0)	(0.0, 0.0)
Ovarian mass	1 (0.0)	(0.0, 0.0)
Rectocele	1 (0.0)	(0.0, 0.0)
Vaginal prolapse	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	15 (0.1)	(0.0, 0.1)
Pulmonary embolism	7 (0.0)	(0.0, 0.1)
Acute respiratory failure	2 (0.0)	(0.0, 0.0)
Asthmatic crisis	1 (0.0)	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.0)
Hypoxia	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)
Pneumothorax	1 (0.0)	(0.0, 0.0)
Pulmonary mass	1 (0.0)	(0.0, 0.0)
Respiratory arrest	1 (0.0)	(0.0, 0.0)

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14.55. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=21911) n[b] (%)	 (95% CI[c])
Respiratory failure	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	1 (0.0)	(0.0, 0.0)
Miscarriage of partner	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	13 (0.1)	(0.0, 0.1)
Deep vein thrombosis	4 (0.0)	(0.0, 0.0)
Aortic stenosis	2 (0.0)	(0.0, 0.0)
Orthostatic hypotension	2 (0.0)	(0.0, 0.0)
Accelerated hypertension	1 (0.0)	(0.0, 0.0)
Aortic dissection	1 (0.0)	(0.0, 0.0)
Hypertensive emergency	1 (0.0)	(0.0, 0.0)
Peripheral artery stenosis	1 (0.0)	(0.0, 0.0)
Superficial vein thrombosis	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:03)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2p

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14.56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=21910)		Original Placebo/BNT162b2 (30 µg) (N[a]=20267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	428 (2.0)	(1.8, 2.1)	353 (1.7)	(1.6, 1.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	4 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Anaemia	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Febrile neutropenia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Anaemia macrocytic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood loss anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancytopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	64 (0.3)	(0.2, 0.4)	43 (0.2)	(0.2, 0.3)
Acute myocardial infarction	13 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Atrial fibrillation	7 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Myocardial infarction	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Cardiac failure congestive	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Cardiac arrest	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Coronary artery disease	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute coronary syndrome	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angina pectoris	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardio-respiratory arrest	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ventricular tachycardia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coronary artery occlusion	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive heart disease	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocardial ischaemia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Palpitations	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular fibrillation	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Accelerated idioventricular rhythm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Atrioventricular block complete	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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14.56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=21910)		Original Placebo/BNT162b2 (30 µg) (N[a]=20267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cardiovascular disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conduction disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ischaemic cardiomyopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mitral valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postural orthostatic tachycardia syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus node dysfunction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Supraventricular extrasystoles	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular extrasystoles	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
BRCA1 gene mutation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertrophic cardiomyopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vertigo	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blindness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid ptosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ophthalmic vein thrombosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Optic ischaemic neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal detachment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal tear	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	38 (0.2)	(0.1, 0.2)	29 (0.1)	(0.1, 0.2)
Small intestinal obstruction	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Intestinal obstruction	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Pancreatitis acute	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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14.56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=21910)		Original Placebo/BNT162b2 (30 µg) (N[a]=20267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Colitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Constipation	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastritis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrooesophageal reflux disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Inguinal hernia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lower gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal compartment syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis ulcerative	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Duodenal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Duodenal ulcer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Enterocolitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric ulcer haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal necrosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoids	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hiatus hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impaired gastric emptying	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Incarcerated inguinal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal ischaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intestinal perforation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal strangulation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal ulcer perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nausea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis necrotising	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peptic ulcer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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14.56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=21910)		Original Placebo/BNT162b2 (30 µg) (N[a]=20267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rectal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Splenic artery aneurysm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper gastrointestinal haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vomiting	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	17 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Chest pain	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Death	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Electrocution	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypothermia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Impaired healing	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyrexia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sudden death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Treatment noncompliance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	20 (0.1)	(0.1, 0.1)	13 (0.1)	(0.0, 0.1)
Cholelithiasis	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Cholecystitis acute	7 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bile duct stone	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Biliary colic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute hepatic failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Autoimmune hepatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Biliary dyskinesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholangitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholelithiasis obstructive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Portal vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Portosplenomesenteric venous thrombosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

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14.56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=21910)		Original Placebo/BNT162b2 (30 µg) (N[a]=20267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactoid reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	71 (0.3)	(0.3, 0.4)	49 (0.2)	(0.2, 0.3)
Appendicitis	17 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pneumonia	6 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Diverticulitis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Urinary tract infection	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Sepsis	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Gastroenteritis	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Cellulitis	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
COVID-19 pneumonia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Clostridium difficile colitis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Septic shock	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Liver abscess	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic abscess	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Peritonitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis acute	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess limb	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acquired immunodeficiency syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthritis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacteraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Campylobacter gastroenteritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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14.56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=21910)		Original Placebo/BNT162b2 (30 µg) (N[a]=20267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cellulitis staphylococcal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis infective	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Clostridium difficile infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device related infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Emphysematous cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endocarditis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Focal peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gangrene	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HIV infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes zoster oticus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Infected bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Kidney infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Labyrinthitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lower respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mastoiditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic inflammatory disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonia pneumococcal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory syncytial virus bronchiolitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Septic arthritis staphylococcal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shigella sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin candida	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subdiaphragmatic abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinea pedis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	36 (0.2)	(0.1, 0.2)	41 (0.2)	(0.1, 0.3)
Ankle fracture	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=21910)		Original Placebo/BNT162b2 (30 µg) (N[a]=20267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rib fracture	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Overdose	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Road traffic accident	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial bones fracture	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper limb fracture	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fall	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Foot fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fractured sacrum	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ligament rupture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar vertebral fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thoracic vertebral fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tibia fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wrist fracture	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Accidental overdose	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anastomotic complication	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anastomotic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Animal bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arterial injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthropod bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Brain contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Burns second degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns third degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Concussion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hand fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=21910)		Original Placebo/BNT162b2 (30 µg) (N[a]=20267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Meniscus injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Neck injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Open fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Patella fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural complication	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative ileus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural dizziness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Scapula fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin laceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Splenic rupture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subdural haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic liver injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood lactic acid	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	8 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Diabetic ketoacidosis	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Hypokalaemia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyponatraemia	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Type 2 diabetes mellitus	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoglycaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malnutrition	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	25 (0.1)	(0.1, 0.2)	25 (0.1)	(0.1, 0.2)
Osteoarthritis	10 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Intervertebral disc protrusion	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arthritis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

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14.56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=21910)		Original Placebo/BNT162b2 (30 µg) (N[a]=20267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Back pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar spinal stenosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscular weakness	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal stenosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Spondylolisthesis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arthralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Costochondritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc compression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain in extremity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal osteoarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovial cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	69 (0.3)	(0.2, 0.4)	56 (0.3)	(0.2, 0.4)
Prostate cancer	3 (0.0)	(0.0, 0.0)	9 (0.0)	(0.0, 0.1)
Breast cancer	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Adenocarcinoma of colon	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast cancer metastatic	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Endometrial adenocarcinoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Invasive lobular breast carcinoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Malignant melanoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Transitional cell carcinoma	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Basal cell carcinoma	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cancer stage I	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Follicular lymphoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lung adenocarcinoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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14.56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=21910)		Original Placebo/BNT162b2 (30 µg) (N[a]=20267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lung neoplasm malignant	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic carcinoma metastatic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Testis cancer	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angiosarcoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Benign hydatidiform mole	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bladder cancer recurrent	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain neoplasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cancer in situ	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clear cell renal cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colorectal adenoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cutaneous T-cell lymphoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ductal adenocarcinoma of pancreas	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Endometrial cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gallbladder cancer stage II	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hormone receptor positive breast cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypergammaglobulinaemia benign monoclonal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Laryngeal papilloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lipoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lung cancer metastatic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphocytic leukaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mesothelioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to lung	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastatic gastric cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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14.56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=21910)		Original Placebo/BNT162b2 (30 µg) (N[a]=20267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Metastatic malignant melanoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastatic squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mucoepidermoid carcinoma of salivary gland	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuroendocrine carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-small cell lung cancer stage III	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-small cell lung cancer stage IV	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian cancer stage I	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Plasma cell myeloma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer metastatic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer stage II	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhabdomyosarcoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma of the cervix	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thyroid cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tonsil cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transitional cell carcinoma recurrent	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uterine cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uterine leiomyosarcoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vascular neoplasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	34 (0.2)	(0.1, 0.2)	46 (0.2)	(0.2, 0.3)
Cerebrovascular accident	5 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Syncope	3 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Transient ischaemic attack	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Ischaemic stroke	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuropathy peripheral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Optic neuritis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Amyotrophic lateral sclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=21910)		Original Placebo/BNT162b2 (30 µg) (N[a]=20267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Autonomic nervous system imbalance	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Brachial plexopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Brain stem infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carotid artery aneurysm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carotid artery stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dural arteriovenous fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyskinesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Encephalopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intracranial aneurysm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intracranial hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Loss of consciousness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myasthenia gravis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral nerve lesion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Presyncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psychogenic seizure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Reversible cerebral vasoconstriction syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sedation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	6 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Abortion spontaneous	6 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Ectopic pregnancy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	16 (0.1)	(0.0, 0.1)	20 (0.1)	(0.1, 0.2)
Depression	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Bipolar disorder	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Completed suicide	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Alcohol withdrawal syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Anxiety	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Drug abuse	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=21910)		Original Placebo/BNT162b2 (30 µg) (N[a]=20267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Major depression	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suicide attempt	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute psychosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcohol abuse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alcoholism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bipolar I disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Conversion disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hallucination	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental status changes	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obsessive-compulsive disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicidal behaviour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	17 (0.1)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Nephrolithiasis	9 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Acute kidney injury	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Ureterolithiasis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary retention	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bladder prolapse	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomerulonephritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal vein thrombosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urinary tract obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Ovarian cyst	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abnormal uterine bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adnexal torsion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endometrial thickening	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endometriosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heavy menstrual bleeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=21910)		Original Placebo/BNT162b2 (30 µg) (N[a]=20267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	19 (0.1)	(0.1, 0.1)	29 (0.1)	(0.1, 0.2)
Pulmonary embolism	5 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Acute respiratory failure	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthma	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pleural effusion	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Acute respiratory distress syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bronchospasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diaphragmatic paralysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal septum deviation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary sarcoidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pustular psoriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Miscarriage of partner	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pregnancy of partner	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Finger amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	17 (0.1)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Deep vein thrombosis	4 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Hypertension	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive urgency	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aortic dissection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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14.56. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=21910)		Original Placebo/BNT162b2 (30 µg) (N[a]=20267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Aortic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive crisis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive emergency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypovolaemic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iliac artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral artery thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:05)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2b

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14.57. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Age Group, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=13022) n[b] (%)	(95% CI[c])
Any adverse event	124 (1.0)	(0.8, 1.1)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)
Microcytic anaemia	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	12 (0.1)	(0.0, 0.2)
Atrial fibrillation	3 (0.0)	(0.0, 0.1)
Myocardial infarction	3 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)
Acute myocardial infarction	1 (0.0)	(0.0, 0.0)
Arteriospasm coronary	1 (0.0)	(0.0, 0.0)
Cardiac failure chronic	1 (0.0)	(0.0, 0.0)
Cardio-respiratory arrest	1 (0.0)	(0.0, 0.0)
Junctional ectopic tachycardia	1 (0.0)	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)
Congenital ureteropelvic junction obstruction	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.0)
Visual impairment	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	8 (0.1)	(0.0, 0.1)
Pancreatitis acute	2 (0.0)	(0.0, 0.1)
Anal fistula	1 (0.0)	(0.0, 0.0)
Diverticular perforation	1 (0.0)	(0.0, 0.0)
Ileus	1 (0.0)	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.0)
Oesophageal food impaction	1 (0.0)	(0.0, 0.0)
Oesophageal varices haemorrhage	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (0.0)	(0.0, 0.1)
Death	1 (0.0)	(0.0, 0.0)
Influenza like illness	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	5 (0.0)	(0.0, 0.1)
Cholecystitis acute	1 (0.0)	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)
Cholecystitis chronic	1 (0.0)	(0.0, 0.0)
Cholelithiasis	1 (0.0)	(0.0, 0.0)

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14.57. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Age Group, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=13022) n[b] (%)	(95% CI[c])
Hepatocellular injury	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	26 (0.2)	(0.1, 0.3)
COVID-19	5 (0.0)	(0.0, 0.1)
Appendicitis	7 (0.1)	(0.0, 0.1)
Urinary tract infection	3 (0.0)	(0.0, 0.1)
Meningitis bacterial	2 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	1 (0.0)	(0.0, 0.0)
Abdominal abscess	1 (0.0)	(0.0, 0.0)
Diabetic foot infection	1 (0.0)	(0.0, 0.0)
Gastroenteritis	1 (0.0)	(0.0, 0.0)
Gastroenteritis bacterial	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)
Renal abscess	1 (0.0)	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)
Urosepsis	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	12 (0.1)	(0.0, 0.2)
Foot fracture	1 (0.0)	(0.0, 0.0)
Humerus fracture	1 (0.0)	(0.0, 0.0)
Colon injury	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	1 (0.0)	(0.0, 0.0)
Flail chest	1 (0.0)	(0.0, 0.0)
Forearm fracture	1 (0.0)	(0.0, 0.0)
Ligament rupture	1 (0.0)	(0.0, 0.0)
Meniscus injury	1 (0.0)	(0.0, 0.0)
Multiple injuries	1 (0.0)	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	1 (0.0)	(0.0, 0.0)
Ulna fracture	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.0)
Red blood cell morphology abnormal	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	6 (0.0)	(0.0, 0.1)
Hypoglycaemia	2 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	1 (0.0)	(0.0, 0.0)

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14.57. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Age Group, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=13022) n[b] (%)	 (95% CI[c])
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.0)
Hypokalaemia	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	5 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	2 (0.0)	(0.0, 0.1)
Muscular weakness	1 (0.0)	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.0)
Spondylolisthesis	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	16 (0.1)	(0.1, 0.2)
Malignant melanoma	1 (0.0)	(0.0, 0.0)
Breast cancer	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	2 (0.0)	(0.0, 0.1)
Basal cell carcinoma	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	1 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	2 (0.0)	(0.0, 0.1)
Metastases to lymph nodes	1 (0.0)	(0.0, 0.0)
Papillary thyroid cancer	2 (0.0)	(0.0, 0.1)
B-cell lymphoma	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	1 (0.0)	(0.0, 0.0)
Clear cell renal cell carcinoma	1 (0.0)	(0.0, 0.0)
Endometrial adenocarcinoma	1 (0.0)	(0.0, 0.0)
Teratoma	1 (0.0)	(0.0, 0.0)
Transitional cell carcinoma	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	9 (0.1)	(0.0, 0.1)
Syncope	3 (0.0)	(0.0, 0.1)
Transient ischaemic attack	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)
Amnesia	1 (0.0)	(0.0, 0.0)
Guillain-Barre syndrome	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	1 (0.0)	(0.0, 0.0)
Paraesthesia	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	6 (0.0)	(0.0, 0.1)
Abortion spontaneous	3 (0.0)	(0.0, 0.1)
Abortion incomplete	1 (0.0)	(0.0, 0.0)

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14.57. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Age Group, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=13022) n[b] (%)	 (95% CI[c])
Abortion spontaneous incomplete	1 (0.0)	(0.0, 0.0)
Retained products of conception	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	6 (0.0)	(0.0, 0.1)
Major depression	1 (0.0)	(0.0, 0.0)
Suicidal ideation	2 (0.0)	(0.0, 0.1)
Alcohol abuse	1 (0.0)	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.0)
Depression suicidal	1 (0.0)	(0.0, 0.0)
Suicide attempt	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	5 (0.0)	(0.0, 0.1)
Nephrolithiasis	5 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	4 (0.0)	(0.0, 0.1)
Adnexal torsion	2 (0.0)	(0.0, 0.1)
Endometriosis	1 (0.0)	(0.0, 0.0)
Rectocele	1 (0.0)	(0.0, 0.0)
Vaginal prolapse	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	4 (0.0)	(0.0, 0.1)
Pulmonary embolism	1 (0.0)	(0.0, 0.0)
Asthmatic crisis	1 (0.0)	(0.0, 0.0)
Hypoxia	1 (0.0)	(0.0, 0.0)
Respiratory arrest	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	1 (0.0)	(0.0, 0.0)
Miscarriage of partner	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	5 (0.0)	(0.0, 0.1)
Deep vein thrombosis	3 (0.0)	(0.0, 0.1)
Aortic stenosis	1 (0.0)	(0.0, 0.0)
Accelerated hypertension	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:03)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2p_age

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14.58. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Age Group, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=8889) n[b] (%)	(95% CI[c])
Any adverse event	167 (1.9)	(1.6, 2.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)
Thrombocytopenia	2 (0.0)	(0.0, 0.1)
Anaemia	1 (0.0)	(0.0, 0.1)
Neutropenia	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	30 (0.3)	(0.2, 0.5)
Atrial fibrillation	6 (0.1)	(0.0, 0.1)
Myocardial infarction	4 (0.0)	(0.0, 0.1)
Acute coronary syndrome	2 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)
Coronary artery disease	3 (0.0)	(0.0, 0.1)
Aortic valve incompetence	2 (0.0)	(0.0, 0.1)
Cardiac arrest	2 (0.0)	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.1)
Arteriosclerosis coronary artery	1 (0.0)	(0.0, 0.1)
Bradycardia	1 (0.0)	(0.0, 0.1)
Cardiac failure acute	1 (0.0)	(0.0, 0.1)
Cardiac failure congestive	1 (0.0)	(0.0, 0.1)
Coronary artery occlusion	1 (0.0)	(0.0, 0.1)
Mitral valve prolapse	1 (0.0)	(0.0, 0.1)
Pericardial haemorrhage	1 (0.0)	(0.0, 0.1)
Tachyarrhythmia	1 (0.0)	(0.0, 0.1)
Tachycardia	1 (0.0)	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)
Congenital bladder neck obstruction	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.1)
Vertigo	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	2 (0.0)	(0.0, 0.1)
Eye haemorrhage	1 (0.0)	(0.0, 0.1)
Retinal artery occlusion	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	14 (0.2)	(0.1, 0.3)
Pancreatitis acute	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)
Abdominal pain upper	1 (0.0)	(0.0, 0.1)

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14.58. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Age Group, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=8889) n[b] (%)	(95% CI[c])
Colitis ischaemic	1 (0.0)	(0.0, 0.1)
Constipation	1 (0.0)	(0.0, 0.1)
Diverticulum intestinal	1 (0.0)	(0.0, 0.1)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)
Gastrointestinal mucosa hyperaemia	1 (0.0)	(0.0, 0.1)
Hiatus hernia	1 (0.0)	(0.0, 0.1)
Intestinal obstruction	1 (0.0)	(0.0, 0.1)
Large intestine perforation	1 (0.0)	(0.0, 0.1)
Pancreatic cyst	1 (0.0)	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)
Retroperitoneal haematoma	1 (0.0)	(0.0, 0.1)
Salivary gland calculus	1 (0.0)	(0.0, 0.1)
Umbilical hernia	1 (0.0)	(0.0, 0.1)
Volvulus	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.1)
Multiple organ dysfunction syndrome	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	2 (0.0)	(0.0, 0.1)
Cholecystitis acute	2 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)
Anaphylactic shock	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	35 (0.4)	(0.3, 0.5)
COVID-19	8 (0.1)	(0.0, 0.2)
Appendicitis	2 (0.0)	(0.0, 0.1)
Pneumonia	8 (0.1)	(0.0, 0.2)
Urinary tract infection	2 (0.0)	(0.0, 0.1)
COVID-19 pneumonia	2 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)
Complicated appendicitis	2 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)
Brain abscess	1 (0.0)	(0.0, 0.1)
Diverticulitis	1 (0.0)	(0.0, 0.1)
Extradural abscess	1 (0.0)	(0.0, 0.1)
Osteomyelitis	1 (0.0)	(0.0, 0.1)

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14.58. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Age Group, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=8889) n[b] (%)	(95% CI[c])
Peritonitis	1 (0.0)	(0.0, 0.1)
Peritonsillar abscess	1 (0.0)	(0.0, 0.1)
Post procedural infection	1 (0.0)	(0.0, 0.1)
Pyelonephritis	1 (0.0)	(0.0, 0.1)
Septic shock	1 (0.0)	(0.0, 0.1)
Staphylococcal sepsis	1 (0.0)	(0.0, 0.1)
Subacute endocarditis	1 (0.0)	(0.0, 0.1)
Subcutaneous abscess	1 (0.0)	(0.0, 0.1)
Tooth infection	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	14 (0.2)	(0.1, 0.3)
Road traffic accident	3 (0.0)	(0.0, 0.1)
Foot fracture	1 (0.0)	(0.0, 0.1)
Humerus fracture	1 (0.0)	(0.0, 0.1)
Lower limb fracture	2 (0.0)	(0.0, 0.1)
Brain contusion	1 (0.0)	(0.0, 0.1)
Concussion	1 (0.0)	(0.0, 0.1)
Delayed recovery from anaesthesia	1 (0.0)	(0.0, 0.1)
Fall	1 (0.0)	(0.0, 0.1)
Femur fracture	1 (0.0)	(0.0, 0.1)
Head injury	1 (0.0)	(0.0, 0.1)
Hip fracture	1 (0.0)	(0.0, 0.1)
Post procedural haematoma	1 (0.0)	(0.0, 0.1)
Post-traumatic pain	1 (0.0)	(0.0, 0.1)
Radius fracture	1 (0.0)	(0.0, 0.1)
Rib fracture	1 (0.0)	(0.0, 0.1)
Spinal column injury	1 (0.0)	(0.0, 0.1)
Subdural haematoma	1 (0.0)	(0.0, 0.1)
Traumatic haemothorax	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	3 (0.0)	(0.0, 0.1)
Blood glucose abnormal	1 (0.0)	(0.0, 0.1)
Blood pressure increased	1 (0.0)	(0.0, 0.1)
Hepatic enzyme increased	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	5 (0.1)	(0.0, 0.1)
Hyperglycaemia	2 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	1 (0.0)	(0.0, 0.1)

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14.58. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Age Group, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=8889) n[b] (%)	(95% CI[c])
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.1)
Hyponatraemia	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	10 (0.1)	(0.1, 0.2)
Osteoarthritis	6 (0.1)	(0.0, 0.1)
Arthralgia	2 (0.0)	(0.0, 0.1)
Cervical spinal stenosis	1 (0.0)	(0.0, 0.1)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.1)
Lumbar spinal stenosis	1 (0.0)	(0.0, 0.1)
Thoracic spinal stenosis	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	30 (0.3)	(0.2, 0.5)
Malignant melanoma	4 (0.0)	(0.0, 0.1)
Breast cancer	3 (0.0)	(0.0, 0.1)
Uterine leiomyoma	2 (0.0)	(0.0, 0.1)
Basal cell carcinoma	1 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	1 (0.0)	(0.0, 0.1)
Lung adenocarcinoma	2 (0.0)	(0.0, 0.1)
Metastases to lymph nodes	1 (0.0)	(0.0, 0.1)
Pancreatic carcinoma	2 (0.0)	(0.0, 0.1)
Prostate cancer	2 (0.0)	(0.0, 0.1)
Biliary cancer metastatic	1 (0.0)	(0.0, 0.1)
Bladder cancer	1 (0.0)	(0.0, 0.1)
Breast cancer stage I	1 (0.0)	(0.0, 0.1)
Lobular breast carcinoma in situ	1 (0.0)	(0.0, 0.1)
Metastases to liver	1 (0.0)	(0.0, 0.1)
Neuroendocrine tumour	1 (0.0)	(0.0, 0.1)
Non-Hodgkin's lymphoma recurrent	1 (0.0)	(0.0, 0.1)
Oropharyngeal cancer recurrent	1 (0.0)	(0.0, 0.1)
Pancreatic neuroendocrine tumour	1 (0.0)	(0.0, 0.1)
Papillary serous endometrial carcinoma	1 (0.0)	(0.0, 0.1)
Parathyroid tumour benign	1 (0.0)	(0.0, 0.1)
Pituitary tumour benign	1 (0.0)	(0.0, 0.1)
Polycythaemia vera	1 (0.0)	(0.0, 0.1)
Squamous cell carcinoma of head and neck	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	16 (0.2)	(0.1, 0.3)

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14.58. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Age Group, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=8889) n[b] (%)	(95% CI[c])
Syncope	2 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)
Spinal cord compression	2 (0.0)	(0.0, 0.1)
Amyotrophic lateral sclerosis	1 (0.0)	(0.0, 0.1)
Cerebral infarction	1 (0.0)	(0.0, 0.1)
Cerebrovascular accident	1 (0.0)	(0.0, 0.1)
Cervicogenic headache	1 (0.0)	(0.0, 0.1)
Dementia Alzheimer's type	1 (0.0)	(0.0, 0.1)
Dizziness	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	1 (0.0)	(0.0, 0.1)
Intraventricular haemorrhage	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	4 (0.0)	(0.0, 0.1)
Bipolar disorder	2 (0.0)	(0.0, 0.1)
Major depression	1 (0.0)	(0.0, 0.1)
Affective disorder	1 (0.0)	(0.0, 0.1)
Alcohol withdrawal syndrome	1 (0.0)	(0.0, 0.1)
Drug dependence	1 (0.0)	(0.0, 0.1)
Panic attack	1 (0.0)	(0.0, 0.1)
Psychotic disorder	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	2 (0.0)	(0.0, 0.1)
Nephrolithiasis	1 (0.0)	(0.0, 0.1)
Hydronephrosis	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	4 (0.0)	(0.0, 0.1)
Adenomyosis	1 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.1)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)
Ovarian mass	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	11 (0.1)	(0.1, 0.2)
Pulmonary embolism	6 (0.1)	(0.0, 0.1)
Acute respiratory failure	2 (0.0)	(0.0, 0.1)
Dyspnoea	1 (0.0)	(0.0, 0.1)
Interstitial lung disease	1 (0.0)	(0.0, 0.1)
Pneumothorax	1 (0.0)	(0.0, 0.1)

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System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=8889) n[b] (%)	 (95% CI[c])
Pulmonary mass	1 (0.0)	(0.0, 0.1)
Respiratory failure	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	8 (0.1)	(0.0, 0.2)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)
Aortic stenosis	1 (0.0)	(0.0, 0.1)
Orthostatic hypotension	2 (0.0)	(0.0, 0.1)
Aortic dissection	1 (0.0)	(0.0, 0.1)
Hypertensive emergency	1 (0.0)	(0.0, 0.1)
Peripheral artery stenosis	1 (0.0)	(0.0, 0.1)
Superficial vein thrombosis	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:03)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2p_age

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14.59. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Race, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Race: White

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=18025) n[b] (%)	 (95% CI[c])
Any adverse event	259 (1.4)	(1.3, 1.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	1 (0.0)	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	38 (0.2)	(0.1, 0.3)
Atrial fibrillation	8 (0.0)	(0.0, 0.1)
Myocardial infarction	6 (0.0)	(0.0, 0.1)
Acute coronary syndrome	3 (0.0)	(0.0, 0.0)
Acute myocardial infarction	3 (0.0)	(0.0, 0.0)
Coronary artery disease	3 (0.0)	(0.0, 0.0)
Aortic valve incompetence	2 (0.0)	(0.0, 0.0)
Cardiac arrest	1 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)
Arteriosclerosis coronary artery	1 (0.0)	(0.0, 0.0)
Arteriospasm coronary	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)
Cardiac failure chronic	1 (0.0)	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.0)
Cardio-respiratory arrest	1 (0.0)	(0.0, 0.0)
Coronary artery occlusion	1 (0.0)	(0.0, 0.0)
Junctional ectopic tachycardia	1 (0.0)	(0.0, 0.0)
Mitral valve prolapse	1 (0.0)	(0.0, 0.0)
Pericardial haemorrhage	1 (0.0)	(0.0, 0.0)
Tachyarrhythmia	1 (0.0)	(0.0, 0.0)
Tachycardia	1 (0.0)	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2 (0.0)	(0.0, 0.0)
Congenital bladder neck obstruction	1 (0.0)	(0.0, 0.0)
Congenital ureteropelvic junction obstruction	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	3 (0.0)	(0.0, 0.0)
Eye haemorrhage	1 (0.0)	(0.0, 0.0)
Retinal artery occlusion	1 (0.0)	(0.0, 0.0)
Visual impairment	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	19 (0.1)	(0.1, 0.2)
Pancreatitis acute	3 (0.0)	(0.0, 0.0)

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14.59. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Race, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Race: White

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=18025) n[b] (%)	 (95% CI[c])
Small intestinal obstruction	2 (0.0)	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)
Anal fistula	1 (0.0)	(0.0, 0.0)
Colitis ischaemic	1 (0.0)	(0.0, 0.0)
Constipation	1 (0.0)	(0.0, 0.0)
Diverticular perforation	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)
Hiatus hernia	1 (0.0)	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	1 (0.0)	(0.0, 0.0)
Large intestine perforation	1 (0.0)	(0.0, 0.0)
Oesophageal food impaction	1 (0.0)	(0.0, 0.0)
Pancreatic cyst	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)
Retroperitoneal haematoma	1 (0.0)	(0.0, 0.0)
Salivary gland calculus	1 (0.0)	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.0)
Death	1 (0.0)	(0.0, 0.0)
Influenza like illness	1 (0.0)	(0.0, 0.0)
Multiple organ dysfunction syndrome	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	7 (0.0)	(0.0, 0.1)
Cholecystitis acute	3 (0.0)	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)
Cholecystitis chronic	1 (0.0)	(0.0, 0.0)
Cholelithiasis	1 (0.0)	(0.0, 0.0)
Hepatocellular injury	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)
Anaphylactic shock	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	54 (0.3)	(0.2, 0.4)
COVID-19	13 (0.1)	(0.0, 0.1)
Appendicitis	9 (0.0)	(0.0, 0.1)
Pneumonia	6 (0.0)	(0.0, 0.1)
Urinary tract infection	4 (0.0)	(0.0, 0.1)

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	Vaccine Group (as Administered)	
	Placebo (N[a]=18025)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
COVID-19 pneumonia	2 (0.0)	(0.0, 0.0)
Cellulitis	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	2 (0.0)	(0.0, 0.0)
Upper respiratory tract infection	2 (0.0)	(0.0, 0.0)
Abdominal abscess	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)
Brain abscess	1 (0.0)	(0.0, 0.0)
Diabetic foot infection	1 (0.0)	(0.0, 0.0)
Diverticulitis	1 (0.0)	(0.0, 0.0)
Extradural abscess	1 (0.0)	(0.0, 0.0)
Gastroenteritis	1 (0.0)	(0.0, 0.0)
Gastroenteritis bacterial	1 (0.0)	(0.0, 0.0)
Osteomyelitis	1 (0.0)	(0.0, 0.0)
Peritonitis	1 (0.0)	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)
Post procedural infection	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)
Renal abscess	1 (0.0)	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)
Septic shock	1 (0.0)	(0.0, 0.0)
Staphylococcal sepsis	1 (0.0)	(0.0, 0.0)
Subacute endocarditis	1 (0.0)	(0.0, 0.0)
Tooth infection	1 (0.0)	(0.0, 0.0)
Urosepsis	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	24 (0.1)	(0.1, 0.2)
Road traffic accident	2 (0.0)	(0.0, 0.0)
Foot fracture	2 (0.0)	(0.0, 0.0)
Humerus fracture	2 (0.0)	(0.0, 0.0)
Lower limb fracture	2 (0.0)	(0.0, 0.0)
Brain contusion	1 (0.0)	(0.0, 0.0)
Colon injury	1 (0.0)	(0.0, 0.0)
Concussion	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	1 (0.0)	(0.0, 0.0)
Delayed recovery from anaesthesia	1 (0.0)	(0.0, 0.0)
Fall	1 (0.0)	(0.0, 0.0)
Femur fracture	1 (0.0)	(0.0, 0.0)

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System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=18025) n[b] (%)	 (95% CI[c])
Flail chest	1 (0.0)	(0.0, 0.0)
Forearm fracture	1 (0.0)	(0.0, 0.0)
Head injury	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)
Ligament rupture	1 (0.0)	(0.0, 0.0)
Meniscus injury	1 (0.0)	(0.0, 0.0)
Multiple injuries	1 (0.0)	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.0)
Post procedural haematoma	1 (0.0)	(0.0, 0.0)
Post-traumatic pain	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	1 (0.0)	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.0)
Ulna fracture	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	2 (0.0)	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)
Hepatic enzyme increased	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	10 (0.1)	(0.0, 0.1)
Hyperglycaemia	2 (0.0)	(0.0, 0.0)
Hypoglycaemia	2 (0.0)	(0.0, 0.0)
Type 2 diabetes mellitus	1 (0.0)	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.0)
Hypokalaemia	1 (0.0)	(0.0, 0.0)
Hyponatraemia	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	14 (0.1)	(0.0, 0.1)
Osteoarthritis	6 (0.0)	(0.0, 0.1)
Arthralgia	1 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	2 (0.0)	(0.0, 0.0)
Cervical spinal stenosis	1 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)
Lumbar spinal stenosis	1 (0.0)	(0.0, 0.0)
Muscular weakness	1 (0.0)	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.0)
Spondylolisthesis	1 (0.0)	(0.0, 0.0)
Thoracic spinal stenosis	1 (0.0)	(0.0, 0.0)

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	Vaccine Group (as Administered)	
	Placebo (N[a]=18025)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	39 (0.2)	(0.2, 0.3)
Malignant melanoma	5 (0.0)	(0.0, 0.1)
Breast cancer	4 (0.0)	(0.0, 0.1)
Uterine leiomyoma	2 (0.0)	(0.0, 0.0)
Basal cell carcinoma	2 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	2 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	2 (0.0)	(0.0, 0.0)
Lung adenocarcinoma	1 (0.0)	(0.0, 0.0)
Metastases to lymph nodes	2 (0.0)	(0.0, 0.0)
Pancreatic carcinoma	1 (0.0)	(0.0, 0.0)
Papillary thyroid cancer	2 (0.0)	(0.0, 0.0)
Prostate cancer	2 (0.0)	(0.0, 0.0)
B-cell lymphoma	1 (0.0)	(0.0, 0.0)
Biliary cancer metastatic	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	1 (0.0)	(0.0, 0.0)
Clear cell renal cell carcinoma	1 (0.0)	(0.0, 0.0)
Endometrial adenocarcinoma	1 (0.0)	(0.0, 0.0)
Lobular breast carcinoma in situ	1 (0.0)	(0.0, 0.0)
Metastases to liver	1 (0.0)	(0.0, 0.0)
Neuroendocrine tumour	1 (0.0)	(0.0, 0.0)
Non-Hodgkin's lymphoma recurrent	1 (0.0)	(0.0, 0.0)
Oropharyngeal cancer recurrent	1 (0.0)	(0.0, 0.0)
Papillary serous endometrial carcinoma	1 (0.0)	(0.0, 0.0)
Parathyroid tumour benign	1 (0.0)	(0.0, 0.0)
Pituitary tumour benign	1 (0.0)	(0.0, 0.0)
Polycythaemia vera	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma of head and neck	1 (0.0)	(0.0, 0.0)
Teratoma	1 (0.0)	(0.0, 0.0)
Transitional cell carcinoma	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	23 (0.1)	(0.1, 0.2)
Syncope	5 (0.0)	(0.0, 0.1)
Transient ischaemic attack	3 (0.0)	(0.0, 0.0)
Ischaemic stroke	2 (0.0)	(0.0, 0.0)
Spinal cord compression	1 (0.0)	(0.0, 0.0)
Amnesia	1 (0.0)	(0.0, 0.0)
Amyotrophic lateral sclerosis	1 (0.0)	(0.0, 0.0)

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14.59. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Race, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Race: White

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=18025) n[b] (%)	 (95% CI[c])
Cerebral infarction	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	1 (0.0)	(0.0, 0.0)
Cervicogenic headache	1 (0.0)	(0.0, 0.0)
Dementia Alzheimer's type	1 (0.0)	(0.0, 0.0)
Dizziness	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	1 (0.0)	(0.0, 0.0)
Intraventricular haemorrhage	1 (0.0)	(0.0, 0.0)
Paraesthesia	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	4 (0.0)	(0.0, 0.1)
Abortion spontaneous	3 (0.0)	(0.0, 0.0)
Abortion incomplete	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	7 (0.0)	(0.0, 0.1)
Bipolar disorder	2 (0.0)	(0.0, 0.0)
Major depression	2 (0.0)	(0.0, 0.0)
Suicidal ideation	2 (0.0)	(0.0, 0.0)
Affective disorder	1 (0.0)	(0.0, 0.0)
Alcohol withdrawal syndrome	1 (0.0)	(0.0, 0.0)
Depression suicidal	1 (0.0)	(0.0, 0.0)
Drug dependence	1 (0.0)	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	7 (0.0)	(0.0, 0.1)
Nephrolithiasis	6 (0.0)	(0.0, 0.1)
Hydronephrosis	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	7 (0.0)	(0.0, 0.1)
Adnexal torsion	2 (0.0)	(0.0, 0.0)
Adenomyosis	1 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)
Ovarian mass	1 (0.0)	(0.0, 0.0)
Rectocele	1 (0.0)	(0.0, 0.0)
Vaginal prolapse	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	12 (0.1)	(0.0, 0.1)
Pulmonary embolism	5 (0.0)	(0.0, 0.1)

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14.59. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Race, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Race: White

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=18025) n[b] (%)	 (95% CI[c])
Acute respiratory failure	2 (0.0)	(0.0, 0.0)
Asthmatic crisis	1 (0.0)	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)
Pulmonary mass	1 (0.0)	(0.0, 0.0)
Respiratory arrest	1 (0.0)	(0.0, 0.0)
Respiratory failure	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	1 (0.0)	(0.0, 0.0)
Miscarriage of partner	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	12 (0.1)	(0.0, 0.1)
Deep vein thrombosis	4 (0.0)	(0.0, 0.1)
Aortic stenosis	2 (0.0)	(0.0, 0.0)
Orthostatic hypotension	2 (0.0)	(0.0, 0.0)
Accelerated hypertension	1 (0.0)	(0.0, 0.0)
Aortic dissection	1 (0.0)	(0.0, 0.0)
Hypertensive emergency	1 (0.0)	(0.0, 0.0)
Peripheral artery stenosis	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
Note: All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:03)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2p_race

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14.60. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Race, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Race: Black or African American

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=2055) n[b] (%)	(95% CI[c])
Any adverse event	23 (1.1)	(0.7, 1.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	3 (0.1)	(0.0, 0.4)
Thrombocytopenia	1 (0.0)	(0.0, 0.3)
Anaemia	1 (0.0)	(0.0, 0.3)
Microcytic anaemia	1 (0.0)	(0.0, 0.3)
CARDIAC DISORDERS	3 (0.1)	(0.0, 0.4)
Myocardial infarction	1 (0.0)	(0.0, 0.3)
Cardiac arrest	1 (0.0)	(0.0, 0.3)
Cardiac failure acute	1 (0.0)	(0.0, 0.3)
GASTROINTESTINAL DISORDERS	2 (0.1)	(0.0, 0.4)
Gastrointestinal mucosa hyperaemia	1 (0.0)	(0.0, 0.3)
Ileus	1 (0.0)	(0.0, 0.3)
Volvulus	1 (0.0)	(0.0, 0.3)
INFECTIONS AND INFESTATIONS	5 (0.2)	(0.1, 0.6)
Pneumonia	2 (0.1)	(0.0, 0.4)
Cellulitis	1 (0.0)	(0.0, 0.3)
Meningitis bacterial	1 (0.0)	(0.0, 0.3)
Pneumonia aspiration	1 (0.0)	(0.0, 0.3)
Subcutaneous abscess	1 (0.0)	(0.0, 0.3)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.1)	(0.0, 0.4)
Road traffic accident	1 (0.0)	(0.0, 0.3)
Rib fracture	1 (0.0)	(0.0, 0.3)
Spinal column injury	1 (0.0)	(0.0, 0.3)
Subdural haematoma	1 (0.0)	(0.0, 0.3)
Toxicity to various agents	1 (0.0)	(0.0, 0.3)
Traumatic haemothorax	1 (0.0)	(0.0, 0.3)
INVESTIGATIONS	2 (0.1)	(0.0, 0.4)
Blood pressure increased	1 (0.0)	(0.0, 0.3)
Red blood cell morphology abnormal	1 (0.0)	(0.0, 0.3)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.3)
Type 2 diabetes mellitus	1 (0.0)	(0.0, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.3)
Arthralgia	1 (0.0)	(0.0, 0.3)

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14.60. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Race, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Race: Black or African American

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=2055) n[b] (%)	(95% CI[c])
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5 (0.2)	(0.1, 0.6)
Uterine leiomyoma	2 (0.1)	(0.0, 0.4)
Lung adenocarcinoma	1 (0.0)	(0.0, 0.3)
Pancreatic carcinoma	1 (0.0)	(0.0, 0.3)
Pancreatic neuroendocrine tumour	1 (0.0)	(0.0, 0.3)
NERVOUS SYSTEM DISORDERS	1 (0.0)	(0.0, 0.3)
Spinal cord compression	1 (0.0)	(0.0, 0.3)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2 (0.1)	(0.0, 0.4)
Abortion spontaneous incomplete	1 (0.0)	(0.0, 0.3)
Retained products of conception	1 (0.0)	(0.0, 0.3)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.3)
Suicide attempt	1 (0.0)	(0.0, 0.3)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.3)
Endometriosis	1 (0.0)	(0.0, 0.3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (0.1)	(0.0, 0.4)
Pulmonary embolism	2 (0.1)	(0.0, 0.4)
Hypoxia	1 (0.0)	(0.0, 0.3)
Pneumothorax	1 (0.0)	(0.0, 0.3)
VASCULAR DISORDERS	1 (0.0)	(0.0, 0.3)
Superficial vein thrombosis	1 (0.0)	(0.0, 0.3)

Note: MedDRA (v25.1) coding dictionary applied.
Note: All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:03)
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14.61. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Race, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Race: All Others

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=1831) n[b] (%)	 (95% CI[c])
Any adverse event	9 (0.5)	(0.2, 0.9)
CARDIAC DISORDERS	1 (0.1)	(0.0, 0.3)
Atrial fibrillation	1 (0.1)	(0.0, 0.3)
GASTROINTESTINAL DISORDERS	1 (0.1)	(0.0, 0.3)
Oesophageal varices haemorrhage	1 (0.1)	(0.0, 0.3)
INFECTIONS AND INFESTATIONS	2 (0.1)	(0.0, 0.4)
Urinary tract infection	1 (0.1)	(0.0, 0.3)
Meningitis bacterial	1 (0.1)	(0.0, 0.3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.1)	(0.0, 0.4)
Bladder cancer	1 (0.1)	(0.0, 0.3)
Breast cancer stage I	1 (0.1)	(0.0, 0.3)
NERVOUS SYSTEM DISORDERS	1 (0.1)	(0.0, 0.3)
Guillain-Barre syndrome	1 (0.1)	(0.0, 0.3)
PSYCHIATRIC DISORDERS	2 (0.1)	(0.0, 0.4)
Alcohol abuse	1 (0.1)	(0.0, 0.3)
Depression	1 (0.1)	(0.0, 0.3)

Note: MedDRA (v25.1) coding dictionary applied.
Note: All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.62. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Sex, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Sex: Male

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=11023) n[b] (%)	(95% CI[c])
Any adverse event	152 (1.4)	(1.2, 1.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)
Thrombocytopenia	2 (0.0)	(0.0, 0.1)
Anaemia	1 (0.0)	(0.0, 0.1)
Neutropenia	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	32 (0.3)	(0.2, 0.4)
Atrial fibrillation	7 (0.1)	(0.0, 0.1)
Myocardial infarction	6 (0.1)	(0.0, 0.1)
Acute coronary syndrome	2 (0.0)	(0.0, 0.1)
Acute myocardial infarction	3 (0.0)	(0.0, 0.1)
Coronary artery disease	3 (0.0)	(0.0, 0.1)
Aortic valve incompetence	2 (0.0)	(0.0, 0.1)
Cardiac arrest	1 (0.0)	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.1)
Arteriosclerosis coronary artery	1 (0.0)	(0.0, 0.1)
Cardiac failure chronic	1 (0.0)	(0.0, 0.1)
Cardiac failure congestive	1 (0.0)	(0.0, 0.1)
Cardio-respiratory arrest	1 (0.0)	(0.0, 0.1)
Coronary artery occlusion	1 (0.0)	(0.0, 0.1)
Mitral valve prolapse	1 (0.0)	(0.0, 0.1)
Pericardial haemorrhage	1 (0.0)	(0.0, 0.1)
Tachyarrhythmia	1 (0.0)	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2 (0.0)	(0.0, 0.1)
Congenital bladder neck obstruction	1 (0.0)	(0.0, 0.1)
Congenital ureteropelvic junction obstruction	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.1)
Vertigo	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	3 (0.0)	(0.0, 0.1)
Eye haemorrhage	1 (0.0)	(0.0, 0.1)
Retinal artery occlusion	1 (0.0)	(0.0, 0.1)
Visual impairment	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	9 (0.1)	(0.0, 0.2)
Pancreatitis acute	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	1 (0.0)	(0.0, 0.1)

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14.62. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Sex, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Sex: Male

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=11023) n[b] (%)	 (95% CI[c])
Anal fistula	1 (0.0)	(0.0, 0.1)
Diverticular perforation	1 (0.0)	(0.0, 0.1)
Hiatus hernia	1 (0.0)	(0.0, 0.1)
Inguinal hernia	1 (0.0)	(0.0, 0.1)
Intestinal obstruction	1 (0.0)	(0.0, 0.1)
Oesophageal varices haemorrhage	1 (0.0)	(0.0, 0.1)
Retroperitoneal haematoma	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.1)
Multiple organ dysfunction syndrome	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	4 (0.0)	(0.0, 0.1)
Cholecystitis acute	2 (0.0)	(0.0, 0.1)
Cholecystitis	1 (0.0)	(0.0, 0.1)
Cholelithiasis	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)
Anaphylactic shock	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	34 (0.3)	(0.2, 0.4)
COVID-19	8 (0.1)	(0.0, 0.1)
Appendicitis	5 (0.0)	(0.0, 0.1)
Pneumonia	6 (0.1)	(0.0, 0.1)
Urinary tract infection	1 (0.0)	(0.0, 0.1)
COVID-19 pneumonia	1 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)
Meningitis bacterial	1 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	1 (0.0)	(0.0, 0.1)
Abdominal abscess	1 (0.0)	(0.0, 0.1)
Diverticulitis	1 (0.0)	(0.0, 0.1)
Extradural abscess	1 (0.0)	(0.0, 0.1)
Gastroenteritis	1 (0.0)	(0.0, 0.1)
Osteomyelitis	1 (0.0)	(0.0, 0.1)
Pneumonia aspiration	1 (0.0)	(0.0, 0.1)
Pyelonephritis	1 (0.0)	(0.0, 0.1)
Staphylococcal sepsis	1 (0.0)	(0.0, 0.1)
Subacute endocarditis	1 (0.0)	(0.0, 0.1)
Subcutaneous abscess	1 (0.0)	(0.0, 0.1)
Tooth infection	1 (0.0)	(0.0, 0.1)

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14.62. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Sex, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Sex: Male

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=11023) n[b] (%)	 (95% CI[c])
Urosepsis	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	12 (0.1)	(0.1, 0.2)
Road traffic accident	1 (0.0)	(0.0, 0.1)
Foot fracture	1 (0.0)	(0.0, 0.1)
Lower limb fracture	1 (0.0)	(0.0, 0.1)
Brain contusion	1 (0.0)	(0.0, 0.1)
Colon injury	1 (0.0)	(0.0, 0.1)
Concussion	1 (0.0)	(0.0, 0.1)
Delayed recovery from anaesthesia	1 (0.0)	(0.0, 0.1)
Fall	1 (0.0)	(0.0, 0.1)
Forearm fracture	1 (0.0)	(0.0, 0.1)
Ligament rupture	1 (0.0)	(0.0, 0.1)
Meniscus injury	1 (0.0)	(0.0, 0.1)
Overdose	1 (0.0)	(0.0, 0.1)
Post procedural haematoma	1 (0.0)	(0.0, 0.1)
Toxicity to various agents	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	3 (0.0)	(0.0, 0.1)
Blood glucose abnormal	1 (0.0)	(0.0, 0.1)
Blood pressure increased	1 (0.0)	(0.0, 0.1)
Hepatic enzyme increased	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	8 (0.1)	(0.0, 0.1)
Hyperglycaemia	2 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	2 (0.0)	(0.0, 0.1)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.1)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.1)
Hypokalaemia	1 (0.0)	(0.0, 0.1)
Hyponatraemia	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	9 (0.1)	(0.0, 0.2)
Osteoarthritis	3 (0.0)	(0.0, 0.1)
Arthralgia	1 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)
Cervical spinal stenosis	1 (0.0)	(0.0, 0.1)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.1)
Lumbar spinal stenosis	1 (0.0)	(0.0, 0.1)
Muscular weakness	1 (0.0)	(0.0, 0.1)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.1)

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14.62. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Sex, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Sex: Male

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=11023) n[b] (%)	 (95% CI[c])
Thoracic spinal stenosis	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	15 (0.1)	(0.1, 0.2)
Malignant melanoma	2 (0.0)	(0.0, 0.1)
Pancreatic carcinoma	2 (0.0)	(0.0, 0.1)
Prostate cancer	2 (0.0)	(0.0, 0.1)
Biliary cancer metastatic	1 (0.0)	(0.0, 0.1)
Bladder cancer	1 (0.0)	(0.0, 0.1)
Chronic myeloid leukaemia	1 (0.0)	(0.0, 0.1)
Clear cell renal cell carcinoma	1 (0.0)	(0.0, 0.1)
Metastases to liver	1 (0.0)	(0.0, 0.1)
Neuroendocrine tumour	1 (0.0)	(0.0, 0.1)
Non-Hodgkin's lymphoma recurrent	1 (0.0)	(0.0, 0.1)
Oropharyngeal cancer recurrent	1 (0.0)	(0.0, 0.1)
Polycythaemia vera	1 (0.0)	(0.0, 0.1)
Squamous cell carcinoma of head and neck	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	13 (0.1)	(0.1, 0.2)
Syncope	4 (0.0)	(0.0, 0.1)
Transient ischaemic attack	1 (0.0)	(0.0, 0.1)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)
Spinal cord compression	1 (0.0)	(0.0, 0.1)
Amnesia	1 (0.0)	(0.0, 0.1)
Amyotrophic lateral sclerosis	1 (0.0)	(0.0, 0.1)
Dizziness	1 (0.0)	(0.0, 0.1)
Guillain-Barre syndrome	1 (0.0)	(0.0, 0.1)
Intraventricular haemorrhage	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	7 (0.1)	(0.0, 0.1)
Bipolar disorder	2 (0.0)	(0.0, 0.1)
Major depression	2 (0.0)	(0.0, 0.1)
Suicidal ideation	2 (0.0)	(0.0, 0.1)
Affective disorder	1 (0.0)	(0.0, 0.1)
Alcohol withdrawal syndrome	1 (0.0)	(0.0, 0.1)
Depression	1 (0.0)	(0.0, 0.1)
Drug dependence	1 (0.0)	(0.0, 0.1)
Panic attack	1 (0.0)	(0.0, 0.1)
Psychotic disorder	1 (0.0)	(0.0, 0.1)

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14.62. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Sex, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Sex: Male

	Vaccine Group (as Administered)	
	Placebo (N[a]=11023)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
RENAL AND URINARY DISORDERS	3 (0.0)	(0.0, 0.1)
Nephrolithiasis	3 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	8 (0.1)	(0.0, 0.1)
Pulmonary embolism	5 (0.0)	(0.0, 0.1)
Hypoxia	1 (0.0)	(0.0, 0.1)
Interstitial lung disease	1 (0.0)	(0.0, 0.1)
Respiratory arrest	1 (0.0)	(0.0, 0.1)
Respiratory failure	1 (0.0)	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	1 (0.0)	(0.0, 0.1)
Miscarriage of partner	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	9 (0.1)	(0.0, 0.2)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)
Aortic stenosis	2 (0.0)	(0.0, 0.1)
Orthostatic hypotension	2 (0.0)	(0.0, 0.1)
Accelerated hypertension	1 (0.0)	(0.0, 0.1)
Aortic dissection	1 (0.0)	(0.0, 0.1)
Hypertensive emergency	1 (0.0)	(0.0, 0.1)
Peripheral artery stenosis	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:03)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2p_sex

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14.63. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Sex, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=10888) n[b] (%)	(95% CI[c])
Any adverse event	139 (1.3)	(1.1, 1.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)
Microcytic anaemia	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	10 (0.1)	(0.0, 0.2)
Atrial fibrillation	2 (0.0)	(0.0, 0.1)
Myocardial infarction	1 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)
Cardiac arrest	1 (0.0)	(0.0, 0.1)
Arteriospasm coronary	1 (0.0)	(0.0, 0.1)
Bradycardia	1 (0.0)	(0.0, 0.1)
Cardiac failure acute	1 (0.0)	(0.0, 0.1)
Junctional ectopic tachycardia	1 (0.0)	(0.0, 0.1)
Tachycardia	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	13 (0.1)	(0.1, 0.2)
Pancreatitis acute	2 (0.0)	(0.0, 0.1)
Small intestinal obstruction	1 (0.0)	(0.0, 0.1)
Abdominal pain upper	1 (0.0)	(0.0, 0.1)
Colitis ischaemic	1 (0.0)	(0.0, 0.1)
Constipation	1 (0.0)	(0.0, 0.1)
Diverticulum intestinal	1 (0.0)	(0.0, 0.1)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)
Gastrointestinal mucosa hyperaemia	1 (0.0)	(0.0, 0.1)
Ileus	1 (0.0)	(0.0, 0.1)
Large intestine perforation	1 (0.0)	(0.0, 0.1)
Oesophageal food impaction	1 (0.0)	(0.0, 0.1)
Pancreatic cyst	1 (0.0)	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)
Salivary gland calculus	1 (0.0)	(0.0, 0.1)
Umbilical hernia	1 (0.0)	(0.0, 0.1)
Volvulus	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (0.0)	(0.0, 0.1)
Death	1 (0.0)	(0.0, 0.1)
Influenza like illness	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	3 (0.0)	(0.0, 0.1)
Cholecystitis acute	1 (0.0)	(0.0, 0.1)

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14.63. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Sex, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=10888) n[b] (%)	 (95% CI[c])
Cholecystitis chronic	1 (0.0)	(0.0, 0.1)
Hepatocellular injury	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	27 (0.2)	(0.2, 0.4)
COVID-19	5 (0.0)	(0.0, 0.1)
Appendicitis	4 (0.0)	(0.0, 0.1)
Pneumonia	2 (0.0)	(0.0, 0.1)
Urinary tract infection	4 (0.0)	(0.0, 0.1)
COVID-19 pneumonia	1 (0.0)	(0.0, 0.1)
Complicated appendicitis	2 (0.0)	(0.0, 0.1)
Meningitis bacterial	1 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)
Brain abscess	1 (0.0)	(0.0, 0.1)
Diabetic foot infection	1 (0.0)	(0.0, 0.1)
Gastroenteritis bacterial	1 (0.0)	(0.0, 0.1)
Peritonitis	1 (0.0)	(0.0, 0.1)
Peritonsillar abscess	1 (0.0)	(0.0, 0.1)
Post procedural infection	1 (0.0)	(0.0, 0.1)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)
Renal abscess	1 (0.0)	(0.0, 0.1)
Sepsis	1 (0.0)	(0.0, 0.1)
Septic shock	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	14 (0.1)	(0.1, 0.2)
Road traffic accident	2 (0.0)	(0.0, 0.1)
Foot fracture	1 (0.0)	(0.0, 0.1)
Humerus fracture	2 (0.0)	(0.0, 0.1)
Lower limb fracture	1 (0.0)	(0.0, 0.1)
Craniocerebral injury	1 (0.0)	(0.0, 0.1)
Femur fracture	1 (0.0)	(0.0, 0.1)
Flail chest	1 (0.0)	(0.0, 0.1)
Head injury	1 (0.0)	(0.0, 0.1)
Hip fracture	1 (0.0)	(0.0, 0.1)
Multiple injuries	1 (0.0)	(0.0, 0.1)
Post-traumatic pain	1 (0.0)	(0.0, 0.1)
Procedural haemorrhage	1 (0.0)	(0.0, 0.1)
Radius fracture	1 (0.0)	(0.0, 0.1)
Rib fracture	1 (0.0)	(0.0, 0.1)

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14.63. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Sex, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=10888) n[b] (%)	 (95% CI[c])
Spinal column injury	1 (0.0)	(0.0, 0.1)
Subdural haematoma	1 (0.0)	(0.0, 0.1)
Traumatic haemothorax	1 (0.0)	(0.0, 0.1)
Ulna fracture	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	1 (0.0)	(0.0, 0.1)
Red blood cell morphology abnormal	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	3 (0.0)	(0.0, 0.1)
Hypoglycaemia	2 (0.0)	(0.0, 0.1)
Hypocalcaemia	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	6 (0.1)	(0.0, 0.1)
Osteoarthritis	3 (0.0)	(0.0, 0.1)
Arthralgia	1 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)
Spondylolisthesis	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	31 (0.3)	(0.2, 0.4)
Malignant melanoma	3 (0.0)	(0.0, 0.1)
Breast cancer	4 (0.0)	(0.0, 0.1)
Uterine leiomyoma	4 (0.0)	(0.0, 0.1)
Basal cell carcinoma	2 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	2 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	2 (0.0)	(0.0, 0.1)
Lung adenocarcinoma	2 (0.0)	(0.0, 0.1)
Metastases to lymph nodes	2 (0.0)	(0.0, 0.1)
Papillary thyroid cancer	2 (0.0)	(0.0, 0.1)
B-cell lymphoma	1 (0.0)	(0.0, 0.1)
Breast cancer stage I	1 (0.0)	(0.0, 0.1)
Endometrial adenocarcinoma	1 (0.0)	(0.0, 0.1)
Lobular breast carcinoma in situ	1 (0.0)	(0.0, 0.1)
Pancreatic neuroendocrine tumour	1 (0.0)	(0.0, 0.1)
Papillary serous endometrial carcinoma	1 (0.0)	(0.0, 0.1)
Parathyroid tumour benign	1 (0.0)	(0.0, 0.1)
Pituitary tumour benign	1 (0.0)	(0.0, 0.1)
Teratoma	1 (0.0)	(0.0, 0.1)
Transitional cell carcinoma	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	12 (0.1)	(0.1, 0.2)

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14.63. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Sex, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=10888) n[b] (%)	 (95% CI[c])
Syncope	1 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)
Spinal cord compression	1 (0.0)	(0.0, 0.1)
Cerebral infarction	1 (0.0)	(0.0, 0.1)
Cerebrovascular accident	1 (0.0)	(0.0, 0.1)
Cervicogenic headache	1 (0.0)	(0.0, 0.1)
Dementia Alzheimer's type	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	1 (0.0)	(0.0, 0.1)
Hemiplegic migraine	1 (0.0)	(0.0, 0.1)
Paraesthesia	1 (0.0)	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	6 (0.1)	(0.0, 0.1)
Abortion spontaneous	3 (0.0)	(0.0, 0.1)
Abortion incomplete	1 (0.0)	(0.0, 0.1)
Abortion spontaneous incomplete	1 (0.0)	(0.0, 0.1)
Retained products of conception	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	3 (0.0)	(0.0, 0.1)
Alcohol abuse	1 (0.0)	(0.0, 0.1)
Depression suicidal	1 (0.0)	(0.0, 0.1)
Suicide attempt	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	4 (0.0)	(0.0, 0.1)
Nephrolithiasis	3 (0.0)	(0.0, 0.1)
Hydronephrosis	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	7 (0.1)	(0.0, 0.1)
Adnexal torsion	2 (0.0)	(0.0, 0.1)
Adenomyosis	1 (0.0)	(0.0, 0.1)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)
Endometriosis	1 (0.0)	(0.0, 0.1)
Ovarian mass	1 (0.0)	(0.0, 0.1)
Rectocele	1 (0.0)	(0.0, 0.1)
Vaginal prolapse	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	7 (0.1)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.1)
Acute respiratory failure	2 (0.0)	(0.0, 0.1)
Asthmatic crisis	1 (0.0)	(0.0, 0.1)
Dyspnoea	1 (0.0)	(0.0, 0.1)

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14.63. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Sex, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Sex: Female

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=10888) n[b] (%)	 (95% CI[c])
Pneumothorax	1 (0.0)	(0.0, 0.1)
Pulmonary mass	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	4 (0.0)	(0.0, 0.1)
Deep vein thrombosis	3 (0.0)	(0.0, 0.1)
Superficial vein thrombosis	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:03)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2p_sex

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14.64. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Ethnicity, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population – Ethnicity: Hispanic/Latino

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=5683) n[b] (%)	 (95% CI[c])
Any adverse event	93 (1.6)	(1.3, 2.0)
CARDIAC DISORDERS	7 (0.1)	(0.0, 0.3)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)
Aortic valve incompetence	1 (0.0)	(0.0, 0.1)
Arteriosclerosis coronary artery	1 (0.0)	(0.0, 0.1)
Cardiac failure chronic	1 (0.0)	(0.0, 0.1)
Cardio-respiratory arrest	1 (0.0)	(0.0, 0.1)
Junctional ectopic tachycardia	1 (0.0)	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)
Congenital bladder neck obstruction	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	5 (0.1)	(0.0, 0.2)
Pancreatitis acute	1 (0.0)	(0.0, 0.1)
Anal fistula	1 (0.0)	(0.0, 0.1)
Diverticular perforation	1 (0.0)	(0.0, 0.1)
Oesophageal food impaction	1 (0.0)	(0.0, 0.1)
Pancreatic cyst	1 (0.0)	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (0.0)	(0.0, 0.1)
Influenza like illness	1 (0.0)	(0.0, 0.1)
Multiple organ dysfunction syndrome	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	3 (0.1)	(0.0, 0.2)
Cholecystitis	1 (0.0)	(0.0, 0.1)
Cholecystitis chronic	1 (0.0)	(0.0, 0.1)
Cholelithiasis	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	26 (0.5)	(0.3, 0.7)
COVID-19	6 (0.1)	(0.0, 0.2)
Appendicitis	5 (0.1)	(0.0, 0.2)
Pneumonia	4 (0.1)	(0.0, 0.2)
Urinary tract infection	4 (0.1)	(0.0, 0.2)
Complicated appendicitis	1 (0.0)	(0.0, 0.1)
Abdominal abscess	1 (0.0)	(0.0, 0.1)

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14.64. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Ethnicity, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Ethnicity: Hispanic/Latino

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=5683) n[b] (%)	(95% CI[c])
Extradural abscess	1 (0.0)	(0.0, 0.1)
Gastroenteritis	1 (0.0)	(0.0, 0.1)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)
Pyelonephritis	1 (0.0)	(0.0, 0.1)
Renal abscess	1 (0.0)	(0.0, 0.1)
Septic shock	1 (0.0)	(0.0, 0.1)
Staphylococcal sepsis	1 (0.0)	(0.0, 0.1)
Subacute endocarditis	1 (0.0)	(0.0, 0.1)
Urosepsis	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	9 (0.2)	(0.1, 0.3)
Foot fracture	1 (0.0)	(0.0, 0.1)
Humerus fracture	2 (0.0)	(0.0, 0.1)
Femur fracture	1 (0.0)	(0.0, 0.1)
Forearm fracture	1 (0.0)	(0.0, 0.1)
Ligament rupture	1 (0.0)	(0.0, 0.1)
Meniscus injury	1 (0.0)	(0.0, 0.1)
Multiple injuries	1 (0.0)	(0.0, 0.1)
Procedural haemorrhage	1 (0.0)	(0.0, 0.1)
Ulna fracture	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	1 (0.0)	(0.0, 0.1)
Blood glucose abnormal	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	5 (0.1)	(0.0, 0.2)
Hyperglycaemia	1 (0.0)	(0.0, 0.1)
Hypoglycaemia	2 (0.0)	(0.0, 0.1)
Hypocalcaemia	1 (0.0)	(0.0, 0.1)
Hyponatraemia	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)
Osteoarthritis	1 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	10 (0.2)	(0.1, 0.3)
Basal cell carcinoma	2 (0.0)	(0.0, 0.1)
Papillary thyroid cancer	2 (0.0)	(0.0, 0.1)
Clear cell renal cell carcinoma	1 (0.0)	(0.0, 0.1)
Endometrial adenocarcinoma	1 (0.0)	(0.0, 0.1)

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14.64. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Ethnicity, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Ethnicity: Hispanic/Latino

System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=5683) n[b] (%)	(95% CI[c])
Non-Hodgkin's lymphoma recurrent	1 (0.0)	(0.0, 0.1)
Pituitary tumour benign	1 (0.0)	(0.0, 0.1)
Polycythaemia vera	1 (0.0)	(0.0, 0.1)
Transitional cell carcinoma	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	10 (0.2)	(0.1, 0.3)
Syncope	3 (0.1)	(0.0, 0.2)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)
Ischaemic stroke	2 (0.0)	(0.0, 0.1)
Amyotrophic lateral sclerosis	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2 (0.0)	(0.0, 0.1)
Abortion spontaneous	1 (0.0)	(0.0, 0.1)
Abortion incomplete	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.1)
Bipolar disorder	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	5 (0.1)	(0.0, 0.2)
Nephrolithiasis	5 (0.1)	(0.0, 0.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.1)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)
Rectocele	1 (0.0)	(0.0, 0.1)
Vaginal prolapse	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	5 (0.1)	(0.0, 0.2)
Pulmonary embolism	2 (0.0)	(0.0, 0.1)
Acute respiratory failure	1 (0.0)	(0.0, 0.1)
Asthmatic crisis	1 (0.0)	(0.0, 0.1)
Pulmonary mass	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	6 (0.1)	(0.0, 0.2)
Deep vein thrombosis	2 (0.0)	(0.0, 0.1)
Aortic stenosis	2 (0.0)	(0.0, 0.1)
Orthostatic hypotension	1 (0.0)	(0.0, 0.1)
Hypertensive emergency	1 (0.0)	(0.0, 0.1)

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14.64. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Ethnicity, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)
	Placebo (N[a]=5683)
System Organ Class Preferred Term	n[b] (%) (95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:03)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2p_eth

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14.65. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Ethnicity, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)	
	Placebo (N[a]=16129)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any adverse event	197 (1.2)	(1.1, 1.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	4 (0.0)	(0.0, 0.1)
Thrombocytopenia	2 (0.0)	(0.0, 0.0)
Anaemia	1 (0.0)	(0.0, 0.0)
Microcytic anaemia	1 (0.0)	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	35 (0.2)	(0.2, 0.3)
Atrial fibrillation	9 (0.1)	(0.0, 0.1)
Myocardial infarction	7 (0.0)	(0.0, 0.1)
Acute coronary syndrome	2 (0.0)	(0.0, 0.0)
Acute myocardial infarction	2 (0.0)	(0.0, 0.0)
Coronary artery disease	3 (0.0)	(0.0, 0.1)
Aortic valve incompetence	1 (0.0)	(0.0, 0.0)
Cardiac arrest	2 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)
Arteriospasm coronary	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)
Cardiac failure acute	1 (0.0)	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.0)
Coronary artery occlusion	1 (0.0)	(0.0, 0.0)
Mitral valve prolapse	1 (0.0)	(0.0, 0.0)
Pericardial haemorrhage	1 (0.0)	(0.0, 0.0)
Tachyarrhythmia	1 (0.0)	(0.0, 0.0)
Tachycardia	1 (0.0)	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)
Congenital ureteropelvic junction obstruction	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	3 (0.0)	(0.0, 0.1)
Eye haemorrhage	1 (0.0)	(0.0, 0.0)
Retinal artery occlusion	1 (0.0)	(0.0, 0.0)
Visual impairment	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	17 (0.1)	(0.1, 0.2)
Pancreatitis acute	2 (0.0)	(0.0, 0.0)

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System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=16129) n[b] (%)	(95% CI[c])
Small intestinal obstruction	2 (0.0)	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)
Colitis ischaemic	1 (0.0)	(0.0, 0.0)
Constipation	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)
Gastrointestinal mucosa hyperaemia	1 (0.0)	(0.0, 0.0)
Hiatus hernia	1 (0.0)	(0.0, 0.0)
Ileus	1 (0.0)	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	1 (0.0)	(0.0, 0.0)
Large intestine perforation	1 (0.0)	(0.0, 0.0)
Oesophageal varices haemorrhage	1 (0.0)	(0.0, 0.0)
Retroperitoneal haematoma	1 (0.0)	(0.0, 0.0)
Salivary gland calculus	1 (0.0)	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)
Volvulus	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (0.0)	(0.0, 0.0)
Chest pain	1 (0.0)	(0.0, 0.0)
Death	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	4 (0.0)	(0.0, 0.1)
Cholecystitis acute	3 (0.0)	(0.0, 0.1)
Hepatocellular injury	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)
Anaphylactic shock	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	35 (0.2)	(0.2, 0.3)
COVID-19	7 (0.0)	(0.0, 0.1)
Appendicitis	4 (0.0)	(0.0, 0.1)
Pneumonia	4 (0.0)	(0.0, 0.1)
Urinary tract infection	1 (0.0)	(0.0, 0.0)
COVID-19 pneumonia	2 (0.0)	(0.0, 0.0)
Cellulitis	2 (0.0)	(0.0, 0.0)
Complicated appendicitis	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	2 (0.0)	(0.0, 0.0)
Upper respiratory tract infection	2 (0.0)	(0.0, 0.0)

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System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=16129) n[b] (%)	(95% CI[c])
Appendicitis perforated	1 (0.0)	(0.0, 0.0)
Brain abscess	1 (0.0)	(0.0, 0.0)
Diabetic foot infection	1 (0.0)	(0.0, 0.0)
Diverticulitis	1 (0.0)	(0.0, 0.0)
Gastroenteritis bacterial	1 (0.0)	(0.0, 0.0)
Osteomyelitis	1 (0.0)	(0.0, 0.0)
Peritonitis	1 (0.0)	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)
Post procedural infection	1 (0.0)	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.0)
Tooth infection	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	17 (0.1)	(0.1, 0.2)
Road traffic accident	3 (0.0)	(0.0, 0.1)
Foot fracture	1 (0.0)	(0.0, 0.0)
Lower limb fracture	2 (0.0)	(0.0, 0.0)
Brain contusion	1 (0.0)	(0.0, 0.0)
Colon injury	1 (0.0)	(0.0, 0.0)
Concussion	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	1 (0.0)	(0.0, 0.0)
Delayed recovery from anaesthesia	1 (0.0)	(0.0, 0.0)
Fall	1 (0.0)	(0.0, 0.0)
Flail chest	1 (0.0)	(0.0, 0.0)
Head injury	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.0)
Post procedural haematoma	1 (0.0)	(0.0, 0.0)
Post-traumatic pain	1 (0.0)	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.0)
Rib fracture	1 (0.0)	(0.0, 0.0)
Spinal column injury	1 (0.0)	(0.0, 0.0)
Subdural haematoma	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	1 (0.0)	(0.0, 0.0)
Traumatic haemothorax	1 (0.0)	(0.0, 0.0)

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System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=16129) n[b] (%)	(95% CI[c])
INVESTIGATIONS	3 (0.0)	(0.0, 0.1)
Blood pressure increased	1 (0.0)	(0.0, 0.0)
Hepatic enzyme increased	1 (0.0)	(0.0, 0.0)
Red blood cell morphology abnormal	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	6 (0.0)	(0.0, 0.1)
Hyperglycaemia	1 (0.0)	(0.0, 0.0)
Type 2 diabetes mellitus	2 (0.0)	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)
Hypokalaemia	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	13 (0.1)	(0.0, 0.1)
Osteoarthritis	5 (0.0)	(0.0, 0.1)
Arthralgia	2 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.0)
Cervical spinal stenosis	1 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)
Lumbar spinal stenosis	1 (0.0)	(0.0, 0.0)
Muscular weakness	1 (0.0)	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.0)
Spondylolisthesis	1 (0.0)	(0.0, 0.0)
Thoracic spinal stenosis	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	36 (0.2)	(0.2, 0.3)
Malignant melanoma	5 (0.0)	(0.0, 0.1)
Breast cancer	4 (0.0)	(0.0, 0.1)
Uterine leiomyoma	4 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	2 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	2 (0.0)	(0.0, 0.0)
Lung adenocarcinoma	2 (0.0)	(0.0, 0.0)
Metastases to lymph nodes	2 (0.0)	(0.0, 0.0)
Pancreatic carcinoma	2 (0.0)	(0.0, 0.0)
Prostate cancer	2 (0.0)	(0.0, 0.0)
B-cell lymphoma	1 (0.0)	(0.0, 0.0)
Biliary cancer metastatic	1 (0.0)	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.0)

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System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=16129) n[b] (%)	 (95% CI[c])
Breast cancer stage I	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	1 (0.0)	(0.0, 0.0)
Lobular breast carcinoma in situ	1 (0.0)	(0.0, 0.0)
Metastases to liver	1 (0.0)	(0.0, 0.0)
Neuroendocrine tumour	1 (0.0)	(0.0, 0.0)
Oropharyngeal cancer recurrent	1 (0.0)	(0.0, 0.0)
Pancreatic neuroendocrine tumour	1 (0.0)	(0.0, 0.0)
Papillary serous endometrial carcinoma	1 (0.0)	(0.0, 0.0)
Parathyroid tumour benign	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma of head and neck	1 (0.0)	(0.0, 0.0)
Teratoma	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	15 (0.1)	(0.1, 0.2)
Syncope	2 (0.0)	(0.0, 0.0)
Transient ischaemic attack	1 (0.0)	(0.0, 0.0)
Spinal cord compression	2 (0.0)	(0.0, 0.0)
Amnesia	1 (0.0)	(0.0, 0.0)
Cerebral infarction	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	1 (0.0)	(0.0, 0.0)
Cervicogenic headache	1 (0.0)	(0.0, 0.0)
Dementia Alzheimer's type	1 (0.0)	(0.0, 0.0)
Dizziness	1 (0.0)	(0.0, 0.0)
Guillain-Barre syndrome	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	1 (0.0)	(0.0, 0.0)
Intraventricular haemorrhage	1 (0.0)	(0.0, 0.0)
Paraesthesia	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	4 (0.0)	(0.0, 0.1)
Abortion spontaneous	2 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	1 (0.0)	(0.0, 0.0)
Retained products of conception	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	8 (0.0)	(0.0, 0.1)
Bipolar disorder	1 (0.0)	(0.0, 0.0)
Major depression	2 (0.0)	(0.0, 0.0)
Suicidal ideation	2 (0.0)	(0.0, 0.0)
Affective disorder	1 (0.0)	(0.0, 0.0)
Alcohol abuse	1 (0.0)	(0.0, 0.0)

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System Organ Class Preferred Term	Vaccine Group (as Administered) Placebo (N[a]=16129) n[b] (%)	(95% CI[c])
Alcohol withdrawal syndrome	1 (0.0)	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.0)
Drug dependence	1 (0.0)	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)
Suicide attempt	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	2 (0.0)	(0.0, 0.0)
Nephrolithiasis	1 (0.0)	(0.0, 0.0)
Hydronephrosis	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	6 (0.0)	(0.0, 0.1)
Adnexal torsion	2 (0.0)	(0.0, 0.0)
Adenomyosis	1 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.0)
Endometriosis	1 (0.0)	(0.0, 0.0)
Ovarian mass	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	10 (0.1)	(0.0, 0.1)
Pulmonary embolism	5 (0.0)	(0.0, 0.1)
Acute respiratory failure	1 (0.0)	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.0)
Hypoxia	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)
Pneumothorax	1 (0.0)	(0.0, 0.0)
Respiratory arrest	1 (0.0)	(0.0, 0.0)
Respiratory failure	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	1 (0.0)	(0.0, 0.0)
Miscarriage of partner	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	7 (0.0)	(0.0, 0.1)
Deep vein thrombosis	2 (0.0)	(0.0, 0.0)
Orthostatic hypotension	1 (0.0)	(0.0, 0.0)
Accelerated hypertension	1 (0.0)	(0.0, 0.0)
Aortic dissection	1 (0.0)	(0.0, 0.0)
Peripheral artery stenosis	1 (0.0)	(0.0, 0.0)
Superficial vein thrombosis	1 (0.0)	(0.0, 0.0)

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14.65. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Ethnicity, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)	
	Placebo (N[a]=16129)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:03)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2p_eth

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14.66. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by Ethnicity, by System Organ Class and Preferred Term – Blinded, Placebo-Controlled Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population Ethnicity: Not Reported

	Vaccine Group (as Administered)	
	Placebo (N[a]=99)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any adverse event	1 (1.0)	(0.0, 5.5)
PSYCHIATRIC DISORDERS	1 (1.0)	(0.0, 5.5)
Depression suicidal	1 (1.0)	(0.0, 5.5)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:03)
(Database Snapshot Date: 28APR2023) Output File: /nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2p_eth

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14.67. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Age Group, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=12989)		Original Placebo/BNT162b2 (30 µg) (N[a]=11913)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	183 (1.4)	(1.2, 1.6)	130 (1.1)	(0.9, 1.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	14 (0.1)	(0.1, 0.2)	10 (0.1)	(0.0, 0.2)
Acute myocardial infarction	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myocardial infarction	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cardiac failure congestive	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardio-respiratory arrest	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocardial ischaemia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Palpitations	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pericarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Conduction disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mitral valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
BRCA1 gene mutation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Blindness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retinal detachment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Visual impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	17 (0.1)	(0.1, 0.2)	11 (0.1)	(0.0, 0.2)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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14.67. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Age Group, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=12989)		Original Placebo/BNT162b2 (30 µg) (N[a]=11913)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Intestinal obstruction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis acute	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal adhesions	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Constipation	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrooesophageal reflux disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Obstructive pancreatitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis ulcerative	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Duodenal ulcer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Food poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal necrosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhoids	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hiatus hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impaired gastric emptying	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Incarcerated inguinal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal perforation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nausea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Drug withdrawal syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Death	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Electrocution	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypothermia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Treatment noncompliance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	12 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)
Cholelithiasis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)

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14.67. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Age Group, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=12989)		Original Placebo/BNT162b2 (30 µg) (N[a]=11913)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cholecystitis acute	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bile duct stone	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Biliary colic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute hepatic failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholelithiasis obstructive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Portal vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactoid reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	38 (0.3)	(0.2, 0.4)	16 (0.1)	(0.1, 0.2)
Appendicitis	15 (0.1)	(0.1, 0.2)	0	(0.0, 0.0)
Pneumonia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Diverticulitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary tract infection	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastroenteritis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Appendicitis perforated	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cellulitis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritonitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess limb	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acquired immunodeficiency syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthritis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cellulitis staphylococcal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis infective	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Focal peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gangrene	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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14.67. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Age Group, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=12989)		Original Placebo/BNT162b2 (30 µg) (N[a]=11913)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
HIV infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes zoster oticus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Infected bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lower respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mastoiditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic inflammatory disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory syncytial virus bronchiolitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin candida	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinea pedis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	15 (0.1)	(0.1, 0.2)	18 (0.2)	(0.1, 0.2)
Ankle fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Rib fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Overdose	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Road traffic accident	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Facial bones fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper limb fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fall	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foot fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Head injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ligament rupture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tibia fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Accidental overdose	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Animal bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arthropod bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Burns second degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns third degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Concussion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hand fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=12989)		Original Placebo/BNT162b2 (30 µg) (N[a]=11913)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meniscus injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neck injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Open fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative ileus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scapula fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Splenic rupture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypokalaemia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyperglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoglycaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malnutrition	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	8 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Osteoarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intervertebral disc protrusion	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Intervertebral disc degeneration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Back pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spondylolisthesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arthralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Costochondritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	19 (0.1)	(0.1, 0.2)	15 (0.1)	(0.1, 0.2)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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14.67. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Age Group, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=12989)		Original Placebo/BNT162b2 (30 µg) (N[a]=11913)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma of colon	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast cancer metastatic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endometrial adenocarcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Invasive lobular breast carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Basal cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast cancer stage I	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lung adenocarcinoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Testis cancer	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Benign hydatidiform mole	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clear cell renal cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hormone receptor positive breast cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Laryngeal papilloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lipoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lung cancer metastatic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastatic malignant melanoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mucoepidermoid carcinoma of salivary gland	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuroendocrine carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Plasma cell myeloma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	14 (0.1)	(0.1, 0.2)	14 (0.1)	(0.1, 0.2)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Transient ischaemic attack	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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14.67. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Age Group, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=12989)		Original Placebo/BNT162b2 (30 µg) (N[a]=11913)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Seizure	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Toxic encephalopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Optic neuritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Amyotrophic lateral sclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Brachial plexopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dural arteriovenous fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyskinesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Encephalopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Loss of consciousness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral nerve lesion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Presyncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	6 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Abortion spontaneous	6 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Ectopic pregnancy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	11 (0.1)	(0.0, 0.2)	15 (0.1)	(0.1, 0.2)
Depression	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Bipolar disorder	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Completed suicide	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alcohol withdrawal syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Anxiety	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Drug abuse	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Major depression	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute psychosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcohol abuse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alcoholism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bipolar I disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Obsessive-compulsive disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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14.67. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Age Group, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=12989)		Original Placebo/BNT162b2 (30 µg) (N[a]=11913)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Suicidal behaviour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	9 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Nephrolithiasis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute kidney injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ureterolithiasis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ovarian cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abnormal uterine bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adnexal torsion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endometrial thickening	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endometriosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heavy menstrual bleeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	6 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.2)
Pulmonary embolism	3 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Acute respiratory failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleural effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal septum deviation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pustular psoriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Miscarriage of partner	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pregnancy of partner	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	7 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Deep vein thrombosis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypertensive urgency	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive emergency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Iliac artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=12989)		Original Placebo/BNT162b2 (30 µg) (N[a]=11913)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:05)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/c4591001_CSR/adae_s130_sae_p23_d2b_age

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14.68. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Age Group, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=8921)		Original Placebo/BNT162b2 (30 µg) (N[a]=8354)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	245 (2.7)	(2.4, 3.1)	223 (2.7)	(2.3, 3.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.2)
Anaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Febrile neutropenia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Anaemia macrocytic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood loss anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lymphadenitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pancytopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CARDIAC DISORDERS	50 (0.6)	(0.4, 0.7)	33 (0.4)	(0.3, 0.6)
Acute myocardial infarction	9 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Atrial fibrillation	7 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)
Myocardial infarction	5 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Cardiac failure congestive	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cardiac arrest	6 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Coronary artery disease	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina pectoris	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cardio-respiratory arrest	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ventricular tachycardia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute left ventricular failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coronary artery occlusion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive heart disease	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Palpitations	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ventricular fibrillation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Accelerated idioventricular rhythm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Atrial flutter	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Atrioventricular block complete	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiovascular disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coronary artery dissection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ischaemic cardiomyopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Postural orthostatic tachycardia syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=8921)		Original Placebo/BNT162b2 (30 µg) (N[a]=8354)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Sinus node dysfunction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Supraventricular extrasystoles	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ventricular extrasystoles	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Heart disease congenital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertrophic cardiomyopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vertigo	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eyelid ptosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ophthalmic vein thrombosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Optic ischaemic neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Retinal tear	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	21 (0.2)	(0.1, 0.4)	18 (0.2)	(0.1, 0.3)
Small intestinal obstruction	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Intestinal obstruction	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Pancreatitis acute	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gastrointestinal haemorrhage	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal adhesions	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lower gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal compartment syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal hernia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dental cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diarrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Duodenal obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Enterocolitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastric ulcer haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

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14.68. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Age Group, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=8921)		Original Placebo/BNT162b2 (30 µg) (N[a]=8354)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Intestinal ischaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intestinal strangulation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intestinal ulcer perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oesophageal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pancreatitis necrotising	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peptic ulcer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rectal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Splenic artery aneurysm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper gastrointestinal haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vomiting	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	9 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Chest pain	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Asthenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Impaired healing	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pyrexia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sudden death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	8 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Cholelithiasis	6 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cholecystitis acute	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Autoimmune hepatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Biliary dyskinesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cholangitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Portosplenomesenteric venous thrombosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypersensitivity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	36 (0.4)	(0.3, 0.6)	33 (0.4)	(0.3, 0.6)
Appendicitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Diverticulitis	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

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14.68. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Age Group, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=8921)		Original Placebo/BNT162b2 (30 µg) (N[a]=8354)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Urinary tract infection	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Sepsis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gastroenteritis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cellulitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
COVID-19 pneumonia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Clostridium difficile colitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonia aspiration	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Septic shock	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Liver abscess	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Meningitis bacterial	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pelvic abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis acute	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urosepsis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bacteraemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Campylobacter gastroenteritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Clostridium difficile infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Device related infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Emphysematous cholecystitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Endocarditis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Kidney infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Labyrinthitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Penile infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonia pneumococcal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Post procedural infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Septic arthritis staphylococcal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Shigella sepsis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

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14.68. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Age Group, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=8921)		Original Placebo/BNT162b2 (30 µg) (N[a]=8354)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Subdiaphragmatic abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	21 (0.2)	(0.1, 0.4)	23 (0.3)	(0.2, 0.4)
Ankle fracture	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rib fracture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Overdose	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Road traffic accident	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial bones fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pelvic fracture	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Upper limb fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Craniocerebral injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fall	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fractured sacrum	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Head injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lumbar vertebral fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Procedural pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Thoracic vertebral fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Wrist fracture	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anastomotic complication	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anastomotic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arterial injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Patella fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post procedural complication	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Procedural dizziness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin laceration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Spinal fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Subdural haematoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=8921)		Original Placebo/BNT162b2 (30 µg) (N[a]=8354)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Traumatic liver injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood lactic acid	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	2 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hyponatraemia	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fluid retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	17 (0.2)	(0.1, 0.3)	17 (0.2)	(0.1, 0.3)
Osteoarthritis	9 (0.1)	(0.0, 0.2)	11 (0.1)	(0.1, 0.2)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arthritis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Back pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lumbar spinal stenosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscular weakness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Spinal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spondylolisthesis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intervertebral disc compression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain in extremity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Spinal osteoarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Synovial cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	50 (0.6)	(0.4, 0.7)	41 (0.5)	(0.4, 0.7)
Prostate cancer	3 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Breast cancer	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Adenocarcinoma of colon	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Adenocarcinoma pancreas	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast cancer metastatic	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Endometrial adenocarcinoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Invasive lobular breast carcinoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Malignant melanoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=8921)		Original Placebo/BNT162b2 (30 µg) (N[a]=8354)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Transitional cell carcinoma	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Basal cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Breast cancer stage I	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Follicular lymphoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lung neoplasm malignant	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pancreatic carcinoma metastatic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenocarcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Adrenal gland cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adrenal neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Angiosarcoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bladder cancer recurrent	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain neoplasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast cancer in situ	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colon cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colorectal adenoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cutaneous T-cell lymphoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ductal adenocarcinoma of pancreas	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Endometrial cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gallbladder cancer stage II	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastric cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypergammaglobulinaemia benign monoclonal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymphocytic leukaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mesothelioma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metastases to lung	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metastatic gastric cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metastatic squamous cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Non-small cell lung cancer stage III	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Non-small cell lung cancer stage IV	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ovarian cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ovarian cancer stage I	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Prostate cancer metastatic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

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14.68. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Age Group, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=8921)		Original Placebo/BNT162b2 (30 µg) (N[a]=8354)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Prostate cancer stage II	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rhabdomyosarcoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Squamous cell carcinoma of the cervix	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thyroid cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tonsil cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Transitional cell carcinoma recurrent	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine leiomyosarcoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vascular neoplasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	20 (0.2)	(0.1, 0.3)	32 (0.4)	(0.3, 0.5)
Cerebrovascular accident	3 (0.0)	(0.0, 0.1)	10 (0.1)	(0.1, 0.2)
Syncope	2 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Ischaemic stroke	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dizziness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Neuropathy peripheral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aphasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Autonomic nervous system imbalance	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Brain stem infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Carotid artery aneurysm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Carotid artery stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intracranial aneurysm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intracranial hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Myasthenia gravis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Psychogenic seizure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Reversible cerebral vasoconstriction syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sedation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spinal cord haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Transient global amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

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14.68. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Age Group, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=8921)		Original Placebo/BNT162b2 (30 µg) (N[a]=8354)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	5 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Depression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Completed suicide	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Suicide attempt	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conversion disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hallucination	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mental status changes	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	8 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)
Nephrolithiasis	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute kidney injury	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Urinary retention	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bladder prolapse	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Glomerulonephritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Renal vein thrombosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary tract obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Benign prostatic hyperplasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	13 (0.1)	(0.1, 0.2)	19 (0.2)	(0.1, 0.4)
Pulmonary embolism	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Acute respiratory failure	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Asthma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pleural effusion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute respiratory distress syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dyspnoea exertional	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Interstitial lung disease	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

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14.68. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Age Group, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=8921)		Original Placebo/BNT162b2 (30 µg) (N[a]=8354)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bronchospasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diaphragmatic paralysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pleurisy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary sarcoidosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Finger amputation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VASCULAR DISORDERS	10 (0.1)	(0.1, 0.2)	12 (0.1)	(0.1, 0.3)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypertension	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Arteriosclerosis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive urgency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Aortic aneurysm	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aortic dissection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Aortic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypertensive crisis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypovolaemic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peripheral artery thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:05)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2b_age

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14.69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=17995)		Original Placebo/BNT162b2 (30 µg) (N[a]=16815)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	355 (2.0)	(1.8, 2.2)	306 (1.8)	(1.6, 2.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Anaemia	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Febrile neutropenia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blood loss anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancytopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	56 (0.3)	(0.2, 0.4)	37 (0.2)	(0.2, 0.3)
Acute myocardial infarction	12 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Atrial fibrillation	7 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Myocardial infarction	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Cardiac failure congestive	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Cardiac arrest	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Coronary artery disease	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute coronary syndrome	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina pectoris	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardio-respiratory arrest	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ventricular tachycardia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute left ventricular failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coronary artery occlusion	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive heart disease	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocardial ischaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Palpitations	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular fibrillation	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Accelerated idioventricular rhythm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Atrioventricular block complete	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiovascular disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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14.69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=17995)		Original Placebo/BNT162b2 (30 µg) (N[a]=16815)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Conduction disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ischaemic cardiomyopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mitral valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postural orthostatic tachycardia syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus node dysfunction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Supraventricular extrasystoles	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular extrasystoles	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
BRCA1 gene mutation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertrophic cardiomyopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blindness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid ptosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ophthalmic vein thrombosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Optic ischaemic neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal detachment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal tear	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	30 (0.2)	(0.1, 0.2)	24 (0.1)	(0.1, 0.2)
Small intestinal obstruction	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Intestinal obstruction	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Pancreatitis acute	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Gastrointestinal haemorrhage	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Constipation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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14.69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=17995)		Original Placebo/BNT162b2 (30 µg) (N[a]=16815)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gastritis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lower gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal compartment syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis ulcerative	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Duodenal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Duodenal ulcer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Enterocolitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric ulcer haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal necrosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhoids	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Impaired gastric emptying	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Incarcerated inguinal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal ischaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intestinal perforation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal strangulation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal ulcer perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nausea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis necrotising	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peptic ulcer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rectal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Splenic artery aneurysm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper gastrointestinal haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vomiting	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	13 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Chest pain	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)

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14.69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=17995)		Original Placebo/BNT162b2 (30 µg) (N[a]=16815)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Non-cardiac chest pain	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Death	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Electrocution	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypothermia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Impaired healing	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyrexia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sudden death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	16 (0.1)	(0.1, 0.1)	11 (0.1)	(0.0, 0.1)
Cholelithiasis	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Cholecystitis acute	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Biliary colic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute hepatic failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Autoimmune hepatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Biliary dyskinesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholangitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholelithiasis obstructive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Portosplenomesenteric venous thrombosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactoid reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	60 (0.3)	(0.3, 0.4)	45 (0.3)	(0.2, 0.4)
Appendicitis	15 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pneumonia	4 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Diverticulitis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Urinary tract infection	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Sepsis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

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14.69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=17995)		Original Placebo/BNT162b2 (30 µg) (N[a]=16815)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gastroenteritis	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Appendicitis perforated	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
COVID-19 pneumonia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Clostridium difficile colitis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Septic shock	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Liver abscess	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic abscess	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Peritonitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess limb	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthritis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacteraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Campylobacter gastroenteritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cellulitis staphylococcal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis infective	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Clostridium difficile infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device related infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Emphysematous cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endocarditis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Focal peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gangrene	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Herpes zoster oticus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Infected bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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14.69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=17995)		Original Placebo/BNT162b2 (30 µg) (N[a]=16815)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Kidney infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Labyrinthitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mastoiditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic inflammatory disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonia pneumococcal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Septic arthritis staphylococcal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shigella sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin candida	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subdiaphragmatic abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinea pedis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	32 (0.2)	(0.1, 0.3)	34 (0.2)	(0.1, 0.3)
Ankle fracture	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Rib fracture	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Overdose	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Road traffic accident	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial bones fracture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper limb fracture	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fall	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foot fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fractured sacrum	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Head injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ligament rupture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar vertebral fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thoracic vertebral fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tibia fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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14.69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=17995)		Original Placebo/BNT162b2 (30 µg) (N[a]=16815)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Wrist fracture	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Accidental overdose	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anastomotic complication	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anastomotic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Animal bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arterial injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns second degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns third degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Concussion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hand fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meniscus injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Neck injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Open fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Patella fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural complication	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative ileus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural dizziness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin laceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Splenic rupture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subdural haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic liver injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Diabetic ketoacidosis	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Hypokalaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyponatraemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

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14.69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=17995)		Original Placebo/BNT162b2 (30 µg) (N[a]=16815)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Type 2 diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malnutrition	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	20 (0.1)	(0.1, 0.2)	23 (0.1)	(0.1, 0.2)
Osteoarthritis	7 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Intervertebral disc protrusion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arthritis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Back pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar spinal stenosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscular weakness	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal stenosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Spondylolisthesis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arthralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc compression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain in extremity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal osteoarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovial cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	64 (0.4)	(0.3, 0.5)	54 (0.3)	(0.2, 0.4)
Prostate cancer	3 (0.0)	(0.0, 0.0)	9 (0.1)	(0.0, 0.1)
Breast cancer	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Adenocarcinoma of colon	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast cancer metastatic	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Endometrial adenocarcinoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Invasive lobular breast carcinoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Malignant melanoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Transitional cell carcinoma	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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14.69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=17995)		Original Placebo/BNT162b2 (30 µg) (N[a]=16815)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Uterine leiomyoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Basal cell carcinoma	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cancer stage I	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Follicular lymphoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lung adenocarcinoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lung neoplasm malignant	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic carcinoma metastatic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Testis cancer	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angiosarcoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Benign hydatidiform mole	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain neoplasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cancer in situ	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clear cell renal cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colorectal adenoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cutaneous T-cell lymphoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ductal adenocarcinoma of pancreas	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Endometrial cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gallbladder cancer stage II	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hormone receptor positive breast cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypergammaglobulinaemia benign monoclonal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lipoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lung cancer metastatic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphocytic leukaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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14.69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=17995)		Original Placebo/BNT162b2 (30 µg) (N[a]=16815)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mesothelioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to lung	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastatic gastric cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastatic malignant melanoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastatic squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuroendocrine carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-small cell lung cancer stage III	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-small cell lung cancer stage IV	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian cancer stage I	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Plasma cell myeloma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer metastatic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer stage II	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhabdomyosarcoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma of the cervix	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thyroid cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transitional cell carcinoma recurrent	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uterine leiomyosarcoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vascular neoplasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	29 (0.2)	(0.1, 0.2)	40 (0.2)	(0.2, 0.3)
Cerebrovascular accident	4 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Syncope	3 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Ischaemic stroke	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuropathy peripheral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Optic neuritis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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14.69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=17995)		Original Placebo/BNT162b2 (30 µg) (N[a]=16815)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Amyotrophic lateral sclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Autonomic nervous system imbalance	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Brachial plexopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carotid artery aneurysm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carotid artery stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyskinesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Encephalopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intracranial aneurysm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intracranial hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myasthenia gravis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral nerve lesion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychogenic seizure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Reversible cerebral vasoconstriction syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sedation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Abortion spontaneous	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Ectopic pregnancy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	11 (0.1)	(0.0, 0.1)	16 (0.1)	(0.1, 0.2)
Depression	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Bipolar disorder	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Completed suicide	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Anxiety	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Major depression	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suicide attempt	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute psychosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcoholism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=17995)		Original Placebo/BNT162b2 (30 µg) (N[a]=16815)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bipolar I disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Conversion disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hallucination	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental status changes	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obsessive-compulsive disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicidal behaviour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	14 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Nephrolithiasis	7 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Acute kidney injury	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Ureterolithiasis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary retention	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bladder prolapse	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomerulonephritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal vein thrombosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Ovarian cyst	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abnormal uterine bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adnexal torsion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Endometrial thickening	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endometriosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heavy menstrual bleeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	15 (0.1)	(0.0, 0.1)	24 (0.1)	(0.1, 0.2)
Pulmonary embolism	3 (0.0)	(0.0, 0.0)	8 (0.0)	(0.0, 0.1)
Acute respiratory failure	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Asthma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pleural effusion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute respiratory distress syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=17995)		Original Placebo/BNT162b2 (30 µg) (N[a]=16815)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bronchospasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diaphragmatic paralysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal septum deviation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pustular psoriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Miscarriage of partner	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pregnancy of partner	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Finger amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	11 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Deep vein thrombosis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Hypertension	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aortic dissection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive crisis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iliac artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral artery thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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14.69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=17995)		Original Placebo/BNT162b2 (30 µg) (N[a]=16815)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
Note: All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:05)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2b_race

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14.70. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=2037)		Original Placebo/BNT162b2 (30 µg) (N[a]=1739)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	39 (1.9)	(1.4, 2.6)	25 (1.4)	(0.9, 2.1)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Anaemia macrocytic	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
CARDIAC DISORDERS	4 (0.2)	(0.1, 0.5)	6 (0.3)	(0.1, 0.7)
Atrial fibrillation	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Myocardial infarction	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Cardiac failure congestive	1 (0.0)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Cardiac arrest	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Coronary artery disease	2 (0.1)	(0.0, 0.4)	0	(0.0, 0.2)
Supraventricular tachycardia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Acute coronary syndrome	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Acute left ventricular failure	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Myocardial ischaemia	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Vertigo	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
GASTROINTESTINAL DISORDERS	6 (0.3)	(0.1, 0.6)	3 (0.2)	(0.0, 0.5)
Intestinal obstruction	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Pancreatitis	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Constipation	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Gastrooesophageal reflux disease	1 (0.0)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Hiatus hernia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (0.1)	(0.0, 0.4)	0	(0.0, 0.2)
Chest pain	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Treatment noncompliance	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Bile duct stone	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	5 (0.2)	(0.1, 0.6)	2 (0.1)	(0.0, 0.4)
Appendicitis	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Pneumonia	1 (0.0)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)

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14.70. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=2037)		Original Placebo/BNT162b2 (30 µg) (N[a]=1739)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Sepsis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Pyelonephritis acute	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Urosepsis	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Acquired immunodeficiency syndrome	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
HIV infection	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Lower respiratory tract infection	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Peritonsillar abscess	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Respiratory syncytial virus bronchiolitis	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.0)	(0.0, 0.3)	2 (0.1)	(0.0, 0.4)
Overdose	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Fall	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Brain contusion	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Scapula fracture	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
METABOLISM AND NUTRITION DISORDERS	4 (0.2)	(0.1, 0.5)	2 (0.1)	(0.0, 0.4)
Diabetic ketoacidosis	2 (0.1)	(0.0, 0.4)	0	(0.0, 0.2)
Hypokalaemia	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Type 2 diabetes mellitus	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Hyperglycaemia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Obesity	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (0.2)	(0.1, 0.5)	1 (0.1)	(0.0, 0.3)
Osteoarthritis	3 (0.1)	(0.0, 0.4)	0	(0.0, 0.2)
Costochondritis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	3 (0.1)	(0.0, 0.4)	1 (0.1)	(0.0, 0.3)
Adenocarcinoma of colon	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Uterine leiomyoma	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Bladder cancer recurrent	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Uterine cancer	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	3 (0.1)	(0.0, 0.4)	4 (0.2)	(0.1, 0.6)
Cerebrovascular accident	1 (0.0)	(0.0, 0.3)	2 (0.1)	(0.0, 0.4)
Seizure	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Brain stem infarction	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Haemorrhagic stroke	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)

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14.70. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=2037)		Original Placebo/BNT162b2 (30 µg) (N[a]=1739)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Presyncope	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	1 (0.0)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Abortion spontaneous	1 (0.0)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
PSYCHIATRIC DISORDERS	2 (0.1)	(0.0, 0.4)	1 (0.1)	(0.0, 0.3)
Depression	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Drug abuse	1 (0.0)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.3)	2 (0.1)	(0.0, 0.4)
Nephrolithiasis	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Acute kidney injury	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Urinary tract obstruction	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (0.1)	(0.0, 0.4)	4 (0.2)	(0.1, 0.6)
Pulmonary embolism	2 (0.1)	(0.0, 0.4)	2 (0.1)	(0.0, 0.4)
Acute respiratory failure	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Pleural effusion	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Pulmonary sarcoidosis	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
SOCIAL CIRCUMSTANCES	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Miscarriage of partner	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
VASCULAR DISORDERS	6 (0.3)	(0.1, 0.6)	0	(0.0, 0.2)
Deep vein thrombosis	3 (0.1)	(0.0, 0.4)	0	(0.0, 0.2)
Hypertension	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Hypertensive urgency	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)
Hypertensive emergency	1 (0.0)	(0.0, 0.3)	0	(0.0, 0.2)

Note: MedDRA (v25.1) coding dictionary applied.
Note: All other = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:05)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2b_race

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14.71. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=1878)		Original Placebo/BNT162b2 (30 µg) (N[a]=1713)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	34 (1.8)	(1.3, 2.5)	22 (1.3)	(0.8, 1.9)
CARDIAC DISORDERS	4 (0.2)	(0.1, 0.5)	0	(0.0, 0.2)
Acute myocardial infarction	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Cardiac failure congestive	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Angina pectoris	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Cardio-respiratory arrest	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Heart disease congenital	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	2 (0.1)	(0.0, 0.4)	2 (0.1)	(0.0, 0.4)
Gastrointestinal haemorrhage	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Pancreatitis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Obstructive pancreatitis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Gastric perforation	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Non-cardiac chest pain	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Shoulder injury related to vaccine administration	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	3 (0.2)	(0.0, 0.5)	2 (0.1)	(0.0, 0.4)
Cholecystitis acute	3 (0.2)	(0.0, 0.5)	0	(0.0, 0.2)
Cholecystitis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Portal vein thrombosis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Anaphylactic reaction	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
INFECTIONS AND INFESTATIONS	9 (0.5)	(0.2, 0.9)	2 (0.1)	(0.0, 0.4)
Appendicitis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Pneumonia	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Urinary tract infection	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Sepsis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Gastroenteritis	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Appendicitis perforated	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Cellulitis	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Pyelonephritis acute	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Respiratory tract infection viral	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3 (0.2)	(0.0, 0.5)	5 (0.3)	(0.1, 0.7)

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14.71. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=1878)		Original Placebo/BNT162b2 (30 µg) (N[a]=1713)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rib fracture	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Road traffic accident	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Facial bones fracture	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Craniocerebral injury	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Fractured sacrum	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Procedural pain	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Arthropod bite	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Clavicle fracture	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Lower limb fracture	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
INVESTIGATIONS	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Blood lactic acid	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Hyponatraemia	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Intervertebral disc protrusion	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Intervertebral disc degeneration	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.1)	(0.0, 0.4)	1 (0.1)	(0.0, 0.3)
Laryngeal papilloma	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Mucoepidermoid carcinoma of salivary gland	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Tonsil cancer	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	2 (0.1)	(0.0, 0.4)	2 (0.1)	(0.0, 0.4)
Transient ischaemic attack	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Subarachnoid haemorrhage	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Dural arteriovenous fistula	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Loss of consciousness	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Abortion spontaneous	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
PSYCHIATRIC DISORDERS	3 (0.2)	(0.0, 0.5)	3 (0.2)	(0.0, 0.5)
Depression	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Suicidal ideation	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Completed suicide	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Alcohol withdrawal syndrome	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.4)
Alcohol abuse	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)

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14.71. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Race, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=1878)		Original Placebo/BNT162b2 (30 µg) (N[a]=1713)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
RENAL AND URINARY DISORDERS	2 (0.1)	(0.0, 0.4)	0	(0.0, 0.2)
Nephrolithiasis	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Acute kidney injury	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
Breast hyperplasia	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.1)	(0.0, 0.3)	1 (0.1)	(0.0, 0.3)
Pulmonary embolism	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Asthma	1 (0.1)	(0.0, 0.3)	0	(0.0, 0.2)
VASCULAR DISORDERS	0	(0.0, 0.2)	2 (0.1)	(0.0, 0.4)
Deep vein thrombosis	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)
Hypovolaemic shock	0	(0.0, 0.2)	1 (0.1)	(0.0, 0.3)

Note: MedDRA (v25.1) coding dictionary applied.
Note: All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:05)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2b_race

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14.72. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Sex, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=11241)		Original Placebo/BNT162b2 (30 µg) (N[a]=10150)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	231 (2.1)	(1.8, 2.3)	171 (1.7)	(1.4, 2.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Febrile neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anaemia macrocytic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pancytopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	48 (0.4)	(0.3, 0.6)	33 (0.3)	(0.2, 0.5)
Acute myocardial infarction	10 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Atrial fibrillation	5 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Myocardial infarction	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cardiac failure congestive	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cardiac arrest	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Coronary artery disease	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Supraventricular tachycardia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute coronary syndrome	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina pectoris	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cardio-respiratory arrest	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ventricular tachycardia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coronary artery occlusion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive heart disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocardial ischaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Palpitations	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pericarditis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular fibrillation	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Accelerated idioventricular rhythm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Atrial flutter	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Atrioventricular block complete	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiovascular disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ischaemic cardiomyopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mitral valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

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14.72. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Sex, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=11241)		Original Placebo/BNT162b2 (30 µg) (N[a]=10150)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Postural orthostatic tachycardia syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus node dysfunction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Supraventricular extrasystoles	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular extrasystoles	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypertrophic cardiomyopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vertigo	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blindness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid ptosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Optic ischaemic neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Retinal tear	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	20 (0.2)	(0.1, 0.3)	13 (0.1)	(0.1, 0.2)
Small intestinal obstruction	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Intestinal obstruction	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Pancreatitis acute	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrooesophageal reflux disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Inguinal hernia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lower gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal compartment syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dental cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastric ulcer haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastrointestinal necrosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoids	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Incarcerated inguinal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal strangulation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis necrotising	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

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14.72. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Sex, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=11241)		Original Placebo/BNT162b2 (30 µg) (N[a]=10150)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Peptic ulcer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rectal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Splenic artery aneurysm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper gastrointestinal haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vomiting	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	12 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Chest pain	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Death	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Asthenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Electrocution	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypothermia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Impaired healing	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pyrexia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sudden death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	11 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)
Cholelithiasis	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cholecystitis acute	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute hepatic failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Autoimmune hepatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Biliary dyskinesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cholangitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cholelithiasis obstructive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Portosplenomesenteric venous thrombosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	44 (0.4)	(0.3, 0.5)	21 (0.2)	(0.1, 0.3)
Appendicitis	8 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonia	3 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)

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14.72. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Sex, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=11241)		Original Placebo/BNT162b2 (30 µg) (N[a]=10150)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diverticulitis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Urinary tract infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sepsis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gastroenteritis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cellulitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
COVID-19 pneumonia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Clostridium difficile colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonia aspiration	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Liver abscess	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess limb	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acquired immunodeficiency syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthritis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacteraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Campylobacter gastroenteritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cellulitis staphylococcal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clostridium difficile infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Device related infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Emphysematous cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endocarditis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gangrene	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HIV infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Herpes zoster oticus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Kidney infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lower respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mastoiditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Penile infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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14.72. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Sex, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=11241)		Original Placebo/BNT162b2 (30 µg) (N[a]=10150)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonia pneumococcal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Post procedural infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Septic arthritis staphylococcal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Shigella sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin candida	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subdiaphragmatic abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinea pedis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	27 (0.2)	(0.2, 0.3)	22 (0.2)	(0.1, 0.3)
Ankle fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rib fracture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Overdose	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Road traffic accident	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pelvic fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Upper limb fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Craniocerebral injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fall	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Foot fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fractured sacrum	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Head injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ligament rupture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Procedural pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tibia fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Wrist fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Accidental overdose	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anastomotic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arthropod bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Brain contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

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14.72. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Sex, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=11241)		Original Placebo/BNT162b2 (30 µg) (N[a]=10150)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Burns second degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns third degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hand fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meniscus injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Open fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Patella fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural complication	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Postoperative ileus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Scapula fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin laceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Subdural haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood lactic acid	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.0)	8 (0.1)	(0.0, 0.2)
Diabetic ketoacidosis	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hyponatraemia	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypoglycaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	12 (0.1)	(0.1, 0.2)	10 (0.1)	(0.0, 0.2)
Osteoarthritis	4 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Intervertebral disc protrusion	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lumbar spinal stenosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscular weakness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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14.72. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Sex, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=11241)		Original Placebo/BNT162b2 (30 µg) (N[a]=10150)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rotator cuff syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal osteoarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	27 (0.2)	(0.2, 0.3)	21 (0.2)	(0.1, 0.3)
Prostate cancer	3 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)
Breast cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma of colon	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Basal cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lung neoplasm malignant	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Oropharyngeal squamous cell carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pancreatic carcinoma metastatic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Testis cancer	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Adenocarcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Adrenal neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign hydatidiform mole	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clear cell renal cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cutaneous T-cell lymphoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypergammaglobulinaemia benign monoclonal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Laryngeal papilloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lipoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lung cancer metastatic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to lung	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastatic gastric cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastatic squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuroendocrine carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Non-small cell lung cancer stage III	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Non-small cell lung cancer stage IV	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer metastatic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer stage II	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

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14.72. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Sex, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=11241)		Original Placebo/BNT162b2 (30 µg) (N[a]=10150)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Skin cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tonsil cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transitional cell carcinoma recurrent	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	19 (0.2)	(0.1, 0.3)	24 (0.2)	(0.2, 0.4)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.2)
Syncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ischaemic stroke	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dizziness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Seizure	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Toxic encephalopathy	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Neuropathy peripheral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Optic neuritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aphasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Autonomic nervous system imbalance	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Carotid artery aneurysm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dural arteriovenous fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dyskinesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myasthenia gravis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peripheral nerve lesion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Presyncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Psychogenic seizure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	7 (0.1)	(0.0, 0.1)	14 (0.1)	(0.1, 0.2)
Depression	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Completed suicide	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Alcohol withdrawal syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anxiety	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Drug abuse	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

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14.72. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Sex, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=11241)		Original Placebo/BNT162b2 (30 µg) (N[a]=10150)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Major depression	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Suicide attempt	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute psychosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Alcoholism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Conversion disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental status changes	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Obsessive-compulsive disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Suicidal behaviour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	12 (0.1)	(0.1, 0.2)	6 (0.1)	(0.0, 0.1)
Nephrolithiasis	6 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Acute kidney injury	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ureterolithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urinary retention	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Renal vein thrombosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urinary tract obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	12 (0.1)	(0.1, 0.2)	17 (0.2)	(0.1, 0.3)
Pulmonary embolism	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Acute respiratory failure	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pleural effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute respiratory distress syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pneumothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Nasal septum deviation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

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14.72. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Sex, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=11241)		Original Placebo/BNT162b2 (30 µg) (N[a]=10150)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pustular psoriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Miscarriage of partner	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pregnancy of partner	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	8 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Deep vein thrombosis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arteriosclerosis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive urgency	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aortic dissection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Aortic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypertensive crisis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peripheral artery thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:05)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2b_sex

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14.73. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Sex, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=10669)		Original Placebo/BNT162b2 (30 µg) (N[a]=10117)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	197 (1.8)	(1.6, 2.1)	182 (1.8)	(1.5, 2.1)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Anaemia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Febrile neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood loss anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lymphadenitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CARDIAC DISORDERS	16 (0.1)	(0.1, 0.2)	10 (0.1)	(0.0, 0.2)
Acute myocardial infarction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Atrial fibrillation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myocardial infarction	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Cardiac failure congestive	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Cardiac arrest	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery disease	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Supraventricular tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardio-respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypertensive heart disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myocardial ischaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Palpitations	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pericarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conduction disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coronary artery dissection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
BRCA1 gene mutation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Heart disease congenital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vertigo	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
ENDOCRINE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Diplopia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=10669)		Original Placebo/BNT162b2 (30 µg) (N[a]=10117)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ophthalmic vein thrombosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Retinal detachment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Visual impairment	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	18 (0.2)	(0.1, 0.3)	16 (0.2)	(0.1, 0.3)
Small intestinal obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Gastrointestinal haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal adhesions	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Constipation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gastritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrooesophageal reflux disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lower gastrointestinal haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Obstructive pancreatitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anal fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis ulcerative	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diarrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Duodenal obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Duodenal ulcer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Enterocolitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastric perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hiatus hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Impaired gastric emptying	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intestinal ischaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intestinal perforation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intestinal ulcer perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Nausea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oesophageal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	5 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=10669)		Original Placebo/BNT162b2 (30 µg) (N[a]=10117)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Drug withdrawal syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Treatment noncompliance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	9 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cholecystitis acute	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bile duct stone	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Biliary colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Portal vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anaphylactoid reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypersensitivity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	30 (0.3)	(0.2, 0.4)	28 (0.3)	(0.2, 0.4)
Appendicitis	9 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Diverticulitis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary tract infection	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Sepsis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Gastroenteritis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Appendicitis perforated	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
COVID-19 pneumonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Clostridium difficile colitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Septic shock	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Meningitis bacterial	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pelvic abscess	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=10669)		Original Placebo/BNT162b2 (30 µg) (N[a]=10117)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pyelonephritis acute	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urosepsis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cholecystitis infective	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Focal peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Infected bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Labyrinthitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pelvic inflammatory disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory syncytial virus bronchiolitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	9 (0.1)	(0.0, 0.2)	19 (0.2)	(0.1, 0.3)
Ankle fracture	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rib fracture	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Overdose	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Road traffic accident	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Facial bones fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pelvic fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Upper limb fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fall	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fractured sacrum	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ligament rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lumbar vertebral fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Procedural pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thoracic vertebral fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Tibia fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Traumatic intracranial haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Wrist fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anastomotic complication	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Animal bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arterial injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Concussion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=10669)		Original Placebo/BNT162b2 (30 µg) (N[a]=10117)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Neck injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Procedural dizziness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Splenic rupture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Traumatic liver injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	7 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diabetic ketoacidosis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypokalaemia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Malnutrition	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	13 (0.1)	(0.1, 0.2)	15 (0.1)	(0.1, 0.2)
Osteoarthritis	6 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arthritis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Intervertebral disc degeneration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Back pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscular weakness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Spinal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spondylolisthesis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arthralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Costochondritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intervertebral disc compression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain in extremity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Synovial cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	42 (0.4)	(0.3, 0.5)	35 (0.3)	(0.2, 0.5)
Breast cancer	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Adenocarcinoma of colon	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Adenocarcinoma pancreas	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=10669)		Original Placebo/BNT162b2 (30 µg) (N[a]=10117)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Breast cancer metastatic	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Endometrial adenocarcinoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Invasive lobular breast carcinoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Malignant melanoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Transitional cell carcinoma	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Uterine leiomyoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Basal cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bladder cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast cancer stage I	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Follicular lymphoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lung adenocarcinoma	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anal cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angiosarcoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bladder cancer recurrent	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain neoplasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast cancer in situ	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colon cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colorectal adenoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ductal adenocarcinoma of pancreas	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Endometrial cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gallbladder cancer stage II	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastric cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hormone receptor positive breast cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymphocytic leukaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mesothelioma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metastatic malignant melanoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mucoepidermoid carcinoma of salivary gland	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ovarian adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ovarian cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

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14.73. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Sex, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=10669)		Original Placebo/BNT162b2 (30 µg) (N[a]=10117)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ovarian cancer stage I	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Plasma cell myeloma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rhabdomyosarcoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Squamous cell carcinoma of the cervix	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Uterine cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine leiomyosarcoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vascular neoplasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	15 (0.1)	(0.1, 0.2)	22 (0.2)	(0.1, 0.3)
Cerebrovascular accident	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Syncope	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Transient ischaemic attack	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ischaemic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Toxic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Idiopathic intracranial hypertension	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Optic neuritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Amyotrophic lateral sclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Brachial plexopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Brain stem infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Carotid artery stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Encephalopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intracranial aneurysm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intracranial hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Loss of consciousness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Paraesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Reversible cerebral vasoconstriction syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sedation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	6 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)
Abortion spontaneous	6 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)

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14.73. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Sex, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=10669)		Original Placebo/BNT162b2 (30 µg) (N[a]=10117)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ectopic pregnancy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	9 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Depression	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Bipolar disorder	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Alcohol withdrawal syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Drug abuse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alcohol abuse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bipolar I disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hallucination	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Nephrolithiasis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute kidney injury	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ureterolithiasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bladder prolapse	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Glomerulonephritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ovarian cyst	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal uterine bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Adnexal torsion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Endometrial thickening	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Endometriosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heavy menstrual bleeding	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	7 (0.1)	(0.0, 0.1)	12 (0.1)	(0.1, 0.2)
Pulmonary embolism	1 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Asthma	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pleural effusion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pneumothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bronchospasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diaphragmatic paralysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

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14.73. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Sex, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=10669)		Original Placebo/BNT162b2 (30 µg) (N[a]=10117)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dyspnoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pleurisy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pulmonary sarcoidosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Finger amputation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VASCULAR DISORDERS	9 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypertension	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive urgency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Aortic aneurysm	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive emergency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypovolaemic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Iliac artery dissection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:05)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2b_sex

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14.74. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Ethnicity, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=5685)		Original Placebo/BNT162b2 (30 µg) (N[a]=5274)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	126 (2.2)	(1.8, 2.6)	80 (1.5)	(1.2, 1.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Anaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Febrile neutropenia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pancytopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
CARDIAC DISORDERS	13 (0.2)	(0.1, 0.4)	15 (0.3)	(0.2, 0.5)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Atrial fibrillation	1 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)
Myocardial infarction	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cardiac failure congestive	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cardiac arrest	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Coronary artery disease	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Supraventricular tachycardia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Angina unstable	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ventricular tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Myocardial ischaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Palpitations	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pericarditis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Ventricular fibrillation	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Accelerated idioventricular rhythm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Atrial flutter	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Conduction disorder	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ischaemic cardiomyopathy	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sinus node dysfunction	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Supraventricular extrasystoles	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Ventricular extrasystoles	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
ENDOCRINE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Goitre	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
EYE DISORDERS	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Ophthalmic vein thrombosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)

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14.74. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Ethnicity, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=5685)		Original Placebo/BNT162b2 (30 µg) (N[a]=5274)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Retinal tear	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	12 (0.2)	(0.1, 0.4)	7 (0.1)	(0.1, 0.3)
Small intestinal obstruction	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pancreatitis acute	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Gastritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Inguinal hernia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Lower gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Abdominal discomfort	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dental cyst	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Duodenal ulcer	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Food poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Haemorrhoids	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Incarcerated inguinal hernia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Intestinal ischaemia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Intestinal perforation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Rectal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)
Chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Non-cardiac chest pain	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Electrocution	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sudden death	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	8 (0.1)	(0.1, 0.3)	6 (0.1)	(0.0, 0.2)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	4 (0.1)	(0.0, 0.2)
Cholecystitis acute	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Bile duct stone	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Biliary colic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Autoimmune hepatitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholangitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholelithiasis obstructive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Portosplenomesenteric venous thrombosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	27 (0.5)	(0.3, 0.7)	18 (0.3)	(0.2, 0.5)
Appendicitis	8 (0.1)	(0.1, 0.3)	0	(0.0, 0.1)
Pneumonia	2 (0.0)	(0.0, 0.1)	7 (0.1)	(0.1, 0.3)

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14.74. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Ethnicity, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=5685)		Original Placebo/BNT162b2 (30 µg) (N[a]=5274)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diverticulitis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urinary tract infection	2 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)
Sepsis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Gastroenteritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Cellulitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
COVID-19 pneumonia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonia aspiration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Pyelonephritis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Septic shock	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Liver abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Meningitis bacterial	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Peritonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Postoperative wound infection	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Acquired immunodeficiency syndrome	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arthritis bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
COVID-19	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cellulitis staphylococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Emphysematous cholecystitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Gangrene	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
HIV infection	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Herpes zoster oticus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Lower respiratory tract infection	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pelvic inflammatory disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Penile infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Septic arthritis staphylococcal	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Shigella sepsis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Skin candida	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Subdiaphragmatic abscess	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tinea pedis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	11 (0.2)	(0.1, 0.3)	5 (0.1)	(0.0, 0.2)
Ankle fracture	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Road traffic accident	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Upper limb fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Head injury	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ligament rupture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)

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14.74. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Ethnicity, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=5685)		Original Placebo/BNT162b2 (30 µg) (N[a]=5274)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lumbar vertebral fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Thoracic vertebral fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tibia fracture	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Wrist fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Anastomotic stenosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arterial injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Burns second degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Burns third degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Hand fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Neck injury	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Patella fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Diabetic ketoacidosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hyponatraemia	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoglycaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	6 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.2)
Osteoarthritis	1 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)
Intervertebral disc protrusion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Back pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Lumbar spinal stenosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Spondylolisthesis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Osteochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	23 (0.4)	(0.3, 0.6)	9 (0.2)	(0.1, 0.3)
Prostate cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Breast cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Adenocarcinoma of colon	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Breast cancer metastatic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Endometrial adenocarcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Invasive lobular breast carcinoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Malignant melanoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Transitional cell carcinoma	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Uterine leiomyoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

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14.74. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Ethnicity, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=5685)		Original Placebo/BNT162b2 (30 µg) (N[a]=5274)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Basal cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Breast cancer stage I	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Follicular lymphoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Lung adenocarcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Pancreatic carcinoma metastatic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Benign hydatidiform mole	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Cutaneous T-cell lymphoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Gastric cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Hypergammaglobulinaemia benign monoclonal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Metastatic gastric cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Metastatic malignant melanoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Ovarian adenoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ovarian cancer	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Plasma cell myeloma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Prostate cancer metastatic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Rhabdomyosarcoma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Squamous cell carcinoma of the cervix	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Transitional cell carcinoma recurrent	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	8 (0.1)	(0.1, 0.3)	8 (0.2)	(0.1, 0.3)
Cerebrovascular accident	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Neuropathy peripheral	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Optic neuritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Carotid artery stenosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Intracranial hypotension	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Peripheral nerve lesion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Psychogenic seizure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Reversible cerebral vasoconstriction syndrome	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	3 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Abortion spontaneous	3 (0.1)	(0.0, 0.2)	0	(0.0, 0.1)

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14.74. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Ethnicity, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=5685)		Original Placebo/BNT162b2 (30 µg) (N[a]=5274)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ectopic pregnancy	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.2)
Depression	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Alcohol withdrawal syndrome	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Major depression	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Psychotic disorder	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bipolar I disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Mental status changes	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Suicidal behaviour	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	6 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Nephrolithiasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Ureterolithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Renal colic	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Renal vein thrombosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Adnexal torsion	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Heavy menstrual bleeding	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (0.1)	(0.0, 0.2)	10 (0.2)	(0.1, 0.3)
Pulmonary embolism	1 (0.0)	(0.0, 0.1)	3 (0.1)	(0.0, 0.2)
Acute respiratory failure	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Asthma	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pleural effusion	0	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute respiratory distress syndrome	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute pulmonary oedema	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bronchospasm	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Pustular psoriasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Finger amputation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)

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14.74. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Ethnicity, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=5685)		Original Placebo/BNT162b2 (30 µg) (N[a]=5274)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
VASCULAR DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Hypertension	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypertensive urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.1)
Peripheral artery thrombosis	0	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:05)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p23_d2b_eth

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14.75. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Ethnicity, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=16151)		Original Placebo/BNT162b2 (30 µg) (N[a]=14898)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	301 (1.9)	(1.7, 2.1)	273 (1.8)	(1.6, 2.1)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Anaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Febrile neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaemia macrocytic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood loss anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	51 (0.3)	(0.2, 0.4)	28 (0.2)	(0.1, 0.3)
Acute myocardial infarction	12 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Atrial fibrillation	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Myocardial infarction	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Cardiac failure congestive	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cardiac arrest	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Coronary artery disease	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angina pectoris	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardio-respiratory arrest	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coronary artery occlusion	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive heart disease	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocardial ischaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pericarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular fibrillation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block complete	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiovascular disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mitral valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postural orthostatic tachycardia syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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14.75. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Ethnicity, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=16151)		Original Placebo/BNT162b2 (30 µg) (N[a]=14898)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
BRCA1 gene mutation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertrophic cardiomyopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vertigo	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
EYE DISORDERS	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blindness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid ptosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Optic ischaemic neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal detachment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Visual impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	26 (0.2)	(0.1, 0.2)	22 (0.1)	(0.1, 0.2)
Small intestinal obstruction	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pancreatitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Constipation	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrooesophageal reflux disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lower gastrointestinal haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal compartment syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis ulcerative	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Duodenal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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14.75. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Ethnicity, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=16151)		Original Placebo/BNT162b2 (30 µg) (N[a]=14898)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Enterocolitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric ulcer haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal necrosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hiatus hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impaired gastric emptying	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal strangulation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal ulcer perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nausea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis necrotising	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peptic ulcer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Splenic artery aneurysm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper gastrointestinal haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vomiting	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	15 (0.1)	(0.1, 0.2)	9 (0.1)	(0.0, 0.1)
Chest pain	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Death	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypothermia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Impaired healing	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyrexia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Treatment noncompliance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	12 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Cholelithiasis	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Cholecystitis acute	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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14.75. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Ethnicity, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=16151)		Original Placebo/BNT162b2 (30 µg) (N[a]=14898)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Acute hepatic failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary dyskinesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Portal vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactoid reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	47 (0.3)	(0.2, 0.4)	31 (0.2)	(0.1, 0.3)
Appendicitis	9 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pneumonia	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Diverticulitis	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Urinary tract infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Gastroenteritis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
COVID-19 pneumonia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Clostridium difficile colitis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Septic shock	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Liver abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic abscess	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess limb	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacteraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=16151)		Original Placebo/BNT162b2 (30 µg) (N[a]=14898)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bacterial sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Campylobacter gastroenteritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholecystitis infective	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Clostridium difficile infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device related infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endocarditis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Focal peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Infected bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Kidney infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Labyrinthitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mastoiditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonia pneumococcal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory syncytial virus bronchiolitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	24 (0.1)	(0.1, 0.2)	36 (0.2)	(0.2, 0.3)
Ankle fracture	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Rib fracture	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Overdose	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Road traffic accident	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Facial bones fracture	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pelvic fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper limb fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fall	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Foot fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=16151)		Original Placebo/BNT162b2 (30 µg) (N[a]=14898)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Fractured sacrum	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ligament rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thoracic vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tibia fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wrist fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Accidental overdose	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anastomotic complication	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Animal bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arthropod bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Brain contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Concussion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meniscus injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Open fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural complication	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative ileus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural dizziness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Scapula fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin laceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Splenic rupture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subdural haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=16151)		Original Placebo/BNT162b2 (30 µg) (N[a]=14898)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Traumatic liver injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood lactic acid	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	7 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Diabetic ketoacidosis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypokalaemia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyponatraemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Type 2 diabetes mellitus	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malnutrition	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	19 (0.1)	(0.1, 0.2)	19 (0.1)	(0.1, 0.2)
Osteoarthritis	9 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Intervertebral disc protrusion	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthritis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Back pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar spinal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscular weakness	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal stenosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Spondylolisthesis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Costochondritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc compression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain in extremity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal osteoarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovial cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	46 (0.3)	(0.2, 0.4)	47 (0.3)	(0.2, 0.4)

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14.75. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Ethnicity, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=16151)		Original Placebo/BNT162b2 (30 µg) (N[a]=14898)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Prostate cancer	2 (0.0)	(0.0, 0.0)	9 (0.1)	(0.0, 0.1)
Breast cancer	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Adenocarcinoma of colon	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast cancer metastatic	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Endometrial adenocarcinoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Invasive lobular breast carcinoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Basal cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cancer stage I	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Follicular lymphoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lung adenocarcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lung neoplasm malignant	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic carcinoma metastatic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Testis cancer	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angiosarcoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bladder cancer recurrent	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain neoplasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cancer in situ	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clear cell renal cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colorectal adenoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ductal adenocarcinoma of pancreas	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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14.75. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Ethnicity, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=16151)		Original Placebo/BNT162b2 (30 µg) (N[a]=14898)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Endometrial cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gallbladder cancer stage II	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hormone receptor positive breast cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Laryngeal papilloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lipoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lung cancer metastatic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphocytic leukaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mesothelioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to lung	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastatic squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mucoepidermoid carcinoma of salivary gland	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuroendocrine carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-small cell lung cancer stage III	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-small cell lung cancer stage IV	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian cancer stage I	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostate cancer stage II	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tonsil cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uterine cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uterine leiomyosarcoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vascular neoplasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	26 (0.2)	(0.1, 0.2)	38 (0.3)	(0.2, 0.3)
Cerebrovascular accident	5 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Syncope	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Transient ischaemic attack	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dizziness	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=16151)		Original Placebo/BNT162b2 (30 µg) (N[a]=14898)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Neuropathy peripheral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Optic neuritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Amyotrophic lateral sclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Autonomic nervous system imbalance	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Brachial plexopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Brain stem infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carotid artery aneurysm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dural arteriovenous fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyskinesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Encephalopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intracranial aneurysm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loss of consciousness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myasthenia gravis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Presyncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sedation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	3 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Abortion spontaneous	3 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	14 (0.1)	(0.0, 0.1)	14 (0.1)	(0.1, 0.2)
Depression	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Bipolar disorder	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Completed suicide	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Alcohol withdrawal syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anxiety	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Drug abuse	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Major depression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=16151)		Original Placebo/BNT162b2 (30 µg) (N[a]=14898)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute psychosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcohol abuse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alcoholism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Conversion disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hallucination	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Obsessive-compulsive disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	11 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Nephrolithiasis	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Acute kidney injury	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Ureterolithiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urinary retention	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bladder prolapse	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomerulonephritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary tract obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ovarian cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abnormal uterine bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endometrial thickening	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endometriosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	16 (0.1)	(0.1, 0.2)	19 (0.1)	(0.1, 0.2)
Pulmonary embolism	4 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Acute respiratory failure	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Asthma	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleural effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute respiratory distress syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=16151)		Original Placebo/BNT162b2 (30 µg) (N[a]=14898)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diaphragmatic paralysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal septum deviation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary sarcoidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Miscarriage of partner	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pregnancy of partner	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	15 (0.1)	(0.1, 0.2)	11 (0.1)	(0.0, 0.1)
Deep vein thrombosis	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypertension	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Arteriosclerosis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aortic dissection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive crisis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive emergency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypovolaemic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iliac artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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14.75. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Ethnicity, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=16151)		Original Placebo/BNT162b2 (30 µg) (N[a]=14898)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.76. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 (BNT162b2) to 6 Months After Dose 2 (BNT162b2), by Ethnicity, by System Organ Class and Preferred Term – Blinded and Open Label Follow-up Period – Phase 2/3 – Subjects ≥16 Years of Age – Safety Population Ethnicity: Not Reported

	Vaccine Group (as Administered)			
	Original BNT162b2 (30 µg) (N[a]=74)		Original Placebo/BNT162b2 (30 µg) (N[a]=95)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	1 (1.4)	(0.0, 7.3)	0	(0.0, 3.8)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (1.4)	(0.0, 7.3)	0	(0.0, 3.8)
Pelvic fracture	1 (1.4)	(0.0, 7.3)	0	(0.0, 3.8)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.77. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: 12-15 Years

	Vaccine Group (as Administered)
Adverse Event	**BNT162b2 (30 µg) (N[a]=825) n[b] (%)**
Any adverse event	153 (18.5)
Related[c]	139 (16.8)
Severe	6 (0.7)
Life-threatening	1 (0.1)
Any serious adverse event	2 (0.2)
Related[c]	0
Severe	2 (0.2)
Life-threatening	1 (0.1)
Any nonserious adverse event	153 (18.5)
Related[c]	139 (16.8)
Severe	6 (0.7)
Life-threatening	0
Any adverse event leading to withdrawal	0
Related[c]	0
Severe	0
Life-threatening	0
Death	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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14.78. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)
Adverse Event	BNT162b2 (30 µg) (N[a]=12834) n[b] (%)
Any adverse event	2418 (18.8)
Related[c]	2181 (17.0)
Severe	43 (0.3)
Life-threatening	2 (0.0)
Any serious adverse event	28 (0.2)
Related[c]	3 (0.0)
Severe	16 (0.1)
Life-threatening	2 (0.0)
Any nonserious adverse event	2401 (18.7)
Related[c]	2181 (17.0)
Severe	27 (0.2)
Life-threatening	0
Any adverse event leading to withdrawal	0
Related[c]	0
Severe	0
Life-threatening	0
Death	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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14.79. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=9636)
Adverse Event	n[b] (%)
Any adverse event	1400 (14.5)
Related[c]	1196 (12.4)
Severe	47 (0.5)
Life-threatening	4 (0.0)
Any serious adverse event	37 (0.4)
Related[c]	0
Severe	24 (0.2)
Life-threatening	4 (0.0)
Any nonserious adverse event	1378 (14.3)
Related[c]	1196 (12.4)
Severe	25 (0.3)
Life-threatening	0
Any adverse event leading to withdrawal	1 (0.0)
Related[c]	0
Severe	0
Life-threatening	1 (0.0)
Death	1 (0.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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14.80. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: White

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	
Adverse Event	12-15 Years (N[a]=689) n[b] (%)	≥16 Years (N[a]=18869) n[b] (%)
Any adverse event	123 (17.9)	3117 (16.5)
Related[c]	111 (16.1)	2731 (14.5)
Severe	5 (0.7)	81 (0.4)
Life-threatening	1 (0.1)	5 (0.0)
Any serious adverse event	1 (0.1)	54 (0.3)
Related[c]	0	2 (0.0)
Severe	1 (0.1)	34 (0.2)
Life-threatening	1 (0.1)	5 (0.0)
Any nonserious adverse event	123 (17.9)	3086 (16.4)
Related[c]	111 (16.1)	2731 (14.5)
Severe	5 (0.7)	49 (0.3)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	1 (0.0)
Related[c]	0	0
Severe	0	0
Life-threatening	0	1 (0.0)
Death	0	1 (0.0)

Note: All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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14.81. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: Black or African American

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	
Adverse Event	12-15 Years (N^a=38) n^b (%)	≥16 Years (N^a=1962) n^b (%)
Any adverse event	5 (13.2)	269 (13.7)
Related[c]	3 (7.9)	234 (11.9)
Severe	1 (2.6)	6 (0.3)
Life-threatening	0	1 (0.1)
Any serious adverse event	1 (2.6)	9 (0.5)
Related[c]	0	0
Severe	1 (2.6)	5 (0.3)
Life-threatening	0	1 (0.1)
Any nonserious adverse event	5 (13.2)	261 (13.3)
Related[c]	3 (7.9)	234 (11.9)
Severe	1 (2.6)	1 (0.1)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

Note: All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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14.82. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: All Others

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	
Adverse Event	12-15 Years (N^a=98) n^b (%)	≥16 Years (N^a=1639) n^b (%)
Any adverse event	25 (25.5)	432 (26.4)
Related[c]	25 (25.5)	412 (25.1)
Severe	0	3 (0.2)
Life-threatening	0	0
Any serious adverse event	0	2 (0.1)
Related[c]	0	1 (0.1)
Severe	0	1 (0.1)
Life-threatening	0	0
Any nonserious adverse event	25 (25.5)	432 (26.4)
Related[c]	25 (25.5)	412 (25.1)
Severe	0	2 (0.1)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

Note: All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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14.83. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Male

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	
Adverse Event	12-15 Years (N^a=407) n^b (%)	≥16 Years (N^a=11267) n^b (%)
Any adverse event	81 (19.9)	1632 (14.5)
Related[c]	77 (18.9)	1469 (13.0)
Severe	2 (0.5)	41 (0.4)
Life-threatening	0	3 (0.0)
Any serious adverse event	0	29 (0.3)
Related[c]	0	1 (0.0)
Severe	0	18 (0.2)
Life-threatening	0	3 (0.0)
Any nonserious adverse event	81 (19.9)	1613 (14.3)
Related[c]	77 (18.9)	1469 (13.0)
Severe	2 (0.5)	24 (0.2)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	1 (0.0)
Related[c]	0	0
Severe	0	0
Life-threatening	0	1 (0.0)
Death	0	1 (0.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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14.84. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Female

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	
Adverse Event	12-15 Years (N^a=418) n^b (%)	≥16 Years (N^a=11203) n^b (%)
Any adverse event	72 (17.2)	2186 (19.5)
Related[c]	62 (14.8)	1908 (17.0)
Severe	4 (1.0)	49 (0.4)
Life-threatening	1 (0.2)	3 (0.0)
Any serious adverse event	2 (0.5)	36 (0.3)
Related[c]	0	2 (0.0)
Severe	2 (0.5)	22 (0.2)
Life-threatening	1 (0.2)	3 (0.0)
Any nonserious adverse event	72 (17.2)	2166 (19.3)
Related[c]	62 (14.8)	1908 (17.0)
Severe	4 (1.0)	28 (0.2)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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14.85. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 - Booster Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	
Adverse Event	12-15 Years (N[a]=89) n[b] (%)	≥16 Years (N[a]=7489) n[b] (%)
Any adverse event	19 (21.3)	1281 (17.1)
Related[c]	18 (20.2)	1058 (14.1)
Severe	0	17 (0.2)
Life-threatening	0	1 (0.0)
Any serious adverse event	0	24 (0.3)
Related[c]	0	1 (0.0)
Severe	0	12 (0.2)
Life-threatening	0	1 (0.0)
Any nonserious adverse event	19 (21.3)	1271 (17.0)
Related[c]	18 (20.2)	1058 (14.1)
Severe	0	5 (0.1)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	
Adverse Event	12-15 Years (N^a=734) n^b (%)	≥16 Years (N^a=14899) n^b (%)
Any adverse event	133 (18.1)	2525 (16.9)
Related[c]	120 (16.3)	2307 (15.5)
Severe	6 (0.8)	73 (0.5)
Life-threatening	1 (0.1)	5 (0.0)
Any serious adverse event	2 (0.3)	41 (0.3)
Related[c]	0	2 (0.0)
Severe	2 (0.3)	28 (0.2)
Life-threatening	1 (0.1)	5 (0.0)
Any nonserious adverse event	133 (18.1)	2496 (16.8)
Related[c]	120 (16.3)	2307 (15.5)
Severe	6 (0.8)	47 (0.3)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	1 (0.0)
Related[c]	0	0
Severe	0	0
Life-threatening	0	1 (0.0)
Death	0	1 (0.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
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14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Not Reported

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	
Adverse Event	12-15 Years (N^a=2) n^b (%)	≥16 Years (N^a=82) n^b (%)
Any adverse event	1 (50.0)	12 (14.6)
Related[c]	1 (50.0)	12 (14.6)
Severe	0	0
Life-threatening	0	0
Any serious adverse event	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Any nonserious adverse event	1 (50.0)	12 (14.6)
Related[c]	1 (50.0)	12 (14.6)
Severe	0	0
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 19MAY2023 (07:02)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s091_p23_d3_eth

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14.88. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose – Phase 2/3 – HIV-Positive Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) ≥16 Years (N[a]=98)
Adverse Event	n[b] (%)
Any adverse event	11 (11.2)
Related[c]	8 (8.2)
Severe	1 (1.0)
Life-threatening	0
Any serious adverse event	1 (1.0)
Related[c]	0
Severe	1 (1.0)
Life-threatening	0
Any nonserious adverse event	10 (10.2)
Related[c]	8 (8.2)
Severe	0
Life-threatening	0
Any adverse event leading to withdrawal	0
Related[c]	0
Severe	0
Life-threatening	0
Death	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:01)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s091_p23_d3_hiv

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14.89. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose – Phase 3 – BNT162b2-Naïve Subjects Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

	Vaccine Group (as Administered)
Adverse Event	BNT162b2 (30 µg) (N[a]=230) n[b] (%)
Any adverse event	27 (11.4)
Related[c]	25 (10.6)
Severe	0
Life-threatening	0
Any serious adverse event	0
Related[c]	0
Severe	0
Life-threatening	0
Any nonserious adverse event	27 (11.4)
Related[c]	25 (10.6)
Severe	0
Life-threatening	0
Any adverse event leading to withdrawal	0
Related[c]	0
Severe	0
Life-threatening	0
Death	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:01)
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14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	153 (18.5)	(15.9, 21.4)	3818 (17.0)	(16.5, 17.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	8 (1.0)	(0.4, 1.9)	360 (1.6)	(1.4, 1.8)
Lymphadenopathy	8 (1.0)	(0.4, 1.9)	347 (1.5)	(1.4, 1.7)
Lymph node pain	0	(0.0, 0.4)	9 (0.0)	(0.0, 0.1)
Anaemia	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Hypochromic anaemia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Iron deficiency anaemia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Normocytic anaemia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Splenic vein thrombosis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	1 (0.1)	(0.0, 0.7)	29 (0.1)	(0.1, 0.2)
Palpitations	0	(0.0, 0.4)	7 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Ventricular extrasystoles	1 (0.1)	(0.0, 0.7)	2 (0.0)	(0.0, 0.0)
Acute coronary syndrome	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Mitral valve incompetence	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Angina pectoris	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Aortic valve disease	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Arrhythmia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Atrioventricular block	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Bradycardia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Bundle branch block left	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Bundle branch block right	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Cardiac failure	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Myocardial ischaemia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Myocarditis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Sinus node dysfunction	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Wolff-Parkinson-White syndrome	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.4)	15 (0.1)	(0.0, 0.1)
Vertigo	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)

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14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tinnitus	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Cerumen impaction	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Deafness	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Deafness neurosensory	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Ear discomfort	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Ear pain	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Middle ear effusion	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Vertigo positional	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	0	(0.0, 0.4)	7 (0.0)	(0.0, 0.1)
Hypothyroidism	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Autoimmune thyroiditis	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Hypopituitarism	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Secondary hyperthyroidism	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	0	(0.0, 0.4)	12 (0.1)	(0.0, 0.1)
Cataract	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Eye pain	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Keratitis	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Blepharitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Dry eye	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Epiretinal membrane	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Photophobia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Retinal degeneration	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	12 (1.5)	(0.8, 2.5)	203 (0.9)	(0.8, 1.0)
Nausea	9 (1.1)	(0.5, 2.1)	93 (0.4)	(0.3, 0.5)
Diarrhoea	0	(0.0, 0.4)	57 (0.3)	(0.2, 0.3)
Vomiting	5 (0.6)	(0.2, 1.4)	33 (0.1)	(0.1, 0.2)
Abdominal pain	1 (0.1)	(0.0, 0.7)	6 (0.0)	(0.0, 0.1)
Abdominal pain upper	1 (0.1)	(0.0, 0.7)	5 (0.0)	(0.0, 0.1)
Gastritis	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Gastrooesophageal reflux disease	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Constipation	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Dyspepsia	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)

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14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rectal haemorrhage	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Abdominal discomfort	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Anogenital dysplasia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Colitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Dental caries	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Dry mouth	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Food poisoning	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Gastric ulcer	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Inguinal hernia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Large intestine polyp	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Lip dry	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Lip haemorrhage	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Lip oedema	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Oesophageal ulcer	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Oesophagitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Oral mucosal blistering	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Retching	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Teething	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Tooth impacted	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Volvulus	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	130 (15.8)	(13.3, 18.4)	2923 (13.0)	(12.6, 13.5)
Injection site pain	66 (8.0)	(6.2, 10.1)	1679 (7.5)	(7.1, 7.8)
Fatigue	61 (7.4)	(5.7, 9.4)	858 (3.8)	(3.6, 4.1)
Pyrexia	28 (3.4)	(2.3, 4.9)	665 (3.0)	(2.7, 3.2)
Chills	22 (2.7)	(1.7, 4.0)	443 (2.0)	(1.8, 2.2)
Pain	24 (2.9)	(1.9, 4.3)	352 (1.6)	(1.4, 1.7)
Asthenia	0	(0.0, 0.4)	81 (0.4)	(0.3, 0.4)
Malaise	3 (0.4)	(0.1, 1.1)	76 (0.3)	(0.3, 0.4)
Injection site erythema	5 (0.6)	(0.2, 1.4)	42 (0.2)	(0.1, 0.3)
Injection site swelling	0	(0.0, 0.4)	37 (0.2)	(0.1, 0.2)

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14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Axillary pain	1 (0.1)	(0.0, 0.7)	26 (0.1)	(0.1, 0.2)
Vaccination site pain	0	(0.0, 0.4)	15 (0.1)	(0.0, 0.1)
Injection site lymphadenopathy	0	(0.0, 0.4)	11 (0.0)	(0.0, 0.1)
Injection site pruritus	0	(0.0, 0.4)	9 (0.0)	(0.0, 0.1)
Injection site warmth	0	(0.0, 0.4)	9 (0.0)	(0.0, 0.1)
Localised oedema	0	(0.0, 0.4)	7 (0.0)	(0.0, 0.1)
Chest pain	0	(0.0, 0.4)	6 (0.0)	(0.0, 0.1)
Swelling	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)
Feeling abnormal	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Injection site bruising	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Injection site mass	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Vaccination site lymphadenopathy	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Injection site induration	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Injection site oedema	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Injection site rash	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Injection site reaction	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Vaccination site swelling	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Chest discomfort	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Facial pain	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Feeling hot	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Inflammation	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Injection site inflammation	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Injection site irritation	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Vaccination site oedema	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Application site erythema	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Cyst	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Face oedema	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Gait disturbance	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Illness	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Injection site discomfort	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Injection site haematoma	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Injection site nodule	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Injection site vesicles	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)

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14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Oedema peripheral	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Peripheral swelling	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Sensation of foreign body	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Thirst	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Vaccination site erythema	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Vaccination site warmth	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	0	(0.0, 0.4)	11 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Cholelithiasis	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Alcoholic liver disease	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Biliary colic	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Biliary obstruction	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Cholecystitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hepatic lesion	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hepatitis acute	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hyperbilirubinaemia neonatal	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Jaundice cholestatic	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.4)	6 (0.0)	(0.0, 0.1)
Immunisation reaction	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Hypersensitivity	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	1 (0.1)	(0.0, 0.7)	111 (0.5)	(0.4, 0.6)
Urinary tract infection	0	(0.0, 0.4)	23 (0.1)	(0.1, 0.2)
Tooth infection	0	(0.0, 0.4)	11 (0.0)	(0.0, 0.1)
Ear infection	0	(0.0, 0.4)	6 (0.0)	(0.0, 0.1)
Herpes zoster	0	(0.0, 0.4)	6 (0.0)	(0.0, 0.1)
Cellulitis	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)
Conjunctivitis	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)
Diverticulitis	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)
Appendicitis	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Otitis externa	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Rhinitis	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Sinusitis	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Cystitis	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Gastroenteritis	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Genital herpes	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)

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14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Localised infection	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Oral herpes	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Syphilis	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Wound infection	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Abscess jaw	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
Adenoviral conjunctivitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Balanitis candida	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Bartholinitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Bronchitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Conjunctivitis bacterial	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Conjunctivitis viral	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Erysipelas	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Focal peritonitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Fungal skin infection	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Gastroenteritis norovirus	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Infected cyst	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Malaria	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Nasopharyngitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Onychomycosis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Periodontitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Pneumonia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Staphylococcal infection	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Tooth abscess	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Vaginal infection	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Vulvovaginal mycotic infection	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 (0.5)	(0.1, 1.2)	104 (0.5)	(0.4, 0.6)
Exposure during pregnancy	0	(0.0, 0.4)	30 (0.1)	(0.1, 0.2)
Fall	1 (0.1)	(0.0, 0.7)	14 (0.1)	(0.0, 0.1)

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14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Maternal exposure during breast feeding	0	(0.0, 0.4)	11 (0.0)	(0.0, 0.1)
Skin laceration	0	(0.0, 0.4)	7 (0.0)	(0.0, 0.1)
Animal bite	0	(0.0, 0.4)	6 (0.0)	(0.0, 0.1)
Ligament sprain	1 (0.1)	(0.0, 0.7)	5 (0.0)	(0.0, 0.1)
Ankle fracture	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Cartilage injury	1 (0.1)	(0.0, 0.7)	2 (0.0)	(0.0, 0.0)
Joint injury	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Wrist fracture	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Cervical vertebral fracture	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Contusion	1 (0.1)	(0.0, 0.7)	1 (0.0)	(0.0, 0.0)
Foot fracture	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Limb injury	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Vaccination complication	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Wound	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Arthropod bite	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Chest injury	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Corneal abrasion	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Eye contusion	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Femur fracture	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Forearm fracture	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
Head injury	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Nasal injury	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Overdose	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Post-traumatic pain	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Radius fracture	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Retinal injury	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Skin abrasion	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Stress fracture	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Tendon injury	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Wound dehiscence	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.4)	61 (0.3)	(0.2, 0.3)
Body temperature increased	0	(0.0, 0.4)	54 (0.2)	(0.2, 0.3)

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14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cardiac murmur	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Heart rate increased	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Blood urine present	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Cardiac stress test abnormal	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Human papilloma virus test positive	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.4)	24 (0.1)	(0.1, 0.2)
Decreased appetite	0	(0.0, 0.4)	11 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Vitamin D deficiency	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Dyslipidaemia	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Gout	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hypoglycaemia neonatal	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hyponatraemia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Increased appetite	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	19 (2.3)	(1.4, 3.6)	646 (2.9)	(2.7, 3.1)
Myalgia	13 (1.6)	(0.8, 2.7)	474 (2.1)	(1.9, 2.3)
Arthralgia	0	(0.0, 0.4)	60 (0.3)	(0.2, 0.3)
Pain in extremity	6 (0.7)	(0.3, 1.6)	49 (0.2)	(0.2, 0.3)
Back pain	0	(0.0, 0.4)	19 (0.1)	(0.1, 0.1)
Musculoskeletal chest pain	1 (0.1)	(0.0, 0.7)	8 (0.0)	(0.0, 0.1)
Neck pain	0	(0.0, 0.4)	9 (0.0)	(0.0, 0.1)
Musculoskeletal pain	0	(0.0, 0.4)	6 (0.0)	(0.0, 0.1)
Muscle spasms	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Muscle contracture	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Muscular weakness	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Musculoskeletal stiffness	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Synovial cyst	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Tendonitis	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Arthritis	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Axillary mass	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Bursitis	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Muscle twitching	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Osteochondritis	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)

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14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Osteoporosis	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Plantar fasciitis	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Rotator cuff syndrome	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Spinal osteoarthritis	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Cervical spinal stenosis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Costochondritis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Fibromyalgia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Flank pain	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Greater trochanteric pain syndrome	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Groin pain	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Kyphosis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Neck mass	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Painful os peroneum syndrome	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Rheumatoid arthritis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Sjogren's syndrome	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.4)	17 (0.1)	(0.0, 0.1)
Basal cell carcinoma	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Adenocarcinoma of colon	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Adenoma benign	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Colon cancer	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Endometrial adenocarcinoma	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Gastrointestinal stromal tumour	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Invasive breast carcinoma	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Papillary thyroid cancer	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Renal neoplasm	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma of skin	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	49 (5.9)	(4.4, 7.8)	632 (2.8)	(2.6, 3.0)
Headache	47 (5.7)	(4.2, 7.5)	559 (2.5)	(2.3, 2.7)
Dizziness	2 (0.2)	(0.0, 0.9)	26 (0.1)	(0.1, 0.2)

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14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lethargy	0	(0.0, 0.4)	13 (0.1)	(0.0, 0.1)
Paraesthesia	0	(0.0, 0.4)	7 (0.0)	(0.0, 0.1)
Syncope	1 (0.1)	(0.0, 0.7)	6 (0.0)	(0.0, 0.1)
Migraine	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)
Sciatica	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)
Hypoaesthesia	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Presyncope	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Cerebrovascular accident	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Nerve compression	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Psychomotor hyperactivity	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Somnolence	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Tremor	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Carotid arteriosclerosis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Cervical radiculopathy	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Formication	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Haemorrhage intracranial	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hepatic encephalopathy	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hyperaesthesia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Intracranial aneurysm	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Parosmia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Seizure	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Taste disorder	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Tension headache	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)
Pregnancy	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Abortion spontaneous	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Abortion threatened	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Gestational hypertension	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	9 (1.1)	(0.5, 2.1)	43 (0.2)	(0.1, 0.3)
Anxiety	3 (0.4)	(0.1, 1.1)	17 (0.1)	(0.0, 0.1)
Insomnia	1 (0.1)	(0.0, 0.7)	6 (0.0)	(0.0, 0.1)
Depression	3 (0.4)	(0.1, 1.1)	3 (0.0)	(0.0, 0.0)
Anxiety disorder	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Attention deficit hyperactivity disorder	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)

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14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Disorientation	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Nightmare	2 (0.2)	(0.0, 0.9)	0	(0.0, 0.0)
Acute stress disorder	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Affective disorder	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Aggression	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
Alcohol abuse	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Bruxism	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Emotional distress	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Gender dysphoria	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Irritability	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Libido decreased	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Major depression	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Psychiatric decompensation	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Suicidal ideation	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
Suicide attempt	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	0	(0.0, 0.4)	8 (0.0)	(0.0, 0.1)
Nephrolithiasis	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Calculus bladder	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Pollakiuria	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Renal colic	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Renal pain	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Stress urinary incontinence	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Trigonitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.2)	(0.0, 0.9)	23 (0.1)	(0.1, 0.2)
Intermenstrual bleeding	1 (0.1)	(0.0, 0.7)	4 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Breast pain	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Heavy menstrual bleeding	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Menstrual disorder	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Atrophic vulvovaginitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Breast inflammation	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Cervical bulla	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Dysmenorrhoea	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
Menstruation irregular	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)

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14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Nipple exudate bloody	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Ovarian cyst	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Pelvic pain	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Prostatitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Testicular pain	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Uterine polyp	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.1)	(0.0, 0.7)	33 (0.1)	(0.1, 0.2)
Nasal congestion	1 (0.1)	(0.0, 0.7)	5 (0.0)	(0.0, 0.1)
Rhinorrhoea	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)
Dyspnoea	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Rhinitis allergic	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Cough	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Epistaxis	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Oropharyngeal pain	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Sinus congestion	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Asthma	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Dysphonia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Pleural effusion	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Sleep apnoea syndrome	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Throat tightness	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Upper-airway cough syndrome	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Vocal cord polyp	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.2)	(0.0, 0.9)	77 (0.3)	(0.3, 0.4)
Rash	0	(0.0, 0.4)	15 (0.1)	(0.0, 0.1)
Hyperhidrosis	0	(0.0, 0.4)	9 (0.0)	(0.0, 0.1)
Night sweats	0	(0.0, 0.4)	7 (0.0)	(0.0, 0.1)
Urticaria	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)
Acne	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Erythema	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Pruritus	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Dermatitis contact	1 (0.1)	(0.0, 0.7)	2 (0.0)	(0.0, 0.0)
Alopecia	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Psoriasis	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)

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14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rash maculo-papular	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Skin lesion	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Angioedema	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Blister	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Cold sweat	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Dermatitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Dermatitis atopic	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Diabetic foot	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Diffuse alopecia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Ecchymosis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hand dermatitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Lichen planus	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Lichen sclerosus	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Pain of skin	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Photosensitivity reaction	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Pityriasis rosea	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Rash papular	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Rash pruritic	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Rosacea	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Sensitive skin	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
Skin oedema	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.1)	(0.0, 0.7)	7 (0.0)	(0.0, 0.1)
Breast conserving surgery	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Cataract operation	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Knee arthroplasty	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Meniscus operation	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Metabolic surgery	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Oral surgery	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
Tooth extraction	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	0	(0.0, 0.4)	43 (0.2)	(0.1, 0.3)
Hypertension	0	(0.0, 0.4)	29 (0.1)	(0.1, 0.2)
Hot flush	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Essential hypertension	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Flushing	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)

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14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lymphoedema	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Aneurysm	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Aortic arteriosclerosis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Arteriosclerosis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hypotension	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Peripheral vascular disorder	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Varicose vein	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Venous thrombosis limb	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:01)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_p23_d3

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14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: 12-15 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=825) n[b] (%)	 (95% CI[c])
Any adverse event	153 (18.5)	(15.9, 21.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	8 (1.0)	(0.4, 1.9)
Lymphadenopathy	8 (1.0)	(0.4, 1.9)
CARDIAC DISORDERS	1 (0.1)	(0.0, 0.7)
Ventricular extrasystoles	1 (0.1)	(0.0, 0.7)
GASTROINTESTINAL DISORDERS	12 (1.5)	(0.8, 2.5)
Nausea	9 (1.1)	(0.5, 2.1)
Vomiting	5 (0.6)	(0.2, 1.4)
Abdominal pain	1 (0.1)	(0.0, 0.7)
Abdominal pain upper	1 (0.1)	(0.0, 0.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	130 (15.8)	(13.3, 18.4)
Injection site pain	66 (8.0)	(6.2, 10.1)
Fatigue	61 (7.4)	(5.7, 9.4)
Pyrexia	28 (3.4)	(2.3, 4.9)
Chills	22 (2.7)	(1.7, 4.0)
Pain	24 (2.9)	(1.9, 4.3)
Malaise	3 (0.4)	(0.1, 1.1)
Injection site erythema	5 (0.6)	(0.2, 1.4)
Axillary pain	1 (0.1)	(0.0, 0.7)
INFECTIONS AND INFESTATIONS	1 (0.1)	(0.0, 0.7)
Abscess jaw	1 (0.1)	(0.0, 0.7)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 (0.5)	(0.1, 1.2)
Fall	1 (0.1)	(0.0, 0.7)
Ligament sprain	1 (0.1)	(0.0, 0.7)
Cartilage injury	1 (0.1)	(0.0, 0.7)
Contusion	1 (0.1)	(0.0, 0.7)
Forearm fracture	1 (0.1)	(0.0, 0.7)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	19 (2.3)	(1.4, 3.6)
Myalgia	13 (1.6)	(0.8, 2.7)
Pain in extremity	6 (0.7)	(0.3, 1.6)
Musculoskeletal chest pain	1 (0.1)	(0.0, 0.7)
NERVOUS SYSTEM DISORDERS	49 (5.9)	(4.4, 7.8)
Headache	47 (5.7)	(4.2, 7.5)
Dizziness	2 (0.2)	(0.0, 0.9)

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14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: 12-15 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=825) n[b] (%)	(95% CI[c])
Syncope	1 (0.1)	(0.0, 0.7)
PSYCHIATRIC DISORDERS	9 (1.1)	(0.5, 2.1)
Anxiety	3 (0.4)	(0.1, 1.1)
Insomnia	1 (0.1)	(0.0, 0.7)
Depression	3 (0.4)	(0.1, 1.1)
Nightmare	2 (0.2)	(0.0, 0.9)
Aggression	1 (0.1)	(0.0, 0.7)
Major depression	1 (0.1)	(0.0, 0.7)
Suicidal ideation	1 (0.1)	(0.0, 0.7)
Suicide attempt	1 (0.1)	(0.0, 0.7)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.2)	(0.0, 0.9)
Intermenstrual bleeding	1 (0.1)	(0.0, 0.7)
Dysmenorrhoea	1 (0.1)	(0.0, 0.7)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.1)	(0.0, 0.7)
Nasal congestion	1 (0.1)	(0.0, 0.7)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.2)	(0.0, 0.9)
Dermatitis contact	1 (0.1)	(0.0, 0.7)
Sensitive skin	1 (0.1)	(0.0, 0.7)
SURGICAL AND MEDICAL PROCEDURES	1 (0.1)	(0.0, 0.7)
Oral surgery	1 (0.1)	(0.0, 0.7)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:01)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_p23_d3_age

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14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12834) n[b] (%)	 (95% CI[c])
Any adverse event	2418 (18.8)	(18.2, 19.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	307 (2.4)	(2.1, 2.7)
Lymphadenopathy	301 (2.3)	(2.1, 2.6)
Lymph node pain	8 (0.1)	(0.0, 0.1)
Anaemia	1 (0.0)	(0.0, 0.0)
Hypochromic anaemia	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	13 (0.1)	(0.1, 0.2)
Palpitations	7 (0.1)	(0.0, 0.1)
Tachycardia	1 (0.0)	(0.0, 0.0)
Ventricular extrasystoles	1 (0.0)	(0.0, 0.0)
Mitral valve incompetence	1 (0.0)	(0.0, 0.0)
Atrioventricular block	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)
Myocarditis	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	9 (0.1)	(0.0, 0.1)
Vertigo	3 (0.0)	(0.0, 0.1)
Tinnitus	2 (0.0)	(0.0, 0.1)
Deafness	1 (0.0)	(0.0, 0.0)
Ear discomfort	1 (0.0)	(0.0, 0.0)
Middle ear effusion	1 (0.0)	(0.0, 0.0)
Tympanic membrane perforation	1 (0.0)	(0.0, 0.0)
Vertigo positional	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	4 (0.0)	(0.0, 0.1)
Hypothyroidism	1 (0.0)	(0.0, 0.0)
Autoimmune thyroiditis	2 (0.0)	(0.0, 0.1)
Secondary hyperthyroidism	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	3 (0.0)	(0.0, 0.1)
Cataract	1 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)
Eye pain	1 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)
Retinal degeneration	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	107 (0.8)	(0.7, 1.0)
Nausea	56 (0.4)	(0.3, 0.6)

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14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12834)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Diarrhoea	33 (0.3)	(0.2, 0.4)
Vomiting	17 (0.1)	(0.1, 0.2)
Abdominal pain	5 (0.0)	(0.0, 0.1)
Gastritis	1 (0.0)	(0.0, 0.0)
Dyspepsia	1 (0.0)	(0.0, 0.0)
Abdominal discomfort	1 (0.0)	(0.0, 0.0)
Anogenital dysplasia	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)
Dental caries	1 (0.0)	(0.0, 0.0)
Food poisoning	1 (0.0)	(0.0, 0.0)
Haemorrhoids	1 (0.0)	(0.0, 0.0)
Oral mucosal blistering	1 (0.0)	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.0)
Volvulus	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1843 (14.4)	(13.8, 15.0)
Injection site pain	1065 (8.3)	(7.8, 8.8)
Fatigue	547 (4.3)	(3.9, 4.6)
Pyrexia	418 (3.3)	(3.0, 3.6)
Chills	268 (2.1)	(1.8, 2.4)
Pain	225 (1.8)	(1.5, 2.0)
Asthenia	45 (0.4)	(0.3, 0.5)
Malaise	45 (0.4)	(0.3, 0.5)
Injection site erythema	24 (0.2)	(0.1, 0.3)
Injection site swelling	23 (0.2)	(0.1, 0.3)
Axillary pain	23 (0.2)	(0.1, 0.3)
Vaccination site pain	10 (0.1)	(0.0, 0.1)
Injection site lymphadenopathy	6 (0.0)	(0.0, 0.1)
Injection site pruritus	4 (0.0)	(0.0, 0.1)
Injection site warmth	4 (0.0)	(0.0, 0.1)
Localised oedema	7 (0.1)	(0.0, 0.1)
Chest pain	5 (0.0)	(0.0, 0.1)
Swelling	4 (0.0)	(0.0, 0.1)
Feeling abnormal	2 (0.0)	(0.0, 0.1)
Injection site bruising	2 (0.0)	(0.0, 0.1)
Injection site mass	4 (0.0)	(0.0, 0.1)
Vaccination site lymphadenopathy	4 (0.0)	(0.0, 0.1)

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14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12834) n[b] (%)	 (95% CI[c])
Injection site oedema	3 (0.0)	(0.0, 0.1)
Injection site rash	2 (0.0)	(0.0, 0.1)
Injection site reaction	2 (0.0)	(0.0, 0.1)
Vaccination site swelling	3 (0.0)	(0.0, 0.1)
Chest discomfort	2 (0.0)	(0.0, 0.1)
Facial pain	1 (0.0)	(0.0, 0.0)
Feeling hot	2 (0.0)	(0.0, 0.1)
Inflammation	1 (0.0)	(0.0, 0.0)
Injection site inflammation	2 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)
Vaccination site oedema	2 (0.0)	(0.0, 0.1)
Application site erythema	1 (0.0)	(0.0, 0.0)
Cyst	1 (0.0)	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)
Influenza like illness	1 (0.0)	(0.0, 0.0)
Injection site discomfort	1 (0.0)	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.0)
Injection site vesicles	1 (0.0)	(0.0, 0.0)
Injury associated with device	1 (0.0)	(0.0, 0.0)
Oedema peripheral	1 (0.0)	(0.0, 0.0)
Peripheral swelling	1 (0.0)	(0.0, 0.0)
Sensation of foreign body	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	5 (0.0)	(0.0, 0.1)
Cholecystitis acute	2 (0.0)	(0.0, 0.1)
Cholelithiasis	1 (0.0)	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)
Hyperbilirubinaemia neonatal	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	4 (0.0)	(0.0, 0.1)
Immunisation reaction	3 (0.0)	(0.0, 0.1)
Hypersensitivity	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	65 (0.5)	(0.4, 0.6)
Urinary tract infection	13 (0.1)	(0.1, 0.2)
Tooth infection	9 (0.1)	(0.0, 0.1)
Ear infection	4 (0.0)	(0.0, 0.1)
Herpes zoster	2 (0.0)	(0.0, 0.1)
Cellulitis	3 (0.0)	(0.0, 0.1)

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14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12834) n[b] (%)	 (95% CI[c])
Conjunctivitis	2 (0.0)	(0.0, 0.1)
Appendicitis	3 (0.0)	(0.0, 0.1)
Otitis externa	2 (0.0)	(0.0, 0.1)
Rhinitis	2 (0.0)	(0.0, 0.1)
Sinusitis	3 (0.0)	(0.0, 0.1)
Cystitis	1 (0.0)	(0.0, 0.0)
Gastroenteritis	2 (0.0)	(0.0, 0.1)
Genital herpes	1 (0.0)	(0.0, 0.0)
Localised infection	1 (0.0)	(0.0, 0.0)
Oral herpes	1 (0.0)	(0.0, 0.0)
Syphilis	2 (0.0)	(0.0, 0.1)
Wound infection	2 (0.0)	(0.0, 0.1)
Adenoviral conjunctivitis	1 (0.0)	(0.0, 0.0)
Balanitis candida	1 (0.0)	(0.0, 0.0)
Bartholinitis	1 (0.0)	(0.0, 0.0)
Conjunctivitis bacterial	1 (0.0)	(0.0, 0.0)
Infected cyst	1 (0.0)	(0.0, 0.0)
Nasopharyngitis	1 (0.0)	(0.0, 0.0)
Onychomycosis	1 (0.0)	(0.0, 0.0)
Pneumonia	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.0)
Vaginal infection	1 (0.0)	(0.0, 0.0)
Vulvovaginal mycotic infection	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	79 (0.6)	(0.5, 0.8)
Exposure during pregnancy	30 (0.2)	(0.2, 0.3)
Fall	7 (0.1)	(0.0, 0.1)
Maternal exposure during breast feeding	11 (0.1)	(0.0, 0.2)
Skin laceration	4 (0.0)	(0.0, 0.1)
Animal bite	4 (0.0)	(0.0, 0.1)
Ligament sprain	5 (0.0)	(0.0, 0.1)
Ankle fracture	4 (0.0)	(0.0, 0.1)
Cartilage injury	2 (0.0)	(0.0, 0.1)
Joint injury	2 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	2 (0.0)	(0.0, 0.1)
Foot fracture	1 (0.0)	(0.0, 0.0)
Limb injury	1 (0.0)	(0.0, 0.0)

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14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12834) n[b] (%)	 (95% CI[c])
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.1)
Road traffic accident	1 (0.0)	(0.0, 0.0)
Vaccination complication	2 (0.0)	(0.0, 0.1)
Wound	2 (0.0)	(0.0, 0.1)
Chest injury	1 (0.0)	(0.0, 0.0)
Femur fracture	1 (0.0)	(0.0, 0.0)
Nasal injury	1 (0.0)	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.0)
Skin abrasion	1 (0.0)	(0.0, 0.0)
Stress fracture	1 (0.0)	(0.0, 0.0)
Wound dehiscence	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	46 (0.4)	(0.3, 0.5)
Body temperature increased	43 (0.3)	(0.2, 0.5)
Heart rate increased	2 (0.0)	(0.0, 0.1)
Human papilloma virus test positive	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	11 (0.1)	(0.0, 0.2)
Decreased appetite	6 (0.0)	(0.0, 0.1)
Vitamin D deficiency	3 (0.0)	(0.0, 0.1)
Hypoglycaemia neonatal	1 (0.0)	(0.0, 0.0)
Increased appetite	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	424 (3.3)	(3.0, 3.6)
Myalgia	324 (2.5)	(2.3, 2.8)
Arthralgia	31 (0.2)	(0.2, 0.3)
Pain in extremity	30 (0.2)	(0.2, 0.3)
Back pain	11 (0.1)	(0.0, 0.2)
Musculoskeletal chest pain	8 (0.1)	(0.0, 0.1)
Neck pain	8 (0.1)	(0.0, 0.1)
Musculoskeletal pain	6 (0.0)	(0.0, 0.1)
Muscle spasms	2 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	2 (0.0)	(0.0, 0.1)
Muscle contracture	3 (0.0)	(0.0, 0.1)
Muscular weakness	1 (0.0)	(0.0, 0.0)
Musculoskeletal stiffness	1 (0.0)	(0.0, 0.0)
Synovial cyst	3 (0.0)	(0.0, 0.1)
Tendonitis	1 (0.0)	(0.0, 0.0)
Arthritis	1 (0.0)	(0.0, 0.0)

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14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12834) n[b] (%)	 (95% CI[c])
Axillary mass	2 (0.0)	(0.0, 0.1)
Muscle twitching	2 (0.0)	(0.0, 0.1)
Osteochondritis	2 (0.0)	(0.0, 0.1)
Osteoporosis	1 (0.0)	(0.0, 0.0)
Plantar fasciitis	1 (0.0)	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.0)
Flank pain	1 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	1 (0.0)	(0.0, 0.0)
Neck mass	1 (0.0)	(0.0, 0.0)
Painful os peroneum syndrome	1 (0.0)	(0.0, 0.0)
Sjogren's syndrome	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	4 (0.0)	(0.0, 0.1)
Adenoma benign	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	1 (0.0)	(0.0, 0.0)
Invasive breast carcinoma	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	423 (3.3)	(3.0, 3.6)
Headache	382 (3.0)	(2.7, 3.3)
Dizziness	18 (0.1)	(0.1, 0.2)
Lethargy	6 (0.0)	(0.0, 0.1)
Paraesthesia	4 (0.0)	(0.0, 0.1)
Syncope	2 (0.0)	(0.0, 0.1)
Migraine	5 (0.0)	(0.0, 0.1)
Sciatica	2 (0.0)	(0.0, 0.1)
Hypoaesthesia	3 (0.0)	(0.0, 0.1)
Presyncope	2 (0.0)	(0.0, 0.1)
Nerve compression	1 (0.0)	(0.0, 0.0)
Psychomotor hyperactivity	2 (0.0)	(0.0, 0.1)
Somnolence	2 (0.0)	(0.0, 0.1)
Cervical radiculopathy	1 (0.0)	(0.0, 0.0)
Formication	1 (0.0)	(0.0, 0.0)
Hyperaesthesia	1 (0.0)	(0.0, 0.0)
Intracranial aneurysm	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	5 (0.0)	(0.0, 0.1)
Pregnancy	2 (0.0)	(0.0, 0.1)
Abortion spontaneous	1 (0.0)	(0.0, 0.0)

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14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12834) n[b] (%)	 (95% CI[c])
Abortion threatened	1 (0.0)	(0.0, 0.0)
Gestational hypertension	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	25 (0.2)	(0.1, 0.3)
Anxiety	13 (0.1)	(0.1, 0.2)
Insomnia	1 (0.0)	(0.0, 0.0)
Depression	2 (0.0)	(0.0, 0.1)
Anxiety disorder	2 (0.0)	(0.0, 0.1)
Attention deficit hyperactivity disorder	2 (0.0)	(0.0, 0.1)
Acute stress disorder	1 (0.0)	(0.0, 0.0)
Emotional distress	1 (0.0)	(0.0, 0.0)
Gender dysphoria	1 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	1 (0.0)	(0.0, 0.0)
Mental fatigue	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	2 (0.0)	(0.0, 0.1)
Pollakiuria	1 (0.0)	(0.0, 0.0)
Trigonitis	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	13 (0.1)	(0.1, 0.2)
Intermenstrual bleeding	4 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.0)
Breast pain	1 (0.0)	(0.0, 0.0)
Heavy menstrual bleeding	2 (0.0)	(0.0, 0.1)
Menstrual disorder	2 (0.0)	(0.0, 0.1)
Breast inflammation	1 (0.0)	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.0)
Nipple exudate bloody	1 (0.0)	(0.0, 0.0)
Pelvic pain	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	18 (0.1)	(0.1, 0.2)
Nasal congestion	5 (0.0)	(0.0, 0.1)
Rhinorrhoea	1 (0.0)	(0.0, 0.0)
Dyspnoea	2 (0.0)	(0.0, 0.1)
Rhinitis allergic	2 (0.0)	(0.0, 0.1)
Cough	1 (0.0)	(0.0, 0.0)
Oropharyngeal pain	2 (0.0)	(0.0, 0.1)
Sinus congestion	2 (0.0)	(0.0, 0.1)
Asthma	1 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	1 (0.0)	(0.0, 0.0)

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	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12834)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Upper-airway cough syndrome	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	44 (0.3)	(0.2, 0.5)
Rash	9 (0.1)	(0.0, 0.1)
Hyperhidrosis	7 (0.1)	(0.0, 0.1)
Night sweats	3 (0.0)	(0.0, 0.1)
Urticaria	4 (0.0)	(0.0, 0.1)
Acne	3 (0.0)	(0.0, 0.1)
Erythema	2 (0.0)	(0.0, 0.1)
Pruritus	4 (0.0)	(0.0, 0.1)
Dermatitis contact	1 (0.0)	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	1 (0.0)	(0.0, 0.0)
Skin lesion	1 (0.0)	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)
Dermatitis atopic	1 (0.0)	(0.0, 0.0)
Diffuse alopecia	1 (0.0)	(0.0, 0.0)
Photosensitivity reaction	1 (0.0)	(0.0, 0.0)
Pityriasis rosea	1 (0.0)	(0.0, 0.0)
Rash papular	1 (0.0)	(0.0, 0.0)
Skin oedema	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	3 (0.0)	(0.0, 0.1)
Breast conserving surgery	1 (0.0)	(0.0, 0.0)
Metabolic surgery	1 (0.0)	(0.0, 0.0)
Tooth extraction	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	22 (0.2)	(0.1, 0.3)
Hypertension	14 (0.1)	(0.1, 0.2)
Hot flush	3 (0.0)	(0.0, 0.1)
Essential hypertension	1 (0.0)	(0.0, 0.0)
Flushing	1 (0.0)	(0.0, 0.0)
Lymphoedema	2 (0.0)	(0.0, 0.1)
Varicose vein	1 (0.0)	(0.0, 0.0)

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14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12834)	
System Organ Class Preferred Term	**n[b] (%)**	**(95% CI[c])**

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:01)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_p23_d3_age

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14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9636) n[b] (%)	 (95% CI[c])
Any adverse event	1400 (14.5)	(13.8, 15.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	53 (0.6)	(0.4, 0.7)
Lymphadenopathy	46 (0.5)	(0.3, 0.6)
Lymph node pain	1 (0.0)	(0.0, 0.1)
Anaemia	3 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	1 (0.0)	(0.0, 0.1)
Normocytic anaemia	1 (0.0)	(0.0, 0.1)
Splenic vein thrombosis	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	16 (0.2)	(0.1, 0.3)
Atrial fibrillation	3 (0.0)	(0.0, 0.1)
Tachycardia	2 (0.0)	(0.0, 0.1)
Ventricular extrasystoles	1 (0.0)	(0.0, 0.1)
Acute coronary syndrome	2 (0.0)	(0.0, 0.1)
Coronary artery disease	2 (0.0)	(0.0, 0.1)
Mitral valve incompetence	1 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)
Aortic valve disease	1 (0.0)	(0.0, 0.1)
Arrhythmia	1 (0.0)	(0.0, 0.1)
Bundle branch block left	1 (0.0)	(0.0, 0.1)
Cardiac failure	1 (0.0)	(0.0, 0.1)
Myocardial ischaemia	1 (0.0)	(0.0, 0.1)
Pericardial effusion	1 (0.0)	(0.0, 0.1)
Sinus node dysfunction	1 (0.0)	(0.0, 0.1)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.1)
Wolff-Parkinson-White syndrome	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	6 (0.1)	(0.0, 0.1)
Vertigo	2 (0.0)	(0.0, 0.1)
Tinnitus	1 (0.0)	(0.0, 0.1)
Cerumen impaction	1 (0.0)	(0.0, 0.1)
Deafness neurosensory	1 (0.0)	(0.0, 0.1)
Ear pain	1 (0.0)	(0.0, 0.1)
ENDOCRINE DISORDERS	3 (0.0)	(0.0, 0.1)
Hypothyroidism	2 (0.0)	(0.0, 0.1)
Hypopituitarism	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	9 (0.1)	(0.0, 0.2)

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14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9636) n[b] (%)	 (95% CI[c])
Cataract	2 (0.0)	(0.0, 0.1)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.1)
Eye pain	1 (0.0)	(0.0, 0.1)
Keratitis	2 (0.0)	(0.0, 0.1)
Blepharitis	1 (0.0)	(0.0, 0.1)
Epiretinal membrane	1 (0.0)	(0.0, 0.1)
Photophobia	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	96 (1.0)	(0.8, 1.2)
Nausea	37 (0.4)	(0.3, 0.5)
Diarrhoea	24 (0.2)	(0.2, 0.4)
Vomiting	16 (0.2)	(0.1, 0.3)
Abdominal pain	1 (0.0)	(0.0, 0.1)
Abdominal pain upper	5 (0.1)	(0.0, 0.1)
Gastritis	2 (0.0)	(0.0, 0.1)
Gastrointestinal haemorrhage	3 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	3 (0.0)	(0.0, 0.1)
Constipation	2 (0.0)	(0.0, 0.1)
Dyspepsia	1 (0.0)	(0.0, 0.1)
Dysphagia	2 (0.0)	(0.0, 0.1)
Rectal haemorrhage	2 (0.0)	(0.0, 0.1)
Diverticulum intestinal	1 (0.0)	(0.0, 0.1)
Dry mouth	1 (0.0)	(0.0, 0.1)
Gastric ulcer	1 (0.0)	(0.0, 0.1)
Inguinal hernia	1 (0.0)	(0.0, 0.1)
Large intestine polyp	1 (0.0)	(0.0, 0.1)
Lip dry	1 (0.0)	(0.0, 0.1)
Lip haemorrhage	1 (0.0)	(0.0, 0.1)
Lip oedema	1 (0.0)	(0.0, 0.1)
Mouth ulceration	1 (0.0)	(0.0, 0.1)
Oesophageal ulcer	1 (0.0)	(0.0, 0.1)
Oesophagitis	1 (0.0)	(0.0, 0.1)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	1 (0.0)	(0.0, 0.1)
Teething	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1080 (11.2)	(10.6, 11.9)
Injection site pain	614 (6.4)	(5.9, 6.9)
Fatigue	311 (3.2)	(2.9, 3.6)

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14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9636) n[b] (%)	 (95% CI[c])
Pyrexia	247 (2.6)	(2.3, 2.9)
Chills	175 (1.8)	(1.6, 2.1)
Pain	127 (1.3)	(1.1, 1.6)
Asthenia	36 (0.4)	(0.3, 0.5)
Malaise	31 (0.3)	(0.2, 0.5)
Injection site erythema	18 (0.2)	(0.1, 0.3)
Injection site swelling	14 (0.1)	(0.1, 0.2)
Axillary pain	3 (0.0)	(0.0, 0.1)
Vaccination site pain	5 (0.1)	(0.0, 0.1)
Injection site lymphadenopathy	5 (0.1)	(0.0, 0.1)
Injection site pruritus	5 (0.1)	(0.0, 0.1)
Injection site warmth	5 (0.1)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.1)
Swelling	1 (0.0)	(0.0, 0.1)
Feeling abnormal	2 (0.0)	(0.0, 0.1)
Injection site bruising	2 (0.0)	(0.0, 0.1)
Injection site induration	3 (0.0)	(0.0, 0.1)
Injection site rash	1 (0.0)	(0.0, 0.1)
Injection site reaction	1 (0.0)	(0.0, 0.1)
Facial pain	1 (0.0)	(0.0, 0.1)
Inflammation	1 (0.0)	(0.0, 0.1)
Injection site irritation	2 (0.0)	(0.0, 0.1)
Face oedema	1 (0.0)	(0.0, 0.1)
Gait disturbance	1 (0.0)	(0.0, 0.1)
Injection site nodule	1 (0.0)	(0.0, 0.1)
Thirst	1 (0.0)	(0.0, 0.1)
Vaccination site erythema	1 (0.0)	(0.0, 0.1)
Vaccination site warmth	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	6 (0.1)	(0.0, 0.1)
Cholelithiasis	1 (0.0)	(0.0, 0.1)
Alcoholic liver disease	1 (0.0)	(0.0, 0.1)
Biliary colic	1 (0.0)	(0.0, 0.1)
Biliary obstruction	1 (0.0)	(0.0, 0.1)
Hepatic cirrhosis	1 (0.0)	(0.0, 0.1)
Hepatic lesion	1 (0.0)	(0.0, 0.1)
Hepatitis acute	1 (0.0)	(0.0, 0.1)
Jaundice cholestatic	1 (0.0)	(0.0, 0.1)

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14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=9636)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)
Immunisation reaction	1 (0.0)	(0.0, 0.1)
Hypersensitivity	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	46 (0.5)	(0.3, 0.6)
Urinary tract infection	10 (0.1)	(0.0, 0.2)
Tooth infection	2 (0.0)	(0.0, 0.1)
Ear infection	2 (0.0)	(0.0, 0.1)
Herpes zoster	4 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)
Conjunctivitis	3 (0.0)	(0.0, 0.1)
Diverticulitis	5 (0.1)	(0.0, 0.1)
Appendicitis	1 (0.0)	(0.0, 0.1)
Otitis externa	1 (0.0)	(0.0, 0.1)
Rhinitis	1 (0.0)	(0.0, 0.1)
Cystitis	1 (0.0)	(0.0, 0.1)
Genital herpes	1 (0.0)	(0.0, 0.1)
Localised infection	1 (0.0)	(0.0, 0.1)
Oral herpes	1 (0.0)	(0.0, 0.1)
Abdominal abscess	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)
Bronchitis	1 (0.0)	(0.0, 0.1)
Complicated appendicitis	1 (0.0)	(0.0, 0.1)
Conjunctivitis viral	1 (0.0)	(0.0, 0.1)
Erysipelas	1 (0.0)	(0.0, 0.1)
Focal peritonitis	1 (0.0)	(0.0, 0.1)
Fungal skin infection	1 (0.0)	(0.0, 0.1)
Gastroenteritis norovirus	1 (0.0)	(0.0, 0.1)
Malaria	1 (0.0)	(0.0, 0.1)
Osteomyelitis	1 (0.0)	(0.0, 0.1)
Periodontitis	1 (0.0)	(0.0, 0.1)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)
Staphylococcal infection	1 (0.0)	(0.0, 0.1)
Tooth abscess	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	25 (0.3)	(0.2, 0.4)
Fall	7 (0.1)	(0.0, 0.1)
Skin laceration	3 (0.0)	(0.0, 0.1)
Animal bite	2 (0.0)	(0.0, 0.1)

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	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=9636)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Joint injury	1 (0.0)	(0.0, 0.1)
Wrist fracture	3 (0.0)	(0.0, 0.1)
Contusion	1 (0.0)	(0.0, 0.1)
Foot fracture	1 (0.0)	(0.0, 0.1)
Limb injury	1 (0.0)	(0.0, 0.1)
Road traffic accident	1 (0.0)	(0.0, 0.1)
Arthropod bite	1 (0.0)	(0.0, 0.1)
Corneal abrasion	1 (0.0)	(0.0, 0.1)
Eye contusion	1 (0.0)	(0.0, 0.1)
Head injury	1 (0.0)	(0.0, 0.1)
Humerus fracture	1 (0.0)	(0.0, 0.1)
Post-traumatic pain	1 (0.0)	(0.0, 0.1)
Radius fracture	1 (0.0)	(0.0, 0.1)
Retinal injury	1 (0.0)	(0.0, 0.1)
Tendon injury	1 (0.0)	(0.0, 0.1)
Vulvovaginal injury	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	15 (0.2)	(0.1, 0.3)
Body temperature increased	11 (0.1)	(0.1, 0.2)
Cardiac murmur	2 (0.0)	(0.0, 0.1)
Blood urine present	1 (0.0)	(0.0, 0.1)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	13 (0.1)	(0.1, 0.2)
Decreased appetite	5 (0.1)	(0.0, 0.1)
Hypercholesterolaemia	4 (0.0)	(0.0, 0.1)
Dyslipidaemia	2 (0.0)	(0.0, 0.1)
Gout	1 (0.0)	(0.0, 0.1)
Hyponatraemia	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	222 (2.3)	(2.0, 2.6)
Myalgia	150 (1.6)	(1.3, 1.8)
Arthralgia	29 (0.3)	(0.2, 0.4)
Pain in extremity	19 (0.2)	(0.1, 0.3)
Back pain	8 (0.1)	(0.0, 0.2)
Neck pain	1 (0.0)	(0.0, 0.1)
Muscle spasms	3 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)
Muscular weakness	2 (0.0)	(0.0, 0.1)

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System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9636) n[b] (%)	 (95% CI[c])
Musculoskeletal stiffness	2 (0.0)	(0.0, 0.1)
Tendonitis	2 (0.0)	(0.0, 0.1)
Arthritis	1 (0.0)	(0.0, 0.1)
Bursitis	2 (0.0)	(0.0, 0.1)
Osteoarthritis	2 (0.0)	(0.0, 0.1)
Osteoporosis	1 (0.0)	(0.0, 0.1)
Plantar fasciitis	1 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.1)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.1)
Cervical spinal stenosis	1 (0.0)	(0.0, 0.1)
Costochondritis	1 (0.0)	(0.0, 0.1)
Fibromyalgia	1 (0.0)	(0.0, 0.1)
Greater trochanteric pain syndrome	1 (0.0)	(0.0, 0.1)
Groin pain	1 (0.0)	(0.0, 0.1)
Kyphosis	1 (0.0)	(0.0, 0.1)
Rheumatoid arthritis	1 (0.0)	(0.0, 0.1)
Temporomandibular joint syndrome	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	13 (0.1)	(0.1, 0.2)
Basal cell carcinoma	4 (0.0)	(0.0, 0.1)
Adenocarcinoma of colon	1 (0.0)	(0.0, 0.1)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.1)
Colon cancer	1 (0.0)	(0.0, 0.1)
Endometrial adenocarcinoma	1 (0.0)	(0.0, 0.1)
Gastrointestinal stromal tumour	1 (0.0)	(0.0, 0.1)
Papillary thyroid cancer	1 (0.0)	(0.0, 0.1)
Prostate cancer	1 (0.0)	(0.0, 0.1)
Renal neoplasm	1 (0.0)	(0.0, 0.1)
Squamous cell carcinoma of skin	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	209 (2.2)	(1.9, 2.5)
Headache	177 (1.8)	(1.6, 2.1)
Dizziness	8 (0.1)	(0.0, 0.2)
Lethargy	7 (0.1)	(0.0, 0.1)
Paraesthesia	3 (0.0)	(0.0, 0.1)
Syncope	4 (0.0)	(0.0, 0.1)
Sciatica	3 (0.0)	(0.0, 0.1)
Presyncope	1 (0.0)	(0.0, 0.1)

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	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=9636)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)
Nerve compression	1 (0.0)	(0.0, 0.1)
Tremor	2 (0.0)	(0.0, 0.1)
Carotid arteriosclerosis	1 (0.0)	(0.0, 0.1)
Haemorrhage intracranial	1 (0.0)	(0.0, 0.1)
Hepatic encephalopathy	1 (0.0)	(0.0, 0.1)
Neuropathy peripheral	1 (0.0)	(0.0, 0.1)
Parosmia	1 (0.0)	(0.0, 0.1)
Seizure	1 (0.0)	(0.0, 0.1)
Taste disorder	1 (0.0)	(0.0, 0.1)
Tension headache	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	18 (0.2)	(0.1, 0.3)
Anxiety	4 (0.0)	(0.0, 0.1)
Insomnia	5 (0.1)	(0.0, 0.1)
Depression	1 (0.0)	(0.0, 0.1)
Disorientation	2 (0.0)	(0.0, 0.1)
Affective disorder	1 (0.0)	(0.0, 0.1)
Alcohol abuse	1 (0.0)	(0.0, 0.1)
Bruxism	1 (0.0)	(0.0, 0.1)
Irritability	1 (0.0)	(0.0, 0.1)
Libido decreased	1 (0.0)	(0.0, 0.1)
Psychiatric decompensation	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	6 (0.1)	(0.0, 0.1)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)
Calculus bladder	1 (0.0)	(0.0, 0.1)
Renal colic	1 (0.0)	(0.0, 0.1)
Renal pain	1 (0.0)	(0.0, 0.1)
Stress urinary incontinence	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	10 (0.1)	(0.0, 0.2)
Benign prostatic hyperplasia	3 (0.0)	(0.0, 0.1)
Breast pain	1 (0.0)	(0.0, 0.1)
Atrophic vulvovaginitis	1 (0.0)	(0.0, 0.1)
Cervical bulla	1 (0.0)	(0.0, 0.1)
Ovarian cyst	1 (0.0)	(0.0, 0.1)
Prostatitis	1 (0.0)	(0.0, 0.1)
Testicular pain	1 (0.0)	(0.0, 0.1)

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	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=9636)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Uterine polyp	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	15 (0.2)	(0.1, 0.3)
Rhinorrhoea	4 (0.0)	(0.0, 0.1)
Dyspnoea	1 (0.0)	(0.0, 0.1)
Rhinitis allergic	1 (0.0)	(0.0, 0.1)
Cough	1 (0.0)	(0.0, 0.1)
Epistaxis	2 (0.0)	(0.0, 0.1)
Dysphonia	1 (0.0)	(0.0, 0.1)
Nasal turbinate hypertrophy	1 (0.0)	(0.0, 0.1)
Pleural effusion	1 (0.0)	(0.0, 0.1)
Sleep apnoea syndrome	1 (0.0)	(0.0, 0.1)
Throat tightness	1 (0.0)	(0.0, 0.1)
Vocal cord polyp	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	33 (0.3)	(0.2, 0.5)
Rash	6 (0.1)	(0.0, 0.1)
Hyperhidrosis	2 (0.0)	(0.0, 0.1)
Night sweats	4 (0.0)	(0.0, 0.1)
Urticaria	1 (0.0)	(0.0, 0.1)
Acne	1 (0.0)	(0.0, 0.1)
Erythema	2 (0.0)	(0.0, 0.1)
Dermatitis contact	1 (0.0)	(0.0, 0.1)
Alopecia	2 (0.0)	(0.0, 0.1)
Psoriasis	1 (0.0)	(0.0, 0.1)
Rash maculo-papular	1 (0.0)	(0.0, 0.1)
Skin lesion	1 (0.0)	(0.0, 0.1)
Blister	1 (0.0)	(0.0, 0.1)
Dermatitis	1 (0.0)	(0.0, 0.1)
Diabetic foot	1 (0.0)	(0.0, 0.1)
Ecchymosis	1 (0.0)	(0.0, 0.1)
Hand dermatitis	1 (0.0)	(0.0, 0.1)
Ingrowing nail	1 (0.0)	(0.0, 0.1)
Lichen planus	1 (0.0)	(0.0, 0.1)
Lichen sclerosus	1 (0.0)	(0.0, 0.1)
Pain of skin	1 (0.0)	(0.0, 0.1)
Rash erythematous	1 (0.0)	(0.0, 0.1)
Rash pruritic	1 (0.0)	(0.0, 0.1)
Rosacea	1 (0.0)	(0.0, 0.1)

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	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=9636)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
SURGICAL AND MEDICAL PROCEDURES	4 (0.0)	(0.0, 0.1)
Breast conserving surgery	1 (0.0)	(0.0, 0.1)
Cataract operation	1 (0.0)	(0.0, 0.1)
Knee arthroplasty	1 (0.0)	(0.0, 0.1)
Meniscus operation	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	21 (0.2)	(0.1, 0.3)
Hypertension	15 (0.2)	(0.1, 0.3)
Essential hypertension	1 (0.0)	(0.0, 0.1)
Flushing	1 (0.0)	(0.0, 0.1)
Aneurysm	1 (0.0)	(0.0, 0.1)
Aortic aneurysm	1 (0.0)	(0.0, 0.1)
Aortic arteriosclerosis	1 (0.0)	(0.0, 0.1)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)
Hypotension	1 (0.0)	(0.0, 0.1)
Peripheral vascular disorder	1 (0.0)	(0.0, 0.1)
Venous thrombosis limb	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:01)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_p23_d3_age

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14.94. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=689)		≥16 Years (N[a]=18869)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	123 (17.9)	(15.1, 20.9)	3117 (16.5)	(16.0, 17.1)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	5 (0.7)	(0.2, 1.7)	288 (1.5)	(1.4, 1.7)
Lymphadenopathy	5 (0.7)	(0.2, 1.7)	276 (1.5)	(1.3, 1.6)
Lymph node pain	0	(0.0, 0.5)	8 (0.0)	(0.0, 0.1)
Anaemia	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Normocytic anaemia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Splenic vein thrombosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	1 (0.1)	(0.0, 0.8)	25 (0.1)	(0.1, 0.2)
Palpitations	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Ventricular extrasystoles	1 (0.1)	(0.0, 0.8)	2 (0.0)	(0.0, 0.0)
Acute coronary syndrome	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Mitral valve incompetence	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Angina pectoris	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Aortic valve disease	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Arrhythmia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Atrioventricular block	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Bradycardia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Bundle branch block left	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Bundle branch block right	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Cardiac failure	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Myocardial ischaemia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Myocarditis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Sinus node dysfunction	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Wolff-Parkinson-White syndrome	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.5)	14 (0.1)	(0.0, 0.1)
Vertigo	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Tinnitus	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Cerumen impaction	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Deafness	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.94. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=689)		≥16 Years (N^a=18869)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Deafness neurosensory	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Ear discomfort	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Ear pain	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Middle ear effusion	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Vertigo positional	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	0	(0.0, 0.5)	7 (0.0)	(0.0, 0.1)
Hypothyroidism	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Autoimmune thyroiditis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Hypopituitarism	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Secondary hyperthyroidism	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	0	(0.0, 0.5)	11 (0.1)	(0.0, 0.1)
Cataract	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Eye pain	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Keratitis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Blepharitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Epiretinal membrane	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Photophobia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	10 (1.5)	(0.7, 2.7)	189 (1.0)	(0.9, 1.2)
Nausea	7 (1.0)	(0.4, 2.1)	87 (0.5)	(0.4, 0.6)
Diarrhoea	0	(0.0, 0.5)	53 (0.3)	(0.2, 0.4)
Vomiting	5 (0.7)	(0.2, 1.7)	32 (0.2)	(0.1, 0.2)
Abdominal pain	1 (0.1)	(0.0, 0.8)	5 (0.0)	(0.0, 0.1)
Abdominal pain upper	1 (0.1)	(0.0, 0.8)	4 (0.0)	(0.0, 0.1)
Gastritis	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Gastrooesophageal reflux disease	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Constipation	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Dyspepsia	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Rectal haemorrhage	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Abdominal discomfort	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Anogenital dysplasia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Colitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Dental caries	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.94. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=689)		≥16 Years (N^a=18869)	
System Organ Class Preferred Term	n^b (%)	(95% CI^c)	n^b (%)	(95% CI^c)
Dry mouth	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Food poisoning	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gastric ulcer	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Inguinal hernia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Large intestine polyp	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Lip dry	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Lip haemorrhage	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Lip oedema	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Oesophageal ulcer	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Oesophagitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Oral mucosal blistering	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Retching	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Teething	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Tooth impacted	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Volvulus	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	103 (14.9)	(12.4, 17.8)	2338 (12.4)	(11.9, 12.9)
Injection site pain	52 (7.5)	(5.7, 9.8)	1296 (6.9)	(6.5, 7.2)
Fatigue	48 (7.0)	(5.2, 9.1)	687 (3.6)	(3.4, 3.9)
Pyrexia	26 (3.8)	(2.5, 5.5)	560 (3.0)	(2.7, 3.2)
Chills	16 (2.3)	(1.3, 3.7)	378 (2.0)	(1.8, 2.2)
Pain	18 (2.6)	(1.6, 4.1)	298 (1.6)	(1.4, 1.8)
Asthenia	0	(0.0, 0.5)	76 (0.4)	(0.3, 0.5)
Malaise	1 (0.1)	(0.0, 0.8)	57 (0.3)	(0.2, 0.4)
Injection site erythema	4 (0.6)	(0.2, 1.5)	37 (0.2)	(0.1, 0.3)
Injection site swelling	0	(0.0, 0.5)	31 (0.2)	(0.1, 0.2)
Axillary pain	1 (0.1)	(0.0, 0.8)	23 (0.1)	(0.1, 0.2)
Vaccination site pain	0	(0.0, 0.5)	12 (0.1)	(0.0, 0.1)
Injection site lymphadenopathy	0	(0.0, 0.5)	9 (0.0)	(0.0, 0.1)
Injection site pruritus	0	(0.0, 0.5)	7 (0.0)	(0.0, 0.1)
Injection site warmth	0	(0.0, 0.5)	7 (0.0)	(0.0, 0.1)
Localised oedema	0	(0.0, 0.5)	7 (0.0)	(0.0, 0.1)
Chest pain	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)

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14.94. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=689)		≥16 Years (N[a]=18869)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Swelling	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Feeling abnormal	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Injection site bruising	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Injection site mass	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Vaccination site lymphadenopathy	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Injection site induration	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Injection site oedema	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Injection site rash	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Injection site reaction	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Vaccination site swelling	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Chest discomfort	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Facial pain	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Feeling hot	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Inflammation	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Injection site inflammation	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Injection site irritation	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Application site erythema	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Cyst	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Face oedema	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gait disturbance	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Illness	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Injection site haematoma	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Injection site vesicles	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Sensation of foreign body	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Thirst	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Vaccination site erythema	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Vaccination site warmth	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	0	(0.0, 0.5)	10 (0.1)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Cholelithiasis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Alcoholic liver disease	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Biliary colic	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Biliary obstruction	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Cholecystitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.94. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=689)		≥16 Years (N[a]=18869)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hepatic cirrhosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hepatic lesion	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hepatitis acute	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hyperbilirubinaemia neonatal	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Jaundice cholestatic	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Immunisation reaction	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Hypersensitivity	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	0	(0.0, 0.5)	100 (0.5)	(0.4, 0.6)
Urinary tract infection	0	(0.0, 0.5)	20 (0.1)	(0.1, 0.2)
Tooth infection	0	(0.0, 0.5)	11 (0.1)	(0.0, 0.1)
Ear infection	0	(0.0, 0.5)	6 (0.0)	(0.0, 0.1)
Herpes zoster	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Cellulitis	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Conjunctivitis	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Diverticulitis	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Appendicitis	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Otitis externa	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Rhinitis	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Sinusitis	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Cystitis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Gastroenteritis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Genital herpes	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Localised infection	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Oral herpes	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Syphilis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Wound infection	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Balanitis candida	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Bartholinitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Bronchitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Conjunctivitis bacterial	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Conjunctivitis viral	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Erysipelas	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=689)		≥16 Years (N[a]=18869)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Focal peritonitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Fungal skin infection	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gastroenteritis norovirus	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Infected cyst	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Malaria	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Nasopharyngitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Onychomycosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Periodontitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Staphylococcal infection	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Tooth abscess	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Vaginal infection	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Vulvovaginal mycotic infection	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3 (0.4)	(0.1, 1.3)	80 (0.4)	(0.3, 0.5)
Exposure during pregnancy	0	(0.0, 0.5)	20 (0.1)	(0.1, 0.2)
Fall	0	(0.0, 0.5)	13 (0.1)	(0.0, 0.1)
Maternal exposure during breast feeding	0	(0.0, 0.5)	6 (0.0)	(0.0, 0.1)
Skin laceration	0	(0.0, 0.5)	6 (0.0)	(0.0, 0.1)
Animal bite	0	(0.0, 0.5)	6 (0.0)	(0.0, 0.1)
Ligament sprain	1 (0.1)	(0.0, 0.8)	4 (0.0)	(0.0, 0.1)
Ankle fracture	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Cartilage injury	1 (0.1)	(0.0, 0.8)	2 (0.0)	(0.0, 0.0)
Joint injury	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Wrist fracture	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Cervical vertebral fracture	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Contusion	1 (0.1)	(0.0, 0.8)	1 (0.0)	(0.0, 0.0)
Limb injury	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Vaccination complication	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Wound	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Arthropod bite	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Chest injury	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Corneal abrasion	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.94. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=689)		≥16 Years (N[a]=18869)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Eye contusion	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Femur fracture	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Nasal injury	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Overdose	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Post-traumatic pain	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Radius fracture	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Retinal injury	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Skin abrasion	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Stress fracture	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Tendon injury	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Wound dehiscence	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.5)	49 (0.3)	(0.2, 0.3)
Body temperature increased	0	(0.0, 0.5)	42 (0.2)	(0.2, 0.3)
Cardiac murmur	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Heart rate increased	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Blood urine present	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Cardiac stress test abnormal	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Human papilloma virus test positive	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.5)	18 (0.1)	(0.1, 0.2)
Decreased appetite	0	(0.0, 0.5)	6 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Vitamin D deficiency	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Dyslipidaemia	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Gout	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hypoglycaemia neonatal	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hyponatraemia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	17 (2.5)	(1.4, 3.9)	543 (2.9)	(2.6, 3.1)
Myalgia	12 (1.7)	(0.9, 3.0)	389 (2.1)	(1.9, 2.3)
Arthralgia	0	(0.0, 0.5)	54 (0.3)	(0.2, 0.4)
Pain in extremity	6 (0.9)	(0.3, 1.9)	44 (0.2)	(0.2, 0.3)
Back pain	0	(0.0, 0.5)	18 (0.1)	(0.1, 0.2)
Musculoskeletal chest pain	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Neck pain	0	(0.0, 0.5)	9 (0.0)	(0.0, 0.1)

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14.94. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=689)		≥16 Years (N[a]=18869)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Musculoskeletal pain	0	(0.0, 0.5)	6 (0.0)	(0.0, 0.1)
Muscle spasms	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Muscle contracture	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Muscular weakness	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Musculoskeletal stiffness	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Synovial cyst	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Tendonitis	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Arthritis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Axillary mass	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Bursitis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Muscle twitching	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Osteochondritis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Plantar fasciitis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Rotator cuff syndrome	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Spinal osteoarthritis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Cervical spinal stenosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Costochondritis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Flank pain	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Greater trochanteric pain syndrome	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Groin pain	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Kyphosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Neck mass	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Painful os peroneum syndrome	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Rheumatoid arthritis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Sjogren's syndrome	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.5)	15 (0.1)	(0.0, 0.1)
Basal cell carcinoma	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Adenocarcinoma of colon	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Adenoma benign	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.94. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=689)		≥16 Years (N[a]=18869)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Colon cancer	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Endometrial adenocarcinoma	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gastrointestinal stromal tumour	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Papillary thyroid cancer	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Renal neoplasm	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma of skin	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	40 (5.8)	(4.2, 7.8)	517 (2.7)	(2.5, 3.0)
Headache	38 (5.5)	(3.9, 7.5)	452 (2.4)	(2.2, 2.6)
Dizziness	1 (0.1)	(0.0, 0.8)	25 (0.1)	(0.1, 0.2)
Lethargy	0	(0.0, 0.5)	11 (0.1)	(0.0, 0.1)
Paraesthesia	0	(0.0, 0.5)	6 (0.0)	(0.0, 0.1)
Syncope	1 (0.1)	(0.0, 0.8)	6 (0.0)	(0.0, 0.1)
Migraine	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Sciatica	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Hypoaesthesia	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Presyncope	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Cerebrovascular accident	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Nerve compression	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Psychomotor hyperactivity	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Somnolence	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Tremor	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Carotid arteriosclerosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Cervical radiculopathy	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Formication	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hepatic encephalopathy	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hyperaesthesia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Intracranial aneurysm	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Parosmia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Seizure	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Taste disorder	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Pregnancy	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Abortion threatened	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.94. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=689)		≥16 Years (N[a]=18869)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gestational hypertension	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	7 (1.0)	(0.4, 2.1)	40 (0.2)	(0.2, 0.3)
Anxiety	3 (0.4)	(0.1, 1.3)	16 (0.1)	(0.0, 0.1)
Insomnia	1 (0.1)	(0.0, 0.8)	6 (0.0)	(0.0, 0.1)
Depression	2 (0.3)	(0.0, 1.0)	3 (0.0)	(0.0, 0.0)
Anxiety disorder	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Attention deficit hyperactivity disorder	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Disorientation	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Nightmare	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
Acute stress disorder	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Affective disorder	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Bruxism	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Emotional distress	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gender dysphoria	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Irritability	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Libido decreased	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Major depression	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
Psychiatric decompensation	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Suicidal ideation	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
Suicide attempt	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	0	(0.0, 0.5)	7 (0.0)	(0.0, 0.1)
Nephrolithiasis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Calculus bladder	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pollakiuria	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Renal colic	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Stress urinary incontinence	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Trigonitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.3)	(0.0, 1.0)	18 (0.1)	(0.1, 0.2)
Intermenstrual bleeding	1 (0.1)	(0.0, 0.8)	4 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Breast pain	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Heavy menstrual bleeding	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Menstrual disorder	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Atrophic vulvovaginitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Breast inflammation	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=689)		≥16 Years (N^a=18869)	
System Organ Class Preferred Term	n^b (%)	(95% CI^c)	n^b (%)	(95% CI^c)
Cervical bulla	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Dysmenorrhoea	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
Nipple exudate bloody	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Ovarian cyst	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pelvic pain	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Prostatitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Uterine polyp	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.1)	(0.0, 0.8)	26 (0.1)	(0.1, 0.2)
Nasal congestion	1 (0.1)	(0.0, 0.8)	4 (0.0)	(0.0, 0.1)
Rhinorrhoea	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Dyspnoea	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Rhinitis allergic	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Epistaxis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Oropharyngeal pain	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Sinus congestion	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Dysphonia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pleural effusion	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Sleep apnoea syndrome	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Throat tightness	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Upper-airway cough syndrome	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.3)	(0.0, 1.0)	66 (0.3)	(0.3, 0.4)
Rash	0	(0.0, 0.5)	12 (0.1)	(0.0, 0.1)
Hyperhidrosis	0	(0.0, 0.5)	6 (0.0)	(0.0, 0.1)
Night sweats	0	(0.0, 0.5)	6 (0.0)	(0.0, 0.1)
Urticaria	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Acne	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Erythema	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Pruritus	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Dermatitis contact	1 (0.1)	(0.0, 0.8)	2 (0.0)	(0.0, 0.0)
Alopecia	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Psoriasis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Skin lesion	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.94. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=689)		≥16 Years (N[a]=18869)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Angioedema	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Blister	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Cold sweat	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Dermatitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Dermatitis atopic	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Diabetic foot	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Diffuse alopecia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Ecchymosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hand dermatitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Lichen sclerosus	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pain of skin	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Photosensitivity reaction	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pityriasis rosea	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Rash papular	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Rash pruritic	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Rosacea	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Sensitive skin	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
Skin oedema	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.1)	(0.0, 0.8)	5 (0.0)	(0.0, 0.1)
Breast conserving surgery	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Cataract operation	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Knee arthroplasty	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Meniscus operation	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Oral surgery	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
VASCULAR DISORDERS	0	(0.0, 0.5)	38 (0.2)	(0.1, 0.3)
Hypertension	0	(0.0, 0.5)	26 (0.1)	(0.1, 0.2)
Hot flush	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Essential hypertension	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Flushing	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Lymphoedema	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Aneurysm	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Aortic arteriosclerosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Arteriosclerosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.94. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=689)		≥16 Years (N[a]=18869)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Peripheral vascular disorder	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Varicose vein	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Venous thrombosis limb	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
Note: All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:01)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_p23_d3_race

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14.95. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: Black or African American

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=38)		≥16 Years (N[a]=1962)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	5 (13.2)	(4.4, 28.1)	269 (13.7)	(12.2, 15.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 9.3)	29 (1.5)	(1.0, 2.1)
Lymphadenopathy	0	(0.0, 9.3)	28 (1.4)	(1.0, 2.1)
Hypochromic anaemia	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
CARDIAC DISORDERS	0	(0.0, 9.3)	3 (0.2)	(0.0, 0.4)
Palpitations	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Atrial fibrillation	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Coronary artery disease	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Mitral valve incompetence	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
EAR AND LABYRINTH DISORDERS	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Tympanic membrane perforation	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
GASTROINTESTINAL DISORDERS	0	(0.0, 9.3)	7 (0.4)	(0.1, 0.7)
Nausea	0	(0.0, 9.3)	3 (0.2)	(0.0, 0.4)
Diarrhoea	0	(0.0, 9.3)	3 (0.2)	(0.0, 0.4)
Vomiting	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Abdominal pain upper	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (7.9)	(1.7, 21.4)	212 (10.8)	(9.5, 12.3)
Injection site pain	2 (5.3)	(0.6, 17.7)	148 (7.5)	(6.4, 8.8)
Fatigue	1 (2.6)	(0.1, 13.8)	37 (1.9)	(1.3, 2.6)
Pyrexia	0	(0.0, 9.3)	37 (1.9)	(1.3, 2.6)
Chills	1 (2.6)	(0.1, 13.8)	17 (0.9)	(0.5, 1.4)
Pain	1 (2.6)	(0.1, 13.8)	19 (1.0)	(0.6, 1.5)
Asthenia	0	(0.0, 9.3)	2 (0.1)	(0.0, 0.4)
Malaise	0	(0.0, 9.3)	8 (0.4)	(0.2, 0.8)
Injection site erythema	0	(0.0, 9.3)	2 (0.1)	(0.0, 0.4)
Injection site swelling	0	(0.0, 9.3)	4 (0.2)	(0.1, 0.5)
Vaccination site pain	0	(0.0, 9.3)	2 (0.1)	(0.0, 0.4)
Injection site lymphadenopathy	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Injection site pruritus	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Vaccination site lymphadenopathy	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Injection site rash	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Vaccination site swelling	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)

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14.95. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: Black or African American

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=38)		≥16 Years (N[a]=1962)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Chest discomfort	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Inflammation	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Injection site irritation	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Vaccination site oedema	0	(0.0, 9.3)	2 (0.1)	(0.0, 0.4)
Oedema peripheral	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Peripheral swelling	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
HEPATOBILIARY DISORDERS	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Cholecystitis acute	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
IMMUNE SYSTEM DISORDERS	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Immunisation reaction	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
INFECTIONS AND INFESTATIONS	0	(0.0, 9.3)	7 (0.4)	(0.1, 0.7)
Urinary tract infection	0	(0.0, 9.3)	2 (0.1)	(0.0, 0.4)
Herpes zoster	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Localised infection	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Syphilis	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Pneumonia	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Subcutaneous abscess	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 9.3)	10 (0.5)	(0.2, 0.9)
Exposure during pregnancy	0	(0.0, 9.3)	5 (0.3)	(0.1, 0.6)
Fall	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Maternal exposure during breast feeding	0	(0.0, 9.3)	2 (0.1)	(0.0, 0.4)
Ligament sprain	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Foot fracture	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Road traffic accident	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
INVESTIGATIONS	0	(0.0, 9.3)	2 (0.1)	(0.0, 0.4)
Body temperature increased	0	(0.0, 9.3)	2 (0.1)	(0.0, 0.4)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 9.3)	3 (0.2)	(0.0, 0.4)
Decreased appetite	0	(0.0, 9.3)	2 (0.1)	(0.0, 0.4)
Increased appetite	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (2.6)	(0.1, 13.8)	36 (1.8)	(1.3, 2.5)
Myalgia	0	(0.0, 9.3)	26 (1.3)	(0.9, 1.9)
Arthralgia	0	(0.0, 9.3)	3 (0.2)	(0.0, 0.4)

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14.95. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: Black or African American

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=38)		≥16 Years (N[a]=1962)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pain in extremity	0	(0.0, 9.3)	2 (0.1)	(0.0, 0.4)
Back pain	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Musculoskeletal chest pain	1 (2.6)	(0.1, 13.8)	2 (0.1)	(0.0, 0.4)
Synovial cyst	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Arthritis	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Fibromyalgia	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Intraductal proliferative breast lesion	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
NERVOUS SYSTEM DISORDERS	1 (2.6)	(0.1, 13.8)	35 (1.8)	(1.2, 2.5)
Headache	1 (2.6)	(0.1, 13.8)	29 (1.5)	(1.0, 2.1)
Lethargy	0	(0.0, 9.3)	2 (0.1)	(0.0, 0.4)
Sciatica	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Tremor	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Haemorrhage intracranial	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Neuropathy peripheral	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Tension headache	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
PSYCHIATRIC DISORDERS	1 (2.6)	(0.1, 13.8)	2 (0.1)	(0.0, 0.4)
Anxiety	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Depression	1 (2.6)	(0.1, 13.8)	0	(0.0, 0.2)
Aggression	1 (2.6)	(0.1, 13.8)	0	(0.0, 0.2)
Alcohol abuse	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
RENAL AND URINARY DISORDERS	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Renal pain	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 9.3)	2 (0.1)	(0.0, 0.4)
Breast pain	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Testicular pain	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 9.3)	3 (0.2)	(0.0, 0.4)
Nasal congestion	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Rhinorrhoea	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Epistaxis	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 9.3)	4 (0.2)	(0.1, 0.5)
Hyperhidrosis	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)

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14.95. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: Black or African American

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=38)		≥16 Years (N^a=1962)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Urticaria	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Pruritus	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Skin lesion	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Metabolic surgery	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
VASCULAR DISORDERS	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Hypertension	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)

Note: MedDRA (v25.1) coding dictionary applied.
Note: All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:01)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_p23_d3_race

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14.96. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: All Others

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=98)		≥16 Years (N[a]=1639)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	25 (25.5)	(17.2, 35.3)	432 (26.4)	(24.2, 28.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	3 (3.1)	(0.6, 8.7)	43 (2.6)	(1.9, 3.5)
Lymphadenopathy	3 (3.1)	(0.6, 8.7)	43 (2.6)	(1.9, 3.5)
Lymph node pain	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
CARDIAC DISORDERS	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Palpitations	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
EYE DISORDERS	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Cataract	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Dry eye	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Retinal degeneration	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
GASTROINTESTINAL DISORDERS	2 (2.0)	(0.2, 7.2)	7 (0.4)	(0.2, 0.9)
Nausea	2 (2.0)	(0.2, 7.2)	3 (0.2)	(0.0, 0.5)
Diarrhoea	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Abdominal pain	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Dysphagia	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Paraesthesia oral	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	24 (24.5)	(16.4, 34.2)	373 (22.8)	(20.7, 24.9)
Injection site pain	12 (12.2)	(6.5, 20.4)	235 (14.3)	(12.7, 16.1)
Fatigue	12 (12.2)	(6.5, 20.4)	134 (8.2)	(6.9, 9.6)
Pyrexia	2 (2.0)	(0.2, 7.2)	68 (4.1)	(3.2, 5.2)
Chills	5 (5.1)	(1.7, 11.5)	48 (2.9)	(2.2, 3.9)
Pain	5 (5.1)	(1.7, 11.5)	35 (2.1)	(1.5, 3.0)
Asthenia	0	(0.0, 3.7)	3 (0.2)	(0.0, 0.5)
Malaise	2 (2.0)	(0.2, 7.2)	11 (0.7)	(0.3, 1.2)
Injection site erythema	1 (1.0)	(0.0, 5.6)	3 (0.2)	(0.0, 0.5)
Injection site swelling	0	(0.0, 3.7)	2 (0.1)	(0.0, 0.4)
Axillary pain	0	(0.0, 3.7)	3 (0.2)	(0.0, 0.5)
Vaccination site pain	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Injection site lymphadenopathy	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Injection site pruritus	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Injection site warmth	0	(0.0, 3.7)	2 (0.1)	(0.0, 0.4)
Chest pain	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Injection site bruising	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)

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14.96. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: All Others

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=98)		≥16 Years (N^a=1639)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Vaccination site lymphadenopathy	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Injection site induration	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Injection site oedema	0	(0.0, 3.7)	2 (0.1)	(0.0, 0.4)
Injection site discomfort	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Injection site nodule	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Injury associated with device	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
INFECTIONS AND INFESTATIONS	1 (1.0)	(0.0, 5.6)	4 (0.2)	(0.1, 0.6)
Urinary tract infection	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Herpes zoster	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Cellulitis	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Abscess jaw	1 (1.0)	(0.0, 5.6)	0	(0.0, 0.2)
Adenoviral conjunctivitis	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (1.0)	(0.0, 5.6)	14 (0.9)	(0.5, 1.4)
Exposure during pregnancy	0	(0.0, 3.7)	5 (0.3)	(0.1, 0.7)
Fall	1 (1.0)	(0.0, 5.6)	0	(0.0, 0.2)
Maternal exposure during breast feeding	0	(0.0, 3.7)	3 (0.2)	(0.0, 0.5)
Skin laceration	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Foot fracture	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Limb injury	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Maternal exposure during pregnancy	0	(0.0, 3.7)	2 (0.1)	(0.0, 0.4)
Forearm fracture	1 (1.0)	(0.0, 5.6)	0	(0.0, 0.2)
Head injury	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
INVESTIGATIONS	0	(0.0, 3.7)	10 (0.6)	(0.3, 1.1)
Body temperature increased	0	(0.0, 3.7)	10 (0.6)	(0.3, 1.1)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 3.7)	3 (0.2)	(0.0, 0.5)
Decreased appetite	0	(0.0, 3.7)	3 (0.2)	(0.0, 0.5)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (1.0)	(0.0, 5.6)	67 (4.1)	(3.2, 5.2)
Myalgia	1 (1.0)	(0.0, 5.6)	59 (3.6)	(2.8, 4.6)
Arthralgia	0	(0.0, 3.7)	3 (0.2)	(0.0, 0.5)
Pain in extremity	0	(0.0, 3.7)	3 (0.2)	(0.0, 0.5)
Musculoskeletal chest pain	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Muscle spasms	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Axillary mass	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)

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14.96. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: All Others

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=98)		≥16 Years (N^a=1639)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Invasive breast carcinoma	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
NERVOUS SYSTEM DISORDERS	8 (8.2)	(3.6, 15.5)	80 (4.9)	(3.9, 6.0)
Headache	8 (8.2)	(3.6, 15.5)	78 (4.8)	(3.8, 5.9)
Dizziness	1 (1.0)	(0.0, 5.6)	1 (0.1)	(0.0, 0.3)
Paraesthesia	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 3.7)	2 (0.1)	(0.0, 0.4)
Pregnancy	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Abortion spontaneous	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
PSYCHIATRIC DISORDERS	1 (1.0)	(0.0, 5.6)	1 (0.1)	(0.0, 0.3)
Nightmare	1 (1.0)	(0.0, 5.6)	0	(0.0, 0.2)
Mental fatigue	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 3.7)	3 (0.2)	(0.0, 0.5)
Benign prostatic hyperplasia	0	(0.0, 3.7)	2 (0.1)	(0.0, 0.4)
Menstruation irregular	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 3.7)	4 (0.2)	(0.1, 0.6)
Cough	0	(0.0, 3.7)	2 (0.1)	(0.0, 0.4)
Asthma	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Vocal cord polyp	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 3.7)	7 (0.4)	(0.2, 0.9)
Rash	0	(0.0, 3.7)	3 (0.2)	(0.0, 0.5)
Hyperhidrosis	0	(0.0, 3.7)	2 (0.1)	(0.0, 0.4)
Night sweats	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Lichen planus	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Tooth extraction	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
VASCULAR DISORDERS	0	(0.0, 3.7)	4 (0.2)	(0.1, 0.6)
Hypertension	0	(0.0, 3.7)	2 (0.1)	(0.0, 0.4)
Lymphoedema	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Hypotension	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)

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14.96. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: All Others

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=98)		≥16 Years (N^a=1639)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
Note: All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:01)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_p23_d3_race

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14.97. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=407)		≥16 Years (N[a]=11267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	81 (19.9)	(16.1, 24.1)	1632 (14.5)	(13.8, 15.1)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	6 (1.5)	(0.5, 3.2)	114 (1.0)	(0.8, 1.2)
Lymphadenopathy	6 (1.5)	(0.5, 3.2)	109 (1.0)	(0.8, 1.2)
Lymph node pain	0	(0.0, 0.9)	4 (0.0)	(0.0, 0.1)
Anaemia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Splenic vein thrombosis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	1 (0.2)	(0.0, 1.4)	12 (0.1)	(0.1, 0.2)
Palpitations	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Ventricular extrasystoles	1 (0.2)	(0.0, 1.4)	1 (0.0)	(0.0, 0.0)
Acute coronary syndrome	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Coronary artery disease	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Mitral valve incompetence	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Angina pectoris	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Aortic valve disease	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Bundle branch block left	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Myocardial ischaemia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Myocarditis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Sinus node dysfunction	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.9)	7 (0.1)	(0.0, 0.1)
Vertigo	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Deafness	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Deafness neurosensory	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Ear pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Autoimmune thyroiditis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Hypopituitarism	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Secondary hyperthyroidism	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	0	(0.0, 0.9)	5 (0.0)	(0.0, 0.1)
Cataract	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Eye pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

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14.97. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=407)		≥16 Years (N^a=11267)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Keratitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Blepharitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Epiretinal membrane	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	5 (1.2)	(0.4, 2.8)	78 (0.7)	(0.5, 0.9)
Nausea	4 (1.0)	(0.3, 2.5)	29 (0.3)	(0.2, 0.4)
Diarrhoea	0	(0.0, 0.9)	29 (0.3)	(0.2, 0.4)
Vomiting	1 (0.2)	(0.0, 1.4)	11 (0.1)	(0.0, 0.2)
Abdominal pain	0	(0.0, 0.9)	4 (0.0)	(0.0, 0.1)
Abdominal pain upper	1 (0.2)	(0.0, 1.4)	3 (0.0)	(0.0, 0.1)
Gastritis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Dyspepsia	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Dysphagia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Rectal haemorrhage	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Anogenital dysplasia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Dental caries	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Inguinal hernia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	76 (18.7)	(15.0, 22.8)	1263 (11.2)	(10.6, 11.8)
Injection site pain	35 (8.6)	(6.1, 11.8)	724 (6.4)	(6.0, 6.9)
Fatigue	33 (8.1)	(5.6, 11.2)	378 (3.4)	(3.0, 3.7)
Pyrexia	21 (5.2)	(3.2, 7.8)	261 (2.3)	(2.0, 2.6)
Chills	13 (3.2)	(1.7, 5.4)	201 (1.8)	(1.5, 2.0)
Pain	15 (3.7)	(2.1, 6.0)	133 (1.2)	(1.0, 1.4)
Asthenia	0	(0.0, 0.9)	39 (0.3)	(0.2, 0.5)
Malaise	2 (0.5)	(0.1, 1.8)	36 (0.3)	(0.2, 0.4)
Injection site erythema	2 (0.5)	(0.1, 1.8)	4 (0.0)	(0.0, 0.1)
Injection site swelling	0	(0.0, 0.9)	9 (0.1)	(0.0, 0.2)
Axillary pain	0	(0.0, 0.9)	6 (0.1)	(0.0, 0.1)
Vaccination site pain	0	(0.0, 0.9)	10 (0.1)	(0.0, 0.2)
Injection site lymphadenopathy	0	(0.0, 0.9)	4 (0.0)	(0.0, 0.1)
Injection site pruritus	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Injection site warmth	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)

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14.97. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=407)		≥16 Years (N^a=11267)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Localised oedema	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Chest pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Swelling	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Feeling abnormal	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Injection site bruising	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Injection site mass	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Vaccination site lymphadenopathy	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Injection site oedema	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Injection site rash	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Injection site reaction	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Vaccination site swelling	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Chest discomfort	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Facial pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Injection site irritation	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Cyst	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Gait disturbance	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Injection site vesicles	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Vaccination site warmth	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Alcoholic liver disease	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Biliary obstruction	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Jaundice cholestatic	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Immunisation reaction	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	0	(0.0, 0.9)	40 (0.4)	(0.3, 0.5)
Urinary tract infection	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Tooth infection	0	(0.0, 0.9)	7 (0.1)	(0.0, 0.1)
Ear infection	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Herpes zoster	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Cellulitis	0	(0.0, 0.9)	4 (0.0)	(0.0, 0.1)
Diverticulitis	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Appendicitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Otitis externa	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Rhinitis	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)

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14.97. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=407)		≥16 Years (N^a=11267)	
System Organ Class Preferred Term	n^b (%)	(95% CI^c)	n^b (%)	(95% CI^c)
Sinusitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Cystitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Gastroenteritis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Genital herpes	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Syphilis	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Wound infection	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Adenoviral conjunctivitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Balanitis candida	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Conjunctivitis bacterial	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Conjunctivitis viral	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Erysipelas	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Fungal skin infection	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Malaria	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Periodontitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Tooth abscess	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.5)	(0.1, 1.8)	26 (0.2)	(0.2, 0.3)
Exposure during pregnancy	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Fall	1 (0.2)	(0.0, 1.4)	3 (0.0)	(0.0, 0.1)
Skin laceration	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Animal bite	0	(0.0, 0.9)	4 (0.0)	(0.0, 0.1)
Ligament sprain	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Ankle fracture	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Joint injury	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Cervical vertebral fracture	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Contusion	1 (0.2)	(0.0, 1.4)	0	(0.0, 0.0)
Limb injury	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Vaccination complication	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Wound	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Eye contusion	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Femur fracture	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Forearm fracture	1 (0.2)	(0.0, 1.4)	0	(0.0, 0.0)
Retinal injury	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Skin abrasion	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

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14.97. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=407)		≥16 Years (N^a=11267)	
System Organ Class Preferred Term	n^b (%)	(95% CI^c)	n^b (%)	(95% CI^c)
INVESTIGATIONS	0	(0.0, 0.9)	26 (0.2)	(0.2, 0.3)
Body temperature increased	0	(0.0, 0.9)	24 (0.2)	(0.1, 0.3)
Cardiac murmur	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Blood urine present	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.9)	11 (0.1)	(0.0, 0.2)
Decreased appetite	0	(0.0, 0.9)	5 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Vitamin D deficiency	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Gout	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Increased appetite	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	7 (1.7)	(0.7, 3.5)	270 (2.4)	(2.1, 2.7)
Myalgia	5 (1.2)	(0.4, 2.8)	200 (1.8)	(1.5, 2.0)
Arthralgia	0	(0.0, 0.9)	27 (0.2)	(0.2, 0.3)
Pain in extremity	2 (0.5)	(0.1, 1.8)	20 (0.2)	(0.1, 0.3)
Back pain	0	(0.0, 0.9)	11 (0.1)	(0.0, 0.2)
Musculoskeletal chest pain	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Musculoskeletal pain	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Muscle spasms	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Muscular weakness	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Synovial cyst	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Tendonitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Arthritis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Axillary mass	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Bursitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Muscle twitching	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Osteochondritis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Plantar fasciitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Rotator cuff syndrome	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Costochondritis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Groin pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.9)	8 (0.1)	(0.0, 0.1)
Basal cell carcinoma	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

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14.97. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=407)		≥16 Years (N[a]=11267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Adenocarcinoma of colon	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Adenoma benign	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Gastrointestinal stromal tumour	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Papillary thyroid cancer	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma of skin	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	28 (6.9)	(4.6, 9.8)	241 (2.1)	(1.9, 2.4)
Headache	28 (6.9)	(4.6, 9.8)	212 (1.9)	(1.6, 2.1)
Dizziness	0	(0.0, 0.9)	11 (0.1)	(0.0, 0.2)
Lethargy	0	(0.0, 0.9)	6 (0.1)	(0.0, 0.1)
Paraesthesia	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Syncope	0	(0.0, 0.9)	4 (0.0)	(0.0, 0.1)
Migraine	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Sciatica	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Presyncope	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Nerve compression	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Psychomotor hyperactivity	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Carotid arteriosclerosis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Formication	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Haemorrhage intracranial	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Hepatic encephalopathy	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Parosmia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Seizure	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	4 (1.0)	(0.3, 2.5)	14 (0.1)	(0.1, 0.2)
Anxiety	1 (0.2)	(0.0, 1.4)	3 (0.0)	(0.0, 0.1)
Insomnia	1 (0.2)	(0.0, 1.4)	3 (0.0)	(0.0, 0.1)
Depression	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Anxiety disorder	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Attention deficit hyperactivity disorder	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Disorientation	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Nightmare	2 (0.5)	(0.1, 1.8)	0	(0.0, 0.0)
Irritability	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

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14.97. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=407)		≥16 Years (N^a=11267)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Libido decreased	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	0	(0.0, 0.9)	4 (0.0)	(0.0, 0.1)
Nephrolithiasis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Calculus bladder	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Renal colic	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Renal pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 0.9)	7 (0.1)	(0.0, 0.1)
Benign prostatic hyperplasia	0	(0.0, 0.9)	4 (0.0)	(0.0, 0.1)
Cervical bulla	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Prostatitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Testicular pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.9)	13 (0.1)	(0.1, 0.2)
Nasal congestion	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Rhinorrhoea	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Cough	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Epistaxis	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Oropharyngeal pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Asthma	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Vocal cord polyp	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.5)	(0.1, 1.8)	30 (0.3)	(0.2, 0.4)
Rash	0	(0.0, 0.9)	6 (0.1)	(0.0, 0.1)
Hyperhidrosis	0	(0.0, 0.9)	6 (0.1)	(0.0, 0.1)
Night sweats	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Urticaria	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Acne	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Erythema	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Pruritus	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Dermatitis contact	1 (0.2)	(0.0, 1.4)	2 (0.0)	(0.0, 0.1)
Psoriasis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Blister	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Cold sweat	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Diabetic foot	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Hand dermatitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

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14.97. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=407)		≥16 Years (N[a]=11267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ingrowing nail	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Rosacea	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Sensitive skin	1 (0.2)	(0.0, 1.4)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.2)	(0.0, 1.4)	2 (0.0)	(0.0, 0.1)
Knee arthroplasty	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Meniscus operation	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Oral surgery	1 (0.2)	(0.0, 1.4)	0	(0.0, 0.0)
VASCULAR DISORDERS	0	(0.0, 0.9)	25 (0.2)	(0.1, 0.3)
Hypertension	0	(0.0, 0.9)	19 (0.2)	(0.1, 0.3)
Hot flush	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Essential hypertension	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Aneurysm	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Aortic arteriosclerosis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Arteriosclerosis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Hypotension	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:01)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_p23_d3_sex

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14.98. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=418)		≥16 Years (N[a]=11203)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	72 (17.2)	(13.7, 21.2)	2186 (19.5)	(18.8, 20.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	2 (0.5)	(0.1, 1.7)	246 (2.2)	(1.9, 2.5)
Lymphadenopathy	2 (0.5)	(0.1, 1.7)	238 (2.1)	(1.9, 2.4)
Lymph node pain	0	(0.0, 0.9)	5 (0.0)	(0.0, 0.1)
Anaemia	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Hypochromic anaemia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Iron deficiency anaemia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Normocytic anaemia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	0	(0.0, 0.9)	17 (0.2)	(0.1, 0.2)
Palpitations	0	(0.0, 0.9)	5 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Ventricular extrasystoles	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Arrhythmia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Atrioventricular block	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Bradycardia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Bundle branch block right	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Cardiac failure	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Wolff-Parkinson-White syndrome	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.9)	8 (0.1)	(0.0, 0.1)
Vertigo	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Tinnitus	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Cerumen impaction	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Ear discomfort	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Middle ear effusion	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Vertigo positional	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	0	(0.0, 0.9)	4 (0.0)	(0.0, 0.1)
Hypothyroidism	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Autoimmune thyroiditis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	0	(0.0, 0.9)	7 (0.1)	(0.0, 0.1)
Cataract	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Conjunctival haemorrhage	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Eye pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

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14.98. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=418)		≥16 Years (N[a]=11203)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Keratitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Dry eye	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Photophobia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Retinal degeneration	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	7 (1.7)	(0.7, 3.4)	125 (1.1)	(0.9, 1.3)
Nausea	5 (1.2)	(0.4, 2.8)	64 (0.6)	(0.4, 0.7)
Diarrhoea	0	(0.0, 0.9)	28 (0.2)	(0.2, 0.4)
Vomiting	4 (1.0)	(0.3, 2.4)	22 (0.2)	(0.1, 0.3)
Abdominal pain	1 (0.2)	(0.0, 1.3)	2 (0.0)	(0.0, 0.1)
Abdominal pain upper	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Gastritis	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Gastrointestinal haemorrhage	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Gastrooesophageal reflux disease	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Constipation	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Dysphagia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Rectal haemorrhage	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Abdominal discomfort	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Colitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Dry mouth	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Food poisoning	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Gastric ulcer	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Large intestine polyp	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Lip dry	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Lip haemorrhage	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Lip oedema	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Oesophageal ulcer	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Oesophagitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Oral mucosal blistering	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Retching	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Teething	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Tooth impacted	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Volvulus	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

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14.98. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=418)		≥16 Years (N^a=11203)	
System Organ Class Preferred Term	n^b (%)	(95% CI^c)	n^b (%)	(95% CI^c)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	54 (12.9)	(9.9, 16.5)	1660 (14.8)	(14.2, 15.5)
Injection site pain	31 (7.4)	(5.1, 10.4)	955 (8.5)	(8.0, 9.1)
Fatigue	28 (6.7)	(4.5, 9.5)	480 (4.3)	(3.9, 4.7)
Pyrexia	7 (1.7)	(0.7, 3.4)	404 (3.6)	(3.3, 4.0)
Chills	9 (2.2)	(1.0, 4.0)	242 (2.2)	(1.9, 2.4)
Pain	9 (2.2)	(1.0, 4.0)	219 (2.0)	(1.7, 2.2)
Asthenia	0	(0.0, 0.9)	42 (0.4)	(0.3, 0.5)
Malaise	1 (0.2)	(0.0, 1.3)	40 (0.4)	(0.3, 0.5)
Injection site erythema	3 (0.7)	(0.1, 2.1)	38 (0.3)	(0.2, 0.5)
Injection site swelling	0	(0.0, 0.9)	28 (0.2)	(0.2, 0.4)
Axillary pain	1 (0.2)	(0.0, 1.3)	20 (0.2)	(0.1, 0.3)
Vaccination site pain	0	(0.0, 0.9)	5 (0.0)	(0.0, 0.1)
Injection site lymphadenopathy	0	(0.0, 0.9)	7 (0.1)	(0.0, 0.1)
Injection site pruritus	0	(0.0, 0.9)	7 (0.1)	(0.0, 0.1)
Injection site warmth	0	(0.0, 0.9)	7 (0.1)	(0.0, 0.1)
Localised oedema	0	(0.0, 0.9)	6 (0.1)	(0.0, 0.1)
Chest pain	0	(0.0, 0.9)	5 (0.0)	(0.0, 0.1)
Swelling	0	(0.0, 0.9)	4 (0.0)	(0.0, 0.1)
Feeling abnormal	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Injection site bruising	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Injection site mass	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Vaccination site lymphadenopathy	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Injection site induration	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Injection site oedema	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Injection site rash	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Injection site reaction	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Vaccination site swelling	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Chest discomfort	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Facial pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Feeling hot	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Inflammation	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Injection site inflammation	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Injection site irritation	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Vaccination site oedema	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)

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14.98. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=418)		≥16 Years (N[a]=11203)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Application site erythema	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Face oedema	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Illness	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Injection site discomfort	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Injection site haematoma	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Injection site nodule	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Oedema peripheral	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Peripheral swelling	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Sensation of foreign body	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Thirst	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Vaccination site erythema	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	0	(0.0, 0.9)	9 (0.1)	(0.0, 0.2)
Cholecystitis acute	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Cholelithiasis	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Biliary colic	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Cholecystitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Hepatic lesion	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Hepatitis acute	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Hyperbilirubinaemia neonatal	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.9)	4 (0.0)	(0.0, 0.1)
Immunisation reaction	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Hypersensitivity	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	1 (0.2)	(0.0, 1.3)	71 (0.6)	(0.5, 0.8)
Urinary tract infection	0	(0.0, 0.9)	22 (0.2)	(0.1, 0.3)
Tooth infection	0	(0.0, 0.9)	4 (0.0)	(0.0, 0.1)
Ear infection	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Herpes zoster	0	(0.0, 0.9)	5 (0.0)	(0.0, 0.1)
Cellulitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Conjunctivitis	0	(0.0, 0.9)	5 (0.0)	(0.0, 0.1)
Diverticulitis	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Appendicitis	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Otitis externa	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Sinusitis	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Cystitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

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14.98. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=418)		≥16 Years (N^a=11203)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Gastroenteritis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Genital herpes	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Localised infection	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Oral herpes	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Wound infection	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Abscess jaw	1 (0.2)	(0.0, 1.3)	0	(0.0, 0.0)
Bartholinitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Bronchitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Focal peritonitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Gastroenteritis norovirus	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Infected cyst	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Nasopharyngitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Onychomycosis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Pneumonia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Staphylococcal infection	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Vaginal infection	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Vulvovaginal mycotic infection	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.5)	(0.1, 1.7)	78 (0.7)	(0.6, 0.9)
Exposure during pregnancy	0	(0.0, 0.9)	28 (0.2)	(0.2, 0.4)
Fall	0	(0.0, 0.9)	11 (0.1)	(0.0, 0.2)
Maternal exposure during breast feeding	0	(0.0, 0.9)	11 (0.1)	(0.0, 0.2)
Skin laceration	0	(0.0, 0.9)	4 (0.0)	(0.0, 0.1)
Animal bite	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Ligament sprain	1 (0.2)	(0.0, 1.3)	3 (0.0)	(0.0, 0.1)
Ankle fracture	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Cartilage injury	1 (0.2)	(0.0, 1.3)	2 (0.0)	(0.0, 0.1)
Joint injury	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Wrist fracture	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Contusion	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

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14.98. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=418)		≥16 Years (N^a=11203)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Foot fracture	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Limb injury	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Arthropod bite	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Chest injury	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Corneal abrasion	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Head injury	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Nasal injury	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Overdose	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Post-traumatic pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Radius fracture	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Stress fracture	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Tendon injury	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Wound dehiscence	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.9)	35 (0.3)	(0.2, 0.4)
Body temperature increased	0	(0.0, 0.9)	30 (0.3)	(0.2, 0.4)
Cardiac murmur	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Heart rate increased	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Cardiac stress test abnormal	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Human papilloma virus test positive	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.9)	13 (0.1)	(0.1, 0.2)
Decreased appetite	0	(0.0, 0.9)	6 (0.1)	(0.0, 0.1)
Hypercholesterolaemia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Vitamin D deficiency	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Dyslipidaemia	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Hypoglycaemia neonatal	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Hyponatraemia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	12 (2.9)	(1.5, 5.0)	376 (3.4)	(3.0, 3.7)
Myalgia	8 (1.9)	(0.8, 3.7)	274 (2.4)	(2.2, 2.7)
Arthralgia	0	(0.0, 0.9)	33 (0.3)	(0.2, 0.4)
Pain in extremity	4 (1.0)	(0.3, 2.4)	29 (0.3)	(0.2, 0.4)
Back pain	0	(0.0, 0.9)	8 (0.1)	(0.0, 0.1)
Musculoskeletal chest pain	1 (0.2)	(0.0, 1.3)	5 (0.0)	(0.0, 0.1)

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14.98. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=418)		≥16 Years (N^a=11203)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Neck pain	0	(0.0, 0.9)	9 (0.1)	(0.0, 0.2)
Musculoskeletal pain	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Muscle spasms	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Muscle contracture	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Synovial cyst	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Tendonitis	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Arthritis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Axillary mass	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Bursitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Osteochondritis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Plantar fasciitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Rotator cuff syndrome	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Spinal osteoarthritis	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Cervical spinal stenosis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Fibromyalgia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Flank pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Greater trochanteric pain syndrome	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Kyphosis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Neck mass	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Painful os peroneum syndrome	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Rheumatoid arthritis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Sjogren's syndrome	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.9)	9 (0.1)	(0.0, 0.2)
Basal cell carcinoma	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Colon cancer	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Endometrial adenocarcinoma	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Invasive breast carcinoma	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Renal neoplasm	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

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14.98. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=418)		≥16 Years (N[a]=11203)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Uterine leiomyoma	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	21 (5.0)	(3.1, 7.6)	391 (3.5)	(3.2, 3.8)
Headache	19 (4.5)	(2.8, 7.0)	347 (3.1)	(2.8, 3.4)
Dizziness	2 (0.5)	(0.1, 1.7)	15 (0.1)	(0.1, 0.2)
Lethargy	0	(0.0, 0.9)	7 (0.1)	(0.0, 0.1)
Paraesthesia	0	(0.0, 0.9)	5 (0.0)	(0.0, 0.1)
Syncope	1 (0.2)	(0.0, 1.3)	2 (0.0)	(0.0, 0.1)
Migraine	0	(0.0, 0.9)	4 (0.0)	(0.0, 0.1)
Sciatica	0	(0.0, 0.9)	4 (0.0)	(0.0, 0.1)
Hypoaesthesia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Presyncope	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Nerve compression	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Somnolence	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Tremor	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Cervical radiculopathy	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Hyperaesthesia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Intracranial aneurysm	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Taste disorder	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Tension headache	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.9)	5 (0.0)	(0.0, 0.1)
Pregnancy	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Abortion spontaneous	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Abortion threatened	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Gestational hypertension	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	5 (1.2)	(0.4, 2.8)	29 (0.3)	(0.2, 0.4)
Anxiety	2 (0.5)	(0.1, 1.7)	14 (0.1)	(0.1, 0.2)
Insomnia	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Depression	3 (0.7)	(0.1, 2.1)	2 (0.0)	(0.0, 0.1)
Anxiety disorder	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Attention deficit hyperactivity disorder	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Acute stress disorder	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Affective disorder	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Aggression	1 (0.2)	(0.0, 1.3)	0	(0.0, 0.0)
Alcohol abuse	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Bruxism	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

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14.98. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=418)		≥16 Years (N^a=11203)	
System Organ Class Preferred Term	n^b (%)	(95% CI^c)	n^b (%)	(95% CI^c)
Emotional distress	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Gender dysphoria	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Major depression	1 (0.2)	(0.0, 1.3)	0	(0.0, 0.0)
Psychiatric decompensation	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Suicidal ideation	1 (0.2)	(0.0, 1.3)	0	(0.0, 0.0)
Suicide attempt	1 (0.2)	(0.0, 1.3)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	0	(0.0, 0.9)	4 (0.0)	(0.0, 0.1)
Nephrolithiasis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Pollakiuria	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Stress urinary incontinence	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Trigonitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.5)	(0.1, 1.7)	16 (0.1)	(0.1, 0.2)
Intermenstrual bleeding	1 (0.2)	(0.0, 1.3)	4 (0.0)	(0.0, 0.1)
Breast pain	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Heavy menstrual bleeding	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Menstrual disorder	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Atrophic vulvovaginitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Breast inflammation	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Dysmenorrhoea	1 (0.2)	(0.0, 1.3)	0	(0.0, 0.0)
Menstruation irregular	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Nipple exudate bloody	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Ovarian cyst	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Pelvic pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Uterine polyp	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.2)	(0.0, 1.3)	20 (0.2)	(0.1, 0.3)
Nasal congestion	1 (0.2)	(0.0, 1.3)	2 (0.0)	(0.0, 0.1)
Rhinorrhoea	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Dyspnoea	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Rhinitis allergic	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Oropharyngeal pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Sinus congestion	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Dysphonia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

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14.98. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=418)		≥16 Years (N^a=11203)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Pleural effusion	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Sleep apnoea syndrome	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Throat tightness	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Upper-airway cough syndrome	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 0.9)	47 (0.4)	(0.3, 0.6)
Rash	0	(0.0, 0.9)	9 (0.1)	(0.0, 0.2)
Hyperhidrosis	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Night sweats	0	(0.0, 0.9)	5 (0.0)	(0.0, 0.1)
Urticaria	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Acne	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Erythema	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Pruritus	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Alopecia	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Psoriasis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Skin lesion	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Angioedema	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Dermatitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Dermatitis atopic	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Diffuse alopecia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Ecchymosis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Lichen planus	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Lichen sclerosus	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Pain of skin	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Photosensitivity reaction	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Pityriasis rosea	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Rash papular	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Rash pruritic	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Skin oedema	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.9)	5 (0.0)	(0.0, 0.1)
Breast conserving surgery	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Cataract operation	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Metabolic surgery	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Tooth extraction	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	0	(0.0, 0.9)	18 (0.2)	(0.1, 0.3)

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14.98. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=418)		≥16 Years (N^a=11203)	
System Organ Class Preferred Term	n^b (%)	(95% CI^c)	n^b (%)	(95% CI^c)
Hypertension	0	(0.0, 0.9)	10 (0.1)	(0.0, 0.2)
Hot flush	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Essential hypertension	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Flushing	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Lymphoedema	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Peripheral vascular disorder	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Varicose vein	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Venous thrombosis limb	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:01)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_p23_d3_sex

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14.99. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=89)		≥16 Years (N[a]=7489)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	19 (21.3)	(13.4, 31.3)	1281 (17.1)	(16.3, 18.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (1.1)	(0.0, 6.1)	151 (2.0)	(1.7, 2.4)
Lymphadenopathy	1 (1.1)	(0.0, 6.1)	144 (1.9)	(1.6, 2.3)
Lymph node pain	0	(0.0, 4.1)	4 (0.1)	(0.0, 0.1)
Anaemia	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Normocytic anaemia	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	0	(0.0, 4.1)	10 (0.1)	(0.1, 0.2)
Palpitations	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Ventricular extrasystoles	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Mitral valve incompetence	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Aortic valve disease	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Bradycardia	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Bundle branch block left	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Myocardial ischaemia	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Pericardial effusion	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Sinus node dysfunction	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Supraventricular tachycardia	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Wolff-Parkinson-White syndrome	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	0	(0.0, 4.1)	6 (0.1)	(0.0, 0.2)
Vertigo	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Tinnitus	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Cerumen impaction	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Deafness neurosensory	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Ear pain	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
ENDOCRINE DISORDERS	0	(0.0, 4.1)	4 (0.1)	(0.0, 0.1)
Hypothyroidism	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Hypopituitarism	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Secondary hyperthyroidism	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	0	(0.0, 4.1)	8 (0.1)	(0.0, 0.2)
Cataract	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)

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14.99. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=89)		≥16 Years (N[a]=7489)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Conjunctival haemorrhage	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Eye pain	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Keratitis	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Blepharitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Epiretinal membrane	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Photophobia	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	2 (2.2)	(0.3, 7.9)	59 (0.8)	(0.6, 1.0)
Nausea	2 (2.2)	(0.3, 7.9)	21 (0.3)	(0.2, 0.4)
Diarrhoea	0	(0.0, 4.1)	17 (0.2)	(0.1, 0.4)
Vomiting	1 (1.1)	(0.0, 6.1)	5 (0.1)	(0.0, 0.2)
Abdominal pain	1 (1.1)	(0.0, 6.1)	1 (0.0)	(0.0, 0.1)
Abdominal pain upper	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Gastritis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Gastrointestinal haemorrhage	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Dysphagia	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Anogenital dysplasia	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Colitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Dental caries	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Diverticulum intestinal	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Food poisoning	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Inguinal hernia	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Lip oedema	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Oesophageal ulcer	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Oesophagitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Oral mucosal blistering	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Teething	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Tooth impacted	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Volvulus	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	17 (19.1)	(11.5, 28.8)	834 (11.1)	(10.4, 11.9)
Injection site pain	7 (7.9)	(3.2, 15.5)	477 (6.4)	(5.8, 6.9)
Fatigue	9 (10.1)	(4.7, 18.3)	121 (1.6)	(1.3, 1.9)
Pyrexia	3 (3.4)	(0.7, 9.5)	221 (3.0)	(2.6, 3.4)
Chills	1 (1.1)	(0.0, 6.1)	88 (1.2)	(0.9, 1.4)

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14.99. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=89)		≥16 Years (N[a]=7489)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pain	4 (4.5)	(1.2, 11.1)	83 (1.1)	(0.9, 1.4)
Asthenia	0	(0.0, 4.1)	74 (1.0)	(0.8, 1.2)
Malaise	0	(0.0, 4.1)	11 (0.1)	(0.1, 0.3)
Injection site erythema	1 (1.1)	(0.0, 6.1)	6 (0.1)	(0.0, 0.2)
Injection site swelling	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Axillary pain	1 (1.1)	(0.0, 6.1)	8 (0.1)	(0.0, 0.2)
Injection site lymphadenopathy	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Injection site warmth	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Localised oedema	0	(0.0, 4.1)	7 (0.1)	(0.0, 0.2)
Chest pain	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Swelling	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Injection site mass	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Injection site oedema	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Inflammation	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Injection site inflammation	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Application site erythema	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Illness	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Injection site haematoma	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Injection site vesicles	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Oedema peripheral	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	0	(0.0, 4.1)	5 (0.1)	(0.0, 0.2)
Cholelithiasis	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Alcoholic liver disease	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Biliary colic	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Hepatitis acute	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Hyperbilirubinaemia neonatal	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Hypersensitivity	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	0	(0.0, 4.1)	58 (0.8)	(0.6, 1.0)
Urinary tract infection	0	(0.0, 4.1)	15 (0.2)	(0.1, 0.3)
Tooth infection	0	(0.0, 4.1)	11 (0.1)	(0.1, 0.3)
Ear infection	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Herpes zoster	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Cellulitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)

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14.99. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Hispanic/Latino

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) 12-15 Years (N[a]=89) n[b] (%)	(95% CI[c])	≥16 Years (N[a]=7489) n[b] (%)	(95% CI[c])
Conjunctivitis	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Diverticulitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Appendicitis	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Otitis externa	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Rhinitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Sinusitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Gastroenteritis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Genital herpes	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Oral herpes	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Syphilis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Wound infection	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Abdominal abscess	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Balanitis candida	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Bartholinitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Complicated appendicitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Conjunctivitis viral	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Erysipelas	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Focal peritonitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Onychomycosis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Osteomyelitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Periodontitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Vaginal infection	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 4.1)	44 (0.6)	(0.4, 0.8)
Exposure during pregnancy	0	(0.0, 4.1)	11 (0.1)	(0.1, 0.3)
Fall	0	(0.0, 4.1)	8 (0.1)	(0.0, 0.2)
Maternal exposure during breast feeding	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Skin laceration	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Animal bite	0	(0.0, 4.1)	6 (0.1)	(0.0, 0.2)
Ligament sprain	0	(0.0, 4.1)	4 (0.1)	(0.0, 0.1)
Ankle fracture	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Joint injury	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Wrist fracture	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)

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14.99. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=89)		≥16 Years (N[a]=7489)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Limb injury	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Wound	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Chest injury	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Eye contusion	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Nasal injury	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Overdose	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Stress fracture	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Vulvovaginal injury	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Wound dehiscence	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	0	(0.0, 4.1)	32 (0.4)	(0.3, 0.6)
Body temperature increased	0	(0.0, 4.1)	32 (0.4)	(0.3, 0.6)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 4.1)	10 (0.1)	(0.1, 0.2)
Decreased appetite	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Vitamin D deficiency	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Dyslipidaemia	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Hypoglycaemia neonatal	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (2.2)	(0.3, 7.9)	217 (2.9)	(2.5, 3.3)
Myalgia	1 (1.1)	(0.0, 6.1)	151 (2.0)	(1.7, 2.4)
Arthralgia	0	(0.0, 4.1)	21 (0.3)	(0.2, 0.4)
Pain in extremity	1 (1.1)	(0.0, 6.1)	19 (0.3)	(0.2, 0.4)
Back pain	0	(0.0, 4.1)	13 (0.2)	(0.1, 0.3)
Musculoskeletal chest pain	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Neck pain	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Muscle spasms	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Muscle contracture	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Muscular weakness	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Synovial cyst	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Tendonitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Arthritis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Axillary mass	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Osteoarthritis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Osteochondritis	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)

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14.99. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=89)		≥16 Years (N[a]=7489)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Osteoporosis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Plantar fasciitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Cervical spinal stenosis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Costochondritis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Greater trochanteric pain syndrome	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Adenocarcinoma of colon	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Adenoma benign	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Endometrial adenocarcinoma	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	4 (4.5)	(1.2, 11.1)	161 (2.1)	(1.8, 2.5)
Headache	4 (4.5)	(1.2, 11.1)	142 (1.9)	(1.6, 2.2)
Dizziness	0	(0.0, 4.1)	5 (0.1)	(0.0, 0.2)
Paraesthesia	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Syncope	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Migraine	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Sciatica	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Somnolence	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Carotid arteriosclerosis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Hepatic encephalopathy	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Intracranial aneurysm	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Abortion threatened	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	1 (1.1)	(0.0, 6.1)	11 (0.1)	(0.1, 0.3)
Anxiety	0	(0.0, 4.1)	6 (0.1)	(0.0, 0.2)
Insomnia	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Depression	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Anxiety disorder	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Disorientation	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Nightmare	1 (1.1)	(0.0, 6.1)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Renal colic	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)

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14.99. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=89)		≥16 Years (N[a]=7489)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Trigonitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 4.1)	15 (0.2)	(0.1, 0.3)
Intermenstrual bleeding	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Breast pain	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Heavy menstrual bleeding	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Menstrual disorder	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Atrophic vulvovaginitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Breast inflammation	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Cervical bulla	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Nipple exudate bloody	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Ovarian cyst	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Prostatitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Testicular pain	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Uterine polyp	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 4.1)	12 (0.2)	(0.1, 0.3)
Nasal congestion	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Dyspnoea	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Rhinitis allergic	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Epistaxis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Oropharyngeal pain	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Sinus congestion	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Dysphonia	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Nasal turbinate hypertrophy	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Vocal cord polyp	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 4.1)	27 (0.4)	(0.2, 0.5)
Rash	0	(0.0, 4.1)	5 (0.1)	(0.0, 0.2)
Hyperhidrosis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Urticaria	0	(0.0, 4.1)	4 (0.1)	(0.0, 0.1)
Acne	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Erythema	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Pruritus	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Psoriasis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)

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14.99. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=89)		≥16 Years (N[a]=7489)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rash maculo-papular	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Angioedema	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Blister	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Cold sweat	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Hand dermatitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Lichen planus	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Photosensitivity reaction	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Rash papular	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Rash pruritic	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Rosacea	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Skin oedema	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	0	(0.0, 4.1)	23 (0.3)	(0.2, 0.5)
Hypertension	0	(0.0, 4.1)	16 (0.2)	(0.1, 0.3)
Hot flush	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Essential hypertension	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Lymphoedema	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Aortic arteriosclerosis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Peripheral vascular disorder	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Varicose vein	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Venous thrombosis limb	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 19MAY2023 (04:27)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_p23_d3_eth

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14.100. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=734)		≥16 Years (N[a]=14899)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	133 (18.1)	(15.4, 21.1)	2525 (16.9)	(16.3, 17.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	7 (1.0)	(0.4, 2.0)	209 (1.4)	(1.2, 1.6)
Lymphadenopathy	7 (1.0)	(0.4, 2.0)	203 (1.4)	(1.2, 1.6)
Lymph node pain	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Anaemia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hypochromic anaemia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Iron deficiency anaemia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Splenic vein thrombosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	1 (0.1)	(0.0, 0.8)	19 (0.1)	(0.1, 0.2)
Palpitations	0	(0.0, 0.5)	6 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.1)
Ventricular extrasystoles	1 (0.1)	(0.0, 0.8)	1 (0.0)	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Mitral valve incompetence	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Angina pectoris	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Arrhythmia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Atrioventricular block	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Bundle branch block right	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Cardiac failure	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Myocarditis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.5)	9 (0.1)	(0.0, 0.1)
Vertigo	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Tinnitus	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Deafness	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Ear discomfort	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Middle ear effusion	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Vertigo positional	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.1)
Hypothyroidism	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Autoimmune thyroiditis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
EYE DISORDERS	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)

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14.100. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=734)		≥16 Years (N[a]=14899)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cataract	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Eye pain	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Dry eye	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Retinal degeneration	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	10 (1.4)	(0.7, 2.5)	143 (1.0)	(0.8, 1.1)
Nausea	7 (1.0)	(0.4, 2.0)	71 (0.5)	(0.4, 0.6)
Diarrhoea	0	(0.0, 0.5)	40 (0.3)	(0.2, 0.4)
Vomiting	4 (0.5)	(0.1, 1.4)	28 (0.2)	(0.1, 0.3)
Abdominal pain	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Abdominal pain upper	1 (0.1)	(0.0, 0.8)	2 (0.0)	(0.0, 0.0)
Gastritis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gastrooesophageal reflux disease	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Constipation	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Dyspepsia	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Rectal haemorrhage	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Abdominal discomfort	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Dry mouth	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gastric ulcer	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Large intestine polyp	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Lip dry	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Lip haemorrhage	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Retching	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	112 (15.3)	(12.7, 18.1)	2078 (13.9)	(13.4, 14.5)
Injection site pain	59 (8.0)	(6.2, 10.2)	1200 (8.1)	(7.6, 8.5)
Fatigue	51 (6.9)	(5.2, 9.0)	733 (4.9)	(4.6, 5.3)
Pyrexia	25 (3.4)	(2.2, 5.0)	439 (2.9)	(2.7, 3.2)
Chills	20 (2.7)	(1.7, 4.2)	353 (2.4)	(2.1, 2.6)
Pain	20 (2.7)	(1.7, 4.2)	266 (1.8)	(1.6, 2.0)

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14.100. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=734)		≥16 Years (N^a=14899)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Asthenia	0	(0.0, 0.5)	7 (0.0)	(0.0, 0.1)
Malaise	3 (0.4)	(0.1, 1.2)	65 (0.4)	(0.3, 0.6)
Injection site erythema	4 (0.5)	(0.1, 1.4)	36 (0.2)	(0.2, 0.3)
Injection site swelling	0	(0.0, 0.5)	34 (0.2)	(0.2, 0.3)
Axillary pain	0	(0.0, 0.5)	18 (0.1)	(0.1, 0.2)
Vaccination site pain	0	(0.0, 0.5)	15 (0.1)	(0.1, 0.2)
Injection site lymphadenopathy	0	(0.0, 0.5)	10 (0.1)	(0.0, 0.1)
Injection site pruritus	0	(0.0, 0.5)	9 (0.1)	(0.0, 0.1)
Injection site warmth	0	(0.0, 0.5)	7 (0.0)	(0.0, 0.1)
Chest pain	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Swelling	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Feeling abnormal	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Injection site bruising	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Injection site mass	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.1)
Vaccination site lymphadenopathy	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Injection site induration	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.1)
Injection site oedema	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Injection site rash	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Injection site reaction	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.1)
Vaccination site swelling	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.1)
Chest discomfort	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Facial pain	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Feeling hot	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Inflammation	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Injection site inflammation	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Injection site irritation	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Vaccination site oedema	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Cyst	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Face oedema	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gait disturbance	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Injection site discomfort	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Injection site nodule	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.100. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=734)		≥16 Years (N[a]=14899)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Peripheral swelling	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Sensation of foreign body	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Thirst	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Vaccination site erythema	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Vaccination site warmth	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	0	(0.0, 0.5)	6 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Biliary obstruction	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Cholecystitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hepatic lesion	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Jaundice cholestatic	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Immunisation reaction	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Hypersensitivity	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	1 (0.1)	(0.0, 0.8)	53 (0.4)	(0.3, 0.5)
Urinary tract infection	0	(0.0, 0.5)	8 (0.1)	(0.0, 0.1)
Ear infection	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Herpes zoster	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Cellulitis	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Conjunctivitis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Diverticulitis	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Appendicitis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Rhinitis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Sinusitis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Cystitis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Gastroenteritis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Localised infection	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Oral herpes	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Syphilis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Abscess jaw	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
Adenoviral conjunctivitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Bronchitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.100. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=734)		≥16 Years (N^a=14899)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Conjunctivitis bacterial	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Fungal skin infection	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gastroenteritis norovirus	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Infected cyst	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Malaria	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Nasopharyngitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pneumonia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Staphylococcal infection	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Tooth abscess	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 (0.5)	(0.1, 1.4)	60 (0.4)	(0.3, 0.5)
Exposure during pregnancy	0	(0.0, 0.5)	19 (0.1)	(0.1, 0.2)
Fall	1 (0.1)	(0.0, 0.8)	6 (0.0)	(0.0, 0.1)
Maternal exposure during breast feeding	0	(0.0, 0.5)	8 (0.1)	(0.0, 0.1)
Skin laceration	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Ligament sprain	1 (0.1)	(0.0, 0.8)	1 (0.0)	(0.0, 0.0)
Ankle fracture	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.1)
Cartilage injury	1 (0.1)	(0.0, 0.8)	2 (0.0)	(0.0, 0.0)
Joint injury	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Wrist fracture	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Cervical vertebral fracture	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Contusion	1 (0.1)	(0.0, 0.8)	1 (0.0)	(0.0, 0.0)
Foot fracture	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Limb injury	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Vaccination complication	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Arthropod bite	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Corneal abrasion	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Femur fracture	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Forearm fracture	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
Head injury	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.100. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=734)		≥16 Years (N[a]=14899)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Humerus fracture	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Post-traumatic pain	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Radius fracture	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Retinal injury	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Skin abrasion	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Tendon injury	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.5)	29 (0.2)	(0.1, 0.3)
Body temperature increased	0	(0.0, 0.5)	22 (0.1)	(0.1, 0.2)
Cardiac murmur	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Heart rate increased	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Blood urine present	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Cardiac stress test abnormal	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Human papilloma virus test positive	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.5)	14 (0.1)	(0.1, 0.2)
Decreased appetite	0	(0.0, 0.5)	10 (0.1)	(0.0, 0.1)
Hypercholesterolaemia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gout	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hyponatraemia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Increased appetite	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	17 (2.3)	(1.4, 3.7)	426 (2.9)	(2.6, 3.1)
Myalgia	12 (1.6)	(0.8, 2.8)	320 (2.1)	(1.9, 2.4)
Arthralgia	0	(0.0, 0.5)	39 (0.3)	(0.2, 0.4)
Pain in extremity	5 (0.7)	(0.2, 1.6)	29 (0.2)	(0.1, 0.3)
Back pain	0	(0.0, 0.5)	6 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	1 (0.1)	(0.0, 0.8)	7 (0.0)	(0.0, 0.1)
Neck pain	0	(0.0, 0.5)	6 (0.0)	(0.0, 0.1)
Musculoskeletal pain	0	(0.0, 0.5)	6 (0.0)	(0.0, 0.1)
Muscle spasms	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Muscular weakness	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Musculoskeletal stiffness	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.1)
Synovial cyst	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Tendonitis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Arthritis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Axillary mass	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.100. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=734)		≥16 Years (N^a=14899)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Bursitis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Muscle twitching	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Plantar fasciitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Spinal osteoarthritis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Fibromyalgia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Flank pain	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Groin pain	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Kyphosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Neck mass	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Painful os peroneum syndrome	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Rheumatoid arthritis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Sjogren's syndrome	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.5)	14 (0.1)	(0.1, 0.2)
Basal cell carcinoma	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Adenocarcinoma pancreas	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Colon cancer	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gastrointestinal stromal tumour	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Invasive breast carcinoma	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Papillary thyroid cancer	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Renal neoplasm	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma of skin	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	44 (6.0)	(4.4, 8.0)	468 (3.1)	(2.9, 3.4)
Headache	42 (5.7)	(4.2, 7.7)	414 (2.8)	(2.5, 3.1)
Dizziness	2 (0.3)	(0.0, 1.0)	21 (0.1)	(0.1, 0.2)
Lethargy	0	(0.0, 0.5)	13 (0.1)	(0.0, 0.1)
Paraesthesia	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Syncope	1 (0.1)	(0.0, 0.8)	4 (0.0)	(0.0, 0.1)

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14.100. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=734)		≥16 Years (N[a]=14899)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Migraine	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.1)
Sciatica	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Hypoaesthesia	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.1)
Presyncope	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.1)
Cerebrovascular accident	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Nerve compression	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Psychomotor hyperactivity	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Somnolence	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Tremor	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Cervical radiculopathy	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Formication	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Haemorrhage intracranial	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hyperaesthesia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Parosmia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Seizure	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Taste disorder	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Tension headache	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Pregnancy	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Abortion spontaneous	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gestational hypertension	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	8 (1.1)	(0.5, 2.1)	32 (0.2)	(0.1, 0.3)
Anxiety	3 (0.4)	(0.1, 1.2)	11 (0.1)	(0.0, 0.1)
Insomnia	1 (0.1)	(0.0, 0.8)	5 (0.0)	(0.0, 0.1)
Depression	3 (0.4)	(0.1, 1.2)	2 (0.0)	(0.0, 0.0)
Attention deficit hyperactivity disorder	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Disorientation	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Nightmare	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
Acute stress disorder	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Affective disorder	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Aggression	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
Alcohol abuse	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Bruxism	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.100. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=734)		≥16 Years (N[a]=14899)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Emotional distress	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gender dysphoria	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Irritability	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Libido decreased	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Major depression	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Psychiatric decompensation	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Suicidal ideation	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
Suicide attempt	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	0	(0.0, 0.5)	6 (0.0)	(0.0, 0.1)
Nephrolithiasis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Calculus bladder	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pollakiuria	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Renal pain	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Stress urinary incontinence	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.3)	(0.0, 1.0)	8 (0.1)	(0.0, 0.1)
Intermenstrual bleeding	1 (0.1)	(0.0, 0.8)	1 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.1)
Breast pain	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Heavy menstrual bleeding	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Dysmenorrhoea	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
Menstruation irregular	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pelvic pain	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.1)	(0.0, 0.8)	21 (0.1)	(0.1, 0.2)
Nasal congestion	1 (0.1)	(0.0, 0.8)	4 (0.0)	(0.0, 0.1)
Rhinorrhoea	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Dyspnoea	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Cough	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Epistaxis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Oropharyngeal pain	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Sinus congestion	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Asthma	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pleural effusion	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=734)		≥16 Years (N[a]=14899)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Sleep apnoea syndrome	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Throat tightness	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Upper-airway cough syndrome	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.3)	(0.0, 1.0)	50 (0.3)	(0.2, 0.4)
Rash	0	(0.0, 0.5)	10 (0.1)	(0.0, 0.1)
Hyperhidrosis	0	(0.0, 0.5)	8 (0.1)	(0.0, 0.1)
Night sweats	0	(0.0, 0.5)	7 (0.0)	(0.0, 0.1)
Urticaria	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Acne	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Erythema	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Pruritus	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.1)
Dermatitis contact	1 (0.1)	(0.0, 0.8)	2 (0.0)	(0.0, 0.0)
Alopecia	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Psoriasis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Skin lesion	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Dermatitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Dermatitis atopic	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Diabetic foot	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Diffuse alopecia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Ecchymosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Lichen sclerosus	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pain of skin	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pityriasis rosea	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Sensitive skin	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.1)	(0.0, 0.8)	7 (0.0)	(0.0, 0.1)
Breast conserving surgery	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Cataract operation	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Knee arthroplasty	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Meniscus operation	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Metabolic surgery	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Oral surgery	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
Tooth extraction	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.100. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=734)		≥16 Years (N^a=14899)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
VASCULAR DISORDERS	0	(0.0, 0.5)	20 (0.1)	(0.1, 0.2)
Hypertension	0	(0.0, 0.5)	13 (0.1)	(0.0, 0.1)
Hot flush	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Flushing	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Lymphoedema	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Aneurysm	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Arteriosclerosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hypotension	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 19MAY2023 (04:27)
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14.101. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Not Reported

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=2)		≥16 Years (N[a]=82)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	1 (50.0)	(1.3, 98.7)	12 (14.6)	(7.8, 24.2)
GASTROINTESTINAL DISORDERS	0	(0.0, 84.2)	1 (1.2)	(0.0, 6.6)
Nausea	0	(0.0, 84.2)	1 (1.2)	(0.0, 6.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (50.0)	(1.3, 98.7)	11 (13.4)	(6.9, 22.7)
Injection site pain	0	(0.0, 84.2)	2 (2.4)	(0.3, 8.5)
Fatigue	1 (50.0)	(1.3, 98.7)	4 (4.9)	(1.3, 12.0)
Pyrexia	0	(0.0, 84.2)	5 (6.1)	(2.0, 13.7)
Chills	1 (50.0)	(1.3, 98.7)	2 (2.4)	(0.3, 8.5)
Pain	0	(0.0, 84.2)	3 (3.7)	(0.8, 10.3)
Injection site rash	0	(0.0, 84.2)	1 (1.2)	(0.0, 6.6)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 84.2)	3 (3.7)	(0.8, 10.3)
Myalgia	0	(0.0, 84.2)	3 (3.7)	(0.8, 10.3)
Pain in extremity	0	(0.0, 84.2)	1 (1.2)	(0.0, 6.6)
NERVOUS SYSTEM DISORDERS	1 (50.0)	(1.3, 98.7)	3 (3.7)	(0.8, 10.3)
Headache	1 (50.0)	(1.3, 98.7)	3 (3.7)	(0.8, 10.3)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.102. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – HIV-Positive Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) ≥16 Years (N[a]=98)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any adverse event	11 (11.2)	(5.7, 19.2)
EYE DISORDERS	1 (1.0)	(0.0, 5.6)
Eyelid ptosis	1 (1.0)	(0.0, 5.6)
GASTROINTESTINAL DISORDERS	2 (2.0)	(0.2, 7.2)
Abdominal pain	1 (1.0)	(0.0, 5.6)
Dyspepsia	1 (1.0)	(0.0, 5.6)
Nausea	1 (1.0)	(0.0, 5.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	7 (7.1)	(2.9, 14.2)
Chills	3 (3.1)	(0.6, 8.7)
Fatigue	3 (3.1)	(0.6, 8.7)
Injection site pain	3 (3.1)	(0.6, 8.7)
Pyrexia	2 (2.0)	(0.2, 7.2)
Injection site hyperaesthesia	1 (1.0)	(0.0, 5.6)
INFECTIONS AND INFESTATIONS	1 (1.0)	(0.0, 5.6)
Sepsis	1 (1.0)	(0.0, 5.6)
NERVOUS SYSTEM DISORDERS	1 (1.0)	(0.0, 5.6)
Bell's palsy	1 (1.0)	(0.0, 5.6)
RENAL AND URINARY DISORDERS	1 (1.0)	(0.0, 5.6)
Acute kidney injury	1 (1.0)	(0.0, 5.6)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.103. Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 3 – BNT162b2-Naïve Subjects Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=236) n[b] (%)	 (95% CI[c])
Any adverse event	27 (11.4)	(7.7, 16.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.4)	(0.0, 2.3)
Lymph node pain	1 (0.4)	(0.0, 2.3)
GASTROINTESTINAL DISORDERS	2 (0.8)	(0.1, 3.0)
Nausea	2 (0.8)	(0.1, 3.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	23 (9.7)	(6.3, 14.3)
Injection site pain	11 (4.7)	(2.3, 8.2)
Fatigue	9 (3.8)	(1.8, 7.1)
Pain	5 (2.1)	(0.7, 4.9)
Pyrexia	5 (2.1)	(0.7, 4.9)
Chills	4 (1.7)	(0.5, 4.3)
Injection site swelling	2 (0.8)	(0.1, 3.0)
INFECTIONS AND INFESTATIONS	1 (0.4)	(0.0, 2.3)
Urinary tract infection	1 (0.4)	(0.0, 2.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	6 (2.5)	(0.9, 5.5)
Myalgia	4 (1.7)	(0.5, 4.3)
Arthralgia	1 (0.4)	(0.0, 2.3)
Joint swelling	1 (0.4)	(0.0, 2.3)
NERVOUS SYSTEM DISORDERS	4 (1.7)	(0.5, 4.3)
Headache	4 (1.7)	(0.5, 4.3)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.104. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	139 (16.8)	(14.4, 19.6)	3377 (15.0)	(14.6, 15.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	7 (0.8)	(0.3, 1.7)	349 (1.6)	(1.4, 1.7)
Lymphadenopathy	7 (0.8)	(0.3, 1.7)	344 (1.5)	(1.4, 1.7)
Lymph node pain	0	(0.0, 0.4)	9 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	0	(0.0, 0.4)	9 (0.0)	(0.0, 0.1)
Palpitations	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)
Tachycardia	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Myocarditis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Ventricular extrasystoles	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.4)	6 (0.0)	(0.0, 0.1)
Tinnitus	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Vertigo	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Ear discomfort	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Middle ear effusion	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Vertigo positional	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Eye pain	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	12 (1.5)	(0.8, 2.5)	161 (0.7)	(0.6, 0.8)
Nausea	9 (1.1)	(0.5, 2.1)	89 (0.4)	(0.3, 0.5)
Diarrhoea	0	(0.0, 0.4)	57 (0.3)	(0.2, 0.3)
Vomiting	5 (0.6)	(0.2, 1.4)	32 (0.1)	(0.1, 0.2)
Abdominal pain	1 (0.1)	(0.0, 0.7)	3 (0.0)	(0.0, 0.0)
Abdominal pain upper	1 (0.1)	(0.0, 0.7)	1 (0.0)	(0.0, 0.0)
Abdominal discomfort	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Constipation	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Food poisoning	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Gastritis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Lip dry	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Lip oedema	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Retching	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	129 (15.6)	(13.2, 18.3)	2910 (13.0)	(12.5, 13.4)

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14.104. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site pain	65 (7.9)	(6.1, 9.9)	1678 (7.5)	(7.1, 7.8)
Fatigue	61 (7.4)	(5.7, 9.4)	855 (3.8)	(3.6, 4.1)
Pyrexia	28 (3.4)	(2.3, 4.9)	665 (3.0)	(2.7, 3.2)
Chills	22 (2.7)	(1.7, 4.0)	443 (2.0)	(1.8, 2.2)
Pain	24 (2.9)	(1.9, 4.3)	352 (1.6)	(1.4, 1.7)
Asthenia	0	(0.0, 0.4)	81 (0.4)	(0.3, 0.4)
Malaise	3 (0.4)	(0.1, 1.1)	76 (0.3)	(0.3, 0.4)
Injection site erythema	4 (0.5)	(0.1, 1.2)	42 (0.2)	(0.1, 0.3)
Injection site swelling	0	(0.0, 0.4)	37 (0.2)	(0.1, 0.2)
Axillary pain	1 (0.1)	(0.0, 0.7)	25 (0.1)	(0.1, 0.2)
Vaccination site pain	0	(0.0, 0.4)	15 (0.1)	(0.0, 0.1)
Injection site lymphadenopathy	0	(0.0, 0.4)	10 (0.0)	(0.0, 0.1)
Injection site pruritus	0	(0.0, 0.4)	9 (0.0)	(0.0, 0.1)
Injection site warmth	0	(0.0, 0.4)	9 (0.0)	(0.0, 0.1)
Localised oedema	0	(0.0, 0.4)	7 (0.0)	(0.0, 0.1)
Swelling	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)
Feeling abnormal	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Injection site mass	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Vaccination site lymphadenopathy	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Chest pain	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Injection site bruising	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Injection site induration	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Injection site oedema	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Injection site rash	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Injection site reaction	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Vaccination site swelling	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Facial pain	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Feeling hot	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Inflammation	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Injection site inflammation	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Injection site irritation	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Vaccination site oedema	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Application site erythema	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Face oedema	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Illness	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)

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14.104. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site discomfort	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Injection site haematoma	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Injection site nodule	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Injection site vesicles	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Thirst	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Vaccination site erythema	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)
Immunisation reaction	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Hypersensitivity	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Cellulitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Rhinitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Staphylococcal infection	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.4)	7 (0.0)	(0.0, 0.1)
Maternal exposure during breast feeding	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Vaccination complication	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Contusion	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.4)	57 (0.3)	(0.2, 0.3)
Body temperature increased	0	(0.0, 0.4)	54 (0.2)	(0.2, 0.3)
Heart rate increased	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Cardiac murmur	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.4)	12 (0.1)	(0.0, 0.1)
Decreased appetite	0	(0.0, 0.4)	11 (0.0)	(0.0, 0.1)
Increased appetite	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	18 (2.2)	(1.3, 3.4)	571 (2.5)	(2.3, 2.8)
Myalgia	13 (1.6)	(0.8, 2.7)	473 (2.1)	(1.9, 2.3)
Pain in extremity	6 (0.7)	(0.3, 1.6)	46 (0.2)	(0.1, 0.3)
Arthralgia	0	(0.0, 0.4)	45 (0.2)	(0.1, 0.3)
Back pain	0	(0.0, 0.4)	6 (0.0)	(0.0, 0.1)
Musculoskeletal pain	0	(0.0, 0.4)	6 (0.0)	(0.0, 0.1)
Neck pain	0	(0.0, 0.4)	6 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)

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14.104. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Muscular weakness	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Musculoskeletal stiffness	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Axillary mass	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Muscle spasms	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Synovial cyst	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Arthritis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Bursitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Neck mass	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	49 (5.9)	(4.4, 7.8)	589 (2.6)	(2.4, 2.8)
Headache	47 (5.7)	(4.2, 7.5)	550 (2.4)	(2.2, 2.7)
Dizziness	2 (0.2)	(0.0, 0.9)	20 (0.1)	(0.1, 0.1)
Lethargy	0	(0.0, 0.4)	12 (0.1)	(0.0, 0.1)
Syncope	1 (0.1)	(0.0, 0.7)	4 (0.0)	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Migraine	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Psychomotor hyperactivity	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Somnolence	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Hyperaesthesia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Presyncope	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Taste disorder	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Tremor	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.2)	(0.0, 0.9)	8 (0.0)	(0.0, 0.1)
Insomnia	1 (0.1)	(0.0, 0.7)	3 (0.0)	(0.0, 0.0)
Anxiety	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Depression	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Disorientation	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Irritability	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Nightmare	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Pollakiuria	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)

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14.104. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Breast pain	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Cervical bulla	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Menstruation irregular	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.1)	(0.0, 0.7)	15 (0.1)	(0.0, 0.1)
Nasal congestion	1 (0.1)	(0.0, 0.7)	4 (0.0)	(0.0, 0.0)
Rhinorrhoea	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)
Cough	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Dyspnoea	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Oropharyngeal pain	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Sinus congestion	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Throat tightness	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.1)	(0.0, 0.7)	45 (0.2)	(0.1, 0.3)
Hyperhidrosis	0	(0.0, 0.4)	9 (0.0)	(0.0, 0.1)
Rash	0	(0.0, 0.4)	9 (0.0)	(0.0, 0.1)
Night sweats	0	(0.0, 0.4)	6 (0.0)	(0.0, 0.1)
Erythema	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Pruritus	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Urticaria	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Angioedema	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Blister	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Cold sweat	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Pain of skin	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Photosensitivity reaction	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Rash papular	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Sensitive skin	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
Skin lesion	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Skin oedema	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	0	(0.0, 0.4)	7 (0.0)	(0.0, 0.1)
Flushing	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Hot flush	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)

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14.104. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lymphoedema	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Hypertension	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:09)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_rel_p23_d3

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14.105. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 3 – BNT162b2-Naïve Subjects Assigned to Receive BNT162b2$_{SA}$ Who Received Booster Dose of BNT162b2 (30 µg) – Booster Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=236) n[b] (%)	(95% CI[c])
Any adverse event	25 (10.6)	(7.0, 15.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.4)	(0.0, 2.3)
Lymph node pain	1 (0.4)	(0.0, 2.3)
GASTROINTESTINAL DISORDERS	2 (0.8)	(0.1, 3.0)
Nausea	2 (0.8)	(0.1, 3.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	23 (9.7)	(6.3, 14.3)
Injection site pain	11 (4.7)	(2.3, 8.2)
Fatigue	9 (3.8)	(1.8, 7.1)
Pain	5 (2.1)	(0.7, 4.9)
Pyrexia	5 (2.1)	(0.7, 4.9)
Chills	4 (1.7)	(0.5, 4.3)
Injection site swelling	2 (0.8)	(0.1, 3.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	5 (2.1)	(0.7, 4.9)
Myalgia	4 (1.7)	(0.5, 4.3)
Arthralgia	1 (0.4)	(0.0, 2.3)
NERVOUS SYSTEM DISORDERS	4 (1.7)	(0.5, 4.3)
Headache	4 (1.7)	(0.5, 4.3)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:09)
(Database Snapshot Date: 28APR2023) Output File: ./nda2 unblinded/C4591001 CSR/adae s130 rel na d3

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14.106. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	3 (0.4)	(0.1, 1.1)	84 (0.4)	(0.3, 0.5)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Nausea	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Paraesthesia oral	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (0.4)	(0.1, 1.1)	33 (0.1)	(0.1, 0.2)
Injection site pain	2 (0.2)	(0.0, 0.9)	26 (0.1)	(0.1, 0.2)
Fatigue	1 (0.1)	(0.0, 0.7)	6 (0.0)	(0.0, 0.1)
Asthenia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Chest pain	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Injection site erythema	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Injection site induration	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.4)	31 (0.1)	(0.1, 0.2)
Exposure during pregnancy	0	(0.0, 0.4)	20 (0.1)	(0.1, 0.1)
Maternal exposure during breast feeding	0	(0.0, 0.4)	9 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Arthralgia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Myalgia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.4)	11 (0.0)	(0.0, 0.1)
Headache	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)
Dizziness	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Throat tightness	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Erythema	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Pruritus	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Hypertension	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)

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14.106. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=825)		≥16 Years (N^a=22470)	
System Organ Class Preferred Term	n^b (%)	(95% CI^c)	n^b (%)	(95% CI^c)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:09)
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14.107. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	6 (0.7)	(0.3, 1.6)	90 (0.4)	(0.3, 0.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Lymphadenopathy	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	0	(0.0, 0.4)	7 (0.0)	(0.0, 0.1)
Coronary artery disease	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Acute coronary syndrome	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Angina pectoris	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Atrioventricular block	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Cardiac failure	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Myocarditis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Deafness neurosensory	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.4)	10 (0.0)	(0.0, 0.1)
Abdominal pain upper	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Colitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Diarrhoea	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Nausea	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Rectal haemorrhage	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Volvulus	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (0.4)	(0.1, 1.1)	27 (0.1)	(0.1, 0.2)
Pyrexia	3 (0.4)	(0.1, 1.1)	9 (0.0)	(0.0, 0.1)
Chills	0	(0.0, 0.4)	10 (0.0)	(0.0, 0.1)
Injection site pain	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Pain	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Fatigue	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Asthenia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Chest discomfort	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Gait disturbance	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)

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14.107. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Malaise	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Vaccination site lymphadenopathy	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	0	(0.0, 0.4)	4 (0.0)	(0.0, 0.0)
Alcoholic liver disease	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hyperbilirubinaemia neonatal	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	0	(0.0, 0.4)	6 (0.0)	(0.0, 0.1)
Appendicitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Cellulitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Focal peritonitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Gastroenteritis norovirus	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Pneumonia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.4)	7 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Ankle fracture	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Overdose	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Radius fracture	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Tendon injury	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Wrist fracture	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Hypoglycaemia neonatal	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hyponatraemia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 0.4)	10 (0.0)	(0.0, 0.1)
Myalgia	0	(0.0, 0.4)	5 (0.0)	(0.0, 0.1)
Arthralgia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Back pain	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Kyphosis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Muscular weakness	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Neck pain	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.4)	6 (0.0)	(0.0, 0.1)

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14.107. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Adenocarcinoma of colon	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Colon cancer	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Gastrointestinal stromal tumour	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Invasive breast carcinoma	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.4)	18 (0.1)	(0.0, 0.1)
Headache	0	(0.0, 0.4)	12 (0.1)	(0.0, 0.1)
Cerebrovascular accident	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Dizziness	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Haemorrhage intracranial	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Presyncope	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Sciatica	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Syncope	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.2)	(0.0, 0.9)	3 (0.0)	(0.0, 0.0)
Depression	2 (0.2)	(0.0, 0.9)	0	(0.0, 0.0)
Acute stress disorder	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Aggression	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
Disorientation	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Psychiatric decompensation	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Suicidal ideation	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Nephrolithiasis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Renal colic	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
Dysmenorrhoea	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Cough	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Pleural effusion	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)

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14.107. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=825)		≥16 Years (N^a=22470)	
System Organ Class Preferred Term	n^b (%)	(95% CI^c)	n^b (%)	(95% CI^c)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:38)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/c4591001_CSR/adae_s130_sev_p23_d3

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14.108. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	1 (0.1)	(0.0, 0.7)	6 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Biliary obstruction	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Cholecystitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Appendicitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Renal neoplasm	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
Suicide attempt	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Angioedema	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:08)
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14.109. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	2 (0.2)	(0.0, 0.9)	65 (0.3)	(0.2, 0.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Splenic vein thrombosis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	0	(0.0, 0.4)	9 (0.0)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Angina pectoris	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Atrial fibrillation	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Atrioventricular block	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Cardiac failure	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Myocarditis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Deafness neurosensory	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.4)	7 (0.0)	(0.0, 0.1)
Abdominal pain upper	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Colitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Rectal haemorrhage	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Volvulus	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Chest discomfort	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Chest pain	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	0	(0.0, 0.4)	8 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Alcoholic liver disease	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Biliary obstruction	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Cholecystitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hepatitis acute	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hyperbilirubinaemia neonatal	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Jaundice cholestatic	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)

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14.109. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INFECTIONS AND INFESTATIONS	0	(0.0, 0.4)	11 (0.0)	(0.0, 0.1)
Appendicitis	0	(0.0, 0.4)	3 (0.0)	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Cellulitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Diverticulitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Focal peritonitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Gastroenteritis norovirus	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Pneumonia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Wound infection	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.4)	6 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Ankle fracture	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Exposure during pregnancy	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Overdose	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Hypoglycaemia neonatal	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hyponatraemia	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Back pain	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Kyphosis	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.4)	10 (0.0)	(0.0, 0.1)
Adenocarcinoma of colon	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Colon cancer	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Endometrial adenocarcinoma	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Gastrointestinal stromal tumour	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Invasive breast carcinoma	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Papillary thyroid cancer	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Renal neoplasm	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)

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14.109. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=825)		≥16 Years (N[a]=22470)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.4)	7 (0.0)	(0.0, 0.1)
Cerebrovascular accident	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Haemorrhage intracranial	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Hepatic encephalopathy	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Intracranial aneurysm	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Seizure	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.4)	2 (0.0)	(0.0, 0.0)
Abortion spontaneous	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Gestational hypertension	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.2)	(0.0, 0.9)	2 (0.0)	(0.0, 0.0)
Alcohol abuse	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Anxiety	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Depression	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
Suicidal ideation	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
Suicide attempt	1 (0.1)	(0.0, 0.7)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Renal colic	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Angioedema	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Aneurysm	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:09)
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14.110. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: 12-15 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=825)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any adverse event	2 (0.2)	(0.0, 0.9)
PSYCHIATRIC DISORDERS	2 (0.2)	(0.0, 0.9)
Depression	1 (0.1)	(0.0, 0.7)
Suicidal ideation	1 (0.1)	(0.0, 0.7)
Suicide attempt	1 (0.1)	(0.0, 0.7)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.111. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12834) n[b] (%)	 (95% CI[c])
Any adverse event	28 (0.2)	(0.1, 0.3)
CARDIAC DISORDERS	2 (0.0)	(0.0, 0.1)
Atrioventricular block	1 (0.0)	(0.0, 0.0)
Myocarditis	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	2 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.0)
Volvulus	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.0)	(0.0, 0.0)
Chest discomfort	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	4 (0.0)	(0.0, 0.1)
Cholecystitis acute	2 (0.0)	(0.0, 0.1)
Cholecystitis	1 (0.0)	(0.0, 0.0)
Hyperbilirubinaemia neonatal	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	6 (0.0)	(0.0, 0.1)
Appendicitis	2 (0.0)	(0.0, 0.1)
Cellulitis	1 (0.0)	(0.0, 0.0)
Pneumonia	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.0)
Wound infection	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	2 (0.0)	(0.0, 0.1)
Road traffic accident	1 (0.0)	(0.0, 0.0)
Ankle fracture	1 (0.0)	(0.0, 0.0)
Exposure during pregnancy	1 (0.0)	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.0)
Hypoglycaemia neonatal	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)
Back pain	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	1 (0.0)	(0.0, 0.0)
Invasive breast carcinoma	1 (0.0)	(0.0, 0.0)

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14.111. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12834) n[b] (%)	(95% CI[c])
NERVOUS SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)
Intracranial aneurysm	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2 (0.0)	(0.0, 0.1)
Abortion spontaneous	1 (0.0)	(0.0, 0.0)
Gestational hypertension	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.0)
Anxiety	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.112. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9636) n[b] (%)	 (95% CI[c])
Any adverse event	37 (0.4)	(0.3, 0.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)
Splenic vein thrombosis	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	7 (0.1)	(0.0, 0.1)
Acute coronary syndrome	2 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)
Atrial fibrillation	1 (0.0)	(0.0, 0.1)
Cardiac failure	1 (0.0)	(0.0, 0.1)
Coronary artery disease	1 (0.0)	(0.0, 0.1)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.1)
Deafness neurosensory	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	5 (0.1)	(0.0, 0.1)
Abdominal pain upper	1 (0.0)	(0.0, 0.1)
Dysphagia	1 (0.0)	(0.0, 0.1)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)
Rectal haemorrhage	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	4 (0.0)	(0.0, 0.1)
Alcoholic liver disease	1 (0.0)	(0.0, 0.1)
Biliary obstruction	1 (0.0)	(0.0, 0.1)
Hepatic cirrhosis	1 (0.0)	(0.0, 0.1)
Hepatitis acute	1 (0.0)	(0.0, 0.1)
Jaundice cholestatic	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	5 (0.1)	(0.0, 0.1)
Appendicitis	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)
Complicated appendicitis	1 (0.0)	(0.0, 0.1)
Diverticulitis	1 (0.0)	(0.0, 0.1)
Focal peritonitis	1 (0.0)	(0.0, 0.1)
Gastroenteritis norovirus	1 (0.0)	(0.0, 0.1)

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14.112. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=9636) n[b] (%)	 (95% CI[c])
Osteomyelitis	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.0)	(0.0, 0.1)
Road traffic accident	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.1)
Hyponatraemia	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)
Kyphosis	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	8 (0.1)	(0.0, 0.2)
Adenocarcinoma of colon	1 (0.0)	(0.0, 0.1)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.1)
Colon cancer	1 (0.0)	(0.0, 0.1)
Endometrial adenocarcinoma	1 (0.0)	(0.0, 0.1)
Gastrointestinal stromal tumour	1 (0.0)	(0.0, 0.1)
Papillary thyroid cancer	1 (0.0)	(0.0, 0.1)
Prostate cancer	1 (0.0)	(0.0, 0.1)
Renal neoplasm	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	6 (0.1)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)
Haemorrhage intracranial	1 (0.0)	(0.0, 0.1)
Hepatic encephalopathy	1 (0.0)	(0.0, 0.1)
Neuropathy peripheral	1 (0.0)	(0.0, 0.1)
Seizure	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.1)
Alcohol abuse	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.1)
Renal colic	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	1 (0.0)	(0.0, 0.1)
Aneurysm	1 (0.0)	(0.0, 0.1)
Aortic aneurysm	1 (0.0)	(0.0, 0.1)

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14.112. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=9636)
System Organ Class Preferred Term	n[b] (%) (95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:09)
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14.113. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=689)		≥16 Years (N[a]=18869)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	1 (0.1)	(0.0, 0.8)	54 (0.3)	(0.2, 0.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Splenic vein thrombosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	0	(0.0, 0.5)	8 (0.0)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Angina pectoris	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Atrial fibrillation	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Atrioventricular block	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Cardiac failure	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Myocarditis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Deafness neurosensory	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.5)	6 (0.0)	(0.0, 0.1)
Colitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Rectal haemorrhage	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Volvulus	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Chest pain	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	0	(0.0, 0.5)	7 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Alcoholic liver disease	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Biliary obstruction	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Cholecystitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hepatitis acute	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hyperbilirubinaemia neonatal	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Jaundice cholestatic	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	0	(0.0, 0.5)	10 (0.1)	(0.0, 0.1)

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14.113. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=689)		≥16 Years (N[a]=18869)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Appendicitis	0	(0.0, 0.5)	3 (0.0)	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Cellulitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Diverticulitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Focal peritonitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gastroenteritis norovirus	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Wound infection	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Ankle fracture	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Exposure during pregnancy	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Overdose	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Hypoglycaemia neonatal	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hyponatraemia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Back pain	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Kyphosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.5)	8 (0.0)	(0.0, 0.1)
Adenocarcinoma of colon	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Colon cancer	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Endometrial adenocarcinoma	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gastrointestinal stromal tumour	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Papillary thyroid cancer	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Renal neoplasm	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Cerebrovascular accident	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Hepatic encephalopathy	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.113. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: White

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=689)		≥16 Years (N[a]=18869)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Intracranial aneurysm	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Seizure	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gestational hypertension	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	1 (0.1)	(0.0, 0.8)	1 (0.0)	(0.0, 0.0)
Anxiety	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Suicidal ideation	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
Suicide attempt	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Renal colic	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Angioedema	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Aneurysm	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
Note: All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.114. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: Black or African American

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=38)		≥16 Years (N[a]=1962)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	1 (2.6)	(0.1, 13.8)	9 (0.5)	(0.2, 0.9)
CARDIAC DISORDERS	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Coronary artery disease	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
GASTROINTESTINAL DISORDERS	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Abdominal pain upper	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Chest discomfort	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
HEPATOBILIARY DISORDERS	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Cholecystitis acute	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
INFECTIONS AND INFESTATIONS	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Pneumonia	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Road traffic accident	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Intraductal proliferative breast lesion	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
NERVOUS SYSTEM DISORDERS	0	(0.0, 9.3)	2 (0.1)	(0.0, 0.4)
Haemorrhage intracranial	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Neuropathy peripheral	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
PSYCHIATRIC DISORDERS	1 (2.6)	(0.1, 13.8)	1 (0.1)	(0.0, 0.3)
Alcohol abuse	0	(0.0, 9.3)	1 (0.1)	(0.0, 0.3)
Depression	1 (2.6)	(0.1, 13.8)	0	(0.0, 0.2)

Note: MedDRA (v25.1) coding dictionary applied.
Note: All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.115. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Race – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Race: All Others

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=98)		≥16 Years (N^a=1639)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Any adverse event	0	(0.0, 3.7)	2 (0.1)	(0.0, 0.4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Invasive breast carcinoma	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)
Abortion spontaneous	0	(0.0, 3.7)	1 (0.1)	(0.0, 0.3)

Note: MedDRA (v25.1) coding dictionary applied.
Note: All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.116. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=407)		≥16 Years (N[a]=11267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	0	(0.0, 0.9)	29 (0.3)	(0.2, 0.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Splenic vein thrombosis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	0	(0.0, 0.9)	7 (0.1)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Angina pectoris	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Atrial fibrillation	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Myocarditis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Deafness neurosensory	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Abdominal pain upper	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Chest discomfort	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Alcoholic liver disease	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Biliary obstruction	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Jaundice cholestatic	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Appendicitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Cellulitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Wound infection	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Road traffic accident	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Back pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

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14.116. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Male

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=407)		≥16 Years (N[a]=11267)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.9)	5 (0.0)	(0.0, 0.1)
Adenocarcinoma of colon	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Gastrointestinal stromal tumour	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Papillary thyroid cancer	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.9)	6 (0.1)	(0.0, 0.1)
Cerebrovascular accident	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Haemorrhage intracranial	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Hepatic encephalopathy	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Seizure	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Anxiety	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Renal colic	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Aneurysm	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.117. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=418)		≥16 Years (N[a]=11203)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	2 (0.5)	(0.1, 1.7)	36 (0.3)	(0.2, 0.4)
CARDIAC DISORDERS	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Atrioventricular block	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Cardiac failure	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.9)	5 (0.0)	(0.0, 0.1)
Colitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Rectal haemorrhage	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Volvulus	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Chest pain	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	0	(0.0, 0.9)	6 (0.1)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Cholecystitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Hepatitis acute	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Hyperbilirubinaemia neonatal	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	0	(0.0, 0.9)	8 (0.1)	(0.0, 0.1)
Appendicitis	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Complicated appendicitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Diverticulitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Focal peritonitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Gastroenteritis norovirus	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Pneumonia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.9)	3 (0.0)	(0.0, 0.1)
Ankle fracture	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Exposure during pregnancy	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Overdose	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Hypoglycaemia neonatal	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

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14.117. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Sex – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Sex: Female

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=418)		≥16 Years (N^a=11203)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Hyponatraemia	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Kyphosis	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.9)	5 (0.0)	(0.0, 0.1)
Colon cancer	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Endometrial adenocarcinoma	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Invasive breast carcinoma	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Renal neoplasm	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Intracranial aneurysm	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.9)	2 (0.0)	(0.0, 0.1)
Abortion spontaneous	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Gestational hypertension	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.5)	(0.1, 1.7)	1 (0.0)	(0.0, 0.0)
Alcohol abuse	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Depression	1 (0.2)	(0.0, 1.3)	0	(0.0, 0.0)
Suicidal ideation	1 (0.2)	(0.0, 1.3)	0	(0.0, 0.0)
Suicide attempt	1 (0.2)	(0.0, 1.3)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)
Angioedema	0	(0.0, 0.9)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.118. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=89)		≥16 Years (N[a]=7489)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	0	(0.0, 4.1)	24 (0.3)	(0.2, 0.5)
CARDIAC DISORDERS	0	(0.0, 4.1)	4 (0.1)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Supraventricular tachycardia	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Deafness neurosensory	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Colitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Dysphagia	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Volvulus	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Chest pain	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	0	(0.0, 4.1)	3 (0.0)	(0.0, 0.1)
Alcoholic liver disease	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Hepatitis acute	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Hyperbilirubinaemia neonatal	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	0	(0.0, 4.1)	4 (0.1)	(0.0, 0.1)
Appendicitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Complicated appendicitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Focal peritonitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Osteomyelitis	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Wound infection	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Overdose	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Hypoglycaemia neonatal	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Back pain	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)

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14.118. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=89)		≥16 Years (N[a]=7489)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Adenocarcinoma of colon	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Endometrial adenocarcinoma	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	0	(0.0, 4.1)	2 (0.0)	(0.0, 0.1)
Hepatic encephalopathy	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Intracranial aneurysm	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Anxiety	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Renal colic	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)
Angioedema	0	(0.0, 4.1)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.119. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=734)		≥16 Years (N[a]=14899)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	2 (0.3)	(0.0, 1.0)	41 (0.3)	(0.2, 0.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Splenic vein thrombosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Angina pectoris	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Atrioventricular block	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Cardiac failure	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Myocarditis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Abdominal pain upper	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Rectal haemorrhage	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Chest discomfort	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Biliary obstruction	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Cholecystitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Jaundice cholestatic	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	0	(0.0, 0.5)	7 (0.0)	(0.0, 0.1)
Appendicitis	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Cellulitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Diverticulitis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gastroenteritis norovirus	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pneumonia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.5)	4 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.119. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=734)		≥16 Years (N[a]=14899)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Road traffic accident	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Ankle fracture	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Exposure during pregnancy	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Hyponatraemia	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Kyphosis	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.5)	8 (0.1)	(0.0, 0.1)
Adenocarcinoma pancreas	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Colon cancer	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gastrointestinal stromal tumour	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Invasive breast carcinoma	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Papillary thyroid cancer	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Renal neoplasm	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.5)	5 (0.0)	(0.0, 0.1)
Cerebrovascular accident	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Haemorrhage intracranial	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Seizure	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.5)	2 (0.0)	(0.0, 0.0)
Abortion spontaneous	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Gestational hypertension	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.3)	(0.0, 1.0)	1 (0.0)	(0.0, 0.0)
Alcohol abuse	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Depression	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
Suicidal ideation	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
Suicide attempt	1 (0.1)	(0.0, 0.8)	0	(0.0, 0.0)
VASCULAR DISORDERS	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Aneurysm	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.5)	1 (0.0)	(0.0, 0.0)

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14.119. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=734)		≥16 Years (N[a]=14899)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.120. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population Ethnicity: Not Reported

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N[a]=2)		≥16 Years (N[a]=82)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	0	(0.0, 84.2)	0	(0.0, 4.4)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.121. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – HIV-Positive Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) ≥16 Years (N[a]=98)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any adverse event	1 (1.0)	(0.0, 5.6)
INFECTIONS AND INFESTATIONS	1 (1.0)	(0.0, 5.6)
Sepsis	1 (1.0)	(0.0, 5.6)
RENAL AND URINARY DISORDERS	1 (1.0)	(0.0, 5.6)
Acute kidney injury	1 (1.0)	(0.0, 5.6)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.122. Number (%) of Subjects Withdrawn Because of Adverse Events From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 2/3 – Subjects Who Received Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 18 – Booster Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)			
	12-15 Years (N^a=825)		≥16 Years (N^a=22470)	
System Organ Class Preferred Term	n^b (%)	(95% CI[c])	n^b (%)	(95% CI[c])
Any adverse event	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	0	(0.0, 0.4)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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14.123. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Booster Dose to 6 Months After Booster Dose, by System Organ Class and Preferred Term – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (5 µg)				BNT162b2 (10 µg)			
	18-55 Years (N[a]=26)		>55 Years (N[a]=53)		18-55 Years (N[a]=25)		>55 Years (N[a]=51)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	1 (4.0)	(0.1, 20.4)	0	(0.0, 7.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 13.2)	0	(0.0, 6.7)	1 (4.0)	(0.1, 20.4)	0	(0.0, 7.0)
Lymphadenopathy	0	(0.0, 13.2)	0	(0.0, 6.7)	1 (4.0)	(0.1, 20.4)	0	(0.0, 7.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
Fatigue	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
Dehydration	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
Dizziness	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
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14.124. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Booster Dose to 6 Months After Booster Dose, by System Organ Class and Preferred Term – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (5 µg)				BNT162b2 (10 µg)			
	18-55 Years (N[a]=26)		>55 Years (N[a]=53)		18-55 Years (N[a]=25)		>55 Years (N[a]=51)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)
Back pain	0	(0.0, 13.2)	1 (1.9)	(0.0, 10.1)	0	(0.0, 13.7)	0	(0.0, 7.0)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
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14.125. Number (%) of Subjects Reporting at Least 1 Adverse Event of Special Interest From Booster Dose to 6 Months After Booster Dose, by System Organ Class and Preferred Term – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Booster Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (5 µg)				BNT162b2 (10 µg)			
	18-55 Years (N[a]=26)		>55 Years (N[a]=53)		18-55 Years (N[a]=25)		>55 Years (N[a]=51)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	0	(0.0, 13.2)	0	(0.0, 6.7)	0	(0.0, 13.7)	1 (2.0)	(0.0, 10.4)
EAR AND LABYRINTH DISORDERS	0	(0.0, 13.2)	0	(0.0, 6.7)	0	(0.0, 13.7)	1 (2.0)	(0.0, 10.4)
Deafness unilateral	0	(0.0, 13.2)	0	(0.0, 6.7)	0	(0.0, 13.7)	1 (2.0)	(0.0, 10.4)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
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14.126. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From the Additional Booster Dose to 1 Month After the Additional Booster Dose, by System Organ Class and Preferred Term – Phase 3 – BNT162b2-Experienced Subjects Who Were Previously Rerandomized/Assigned to Receive Booster Dose(s), and Received an Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

	Previous Vaccine Group (as Administered)									
	BNT162b2 (30 µg) (N[a]=182)		BNT162b2$_{SA}$ (30 µg) (N[a]=196)		BNT162b2 (5 µg) (N[a]=33)		BNT162b2 (10 µg) (N[a]=38)		BNT162b2$_{SA}$ (30 µg, 2 Doses) (N[a]=15)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	14 (7.7)	(4.3, 12.6)	16 (8.2)	(4.7, 12.9)	0	(0.0, 10.6)	1 (2.6)	(0.1, 13.8)	0	(0.0, 21.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	2 (1.1)	(0.1, 3.9)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Lymphadenopathy	2 (1.1)	(0.1, 3.9)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	13 (7.1)	(3.9, 11.9)	14 (7.1)	(4.0, 11.7)	0	(0.0, 10.6)	1 (2.6)	(0.1, 13.8)	0	(0.0, 21.8)
Injection site pain	9 (4.9)	(2.3, 9.2)	8 (4.1)	(1.8, 7.9)	0	(0.0, 10.6)	1 (2.6)	(0.1, 13.8)	0	(0.0, 21.8)
Fatigue	4 (2.2)	(0.6, 5.5)	5 (2.6)	(0.8, 5.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Chills	2 (1.1)	(0.1, 3.9)	2 (1.0)	(0.1, 3.6)	0	(0.0, 10.6)	1 (2.6)	(0.1, 13.8)	0	(0.0, 21.8)
Pyrexia	3 (1.6)	(0.3, 4.7)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	1 (2.6)	(0.1, 13.8)	0	(0.0, 21.8)
Pain	1 (0.5)	(0.0, 3.0)	3 (1.5)	(0.3, 4.4)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Axillary pain	0	(0.0, 2.0)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Injection site swelling	1 (0.5)	(0.0, 3.0)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
INVESTIGATIONS	0	(0.0, 2.0)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Body temperature increased	0	(0.0, 2.0)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (2.2)	(0.6, 5.5)	3 (1.5)	(0.3, 4.4)	0	(0.0, 10.6)	1 (2.6)	(0.1, 13.8)	0	(0.0, 21.8)
Myalgia	3 (1.6)	(0.3, 4.7)	3 (1.5)	(0.3, 4.4)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Arthralgia	1 (0.5)	(0.0, 3.0)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	1 (2.6)	(0.1, 13.8)	0	(0.0, 21.8)
NERVOUS SYSTEM DISORDERS	1 (0.5)	(0.0, 3.0)	4 (2.0)	(0.6, 5.1)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Headache	1 (0.5)	(0.0, 3.0)	4 (2.0)	(0.6, 5.1)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.5)	(0.0, 3.0)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Erythema	1 (0.5)	(0.0, 3.0)	0	(0.0, 1.9)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)

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14.126. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From the Additional Booster Dose to 1 Month After the Additional Booster Dose, by System Organ Class and Preferred Term – Phase 3 – BNT162b2-Experienced Subjects Who Were Previously Rerandomized/Assigned to Receive Booster Dose(s), and Received an Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

	Previous Vaccine Group (as Administered)									
	BNT162b2 (30 µg) (N[a]=182)		BNT162b2$_{SA}$ (30 µg) (N[a]=196)		BNT162b2 (5 µg) (N[a]=33)		BNT162b2 (10 µg) (N[a]=38)		BNT162b2$_{SA}$ (30 µg, 2 Doses) (N[a]=15)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: adae Table Generation: 05MAY2023 (03:04)
(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_rel_p3_d4

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14.127. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From the Additional Booster Dose to 1 Month After the Additional Booster Dose, by System Organ Class and Preferred Term – Phase 3 – BNT162b2-Experienced Subjects Who Were Previously Rerandomized/Assigned to Receive Booster Dose(s), and Received an Additional Booster Dose of BNT162b2 (30 µg) as Part of Protocol Amendment 19 – Booster Safety Population

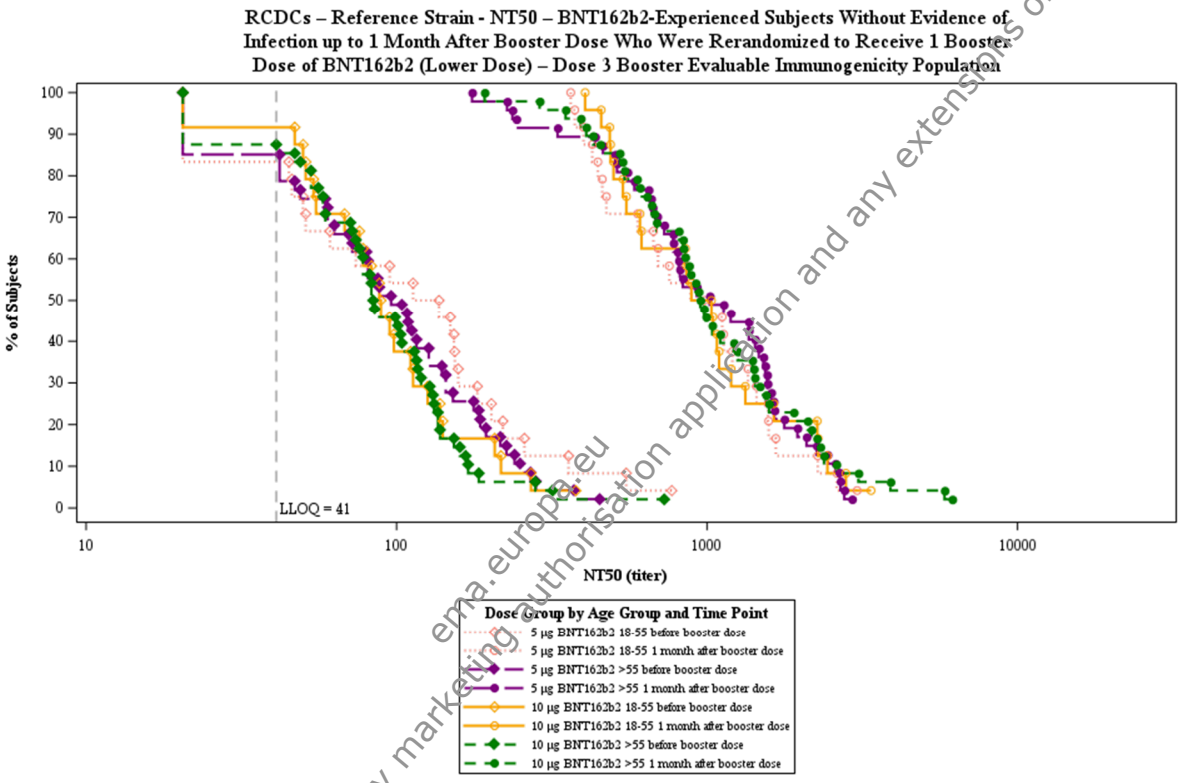
	Previous Vaccine Group (as Administered)									
	BNT162b2 (30 µg) (N[a]=182)		BNT162b2$_{SA}$ (30 µg) (N[a]=196)		BNT162b2 (5 µg) (N[a]=33)		BNT162b2 (10 µg) (N[a]=38)		BNT162b2$_{SA}$ (30 µg, 2 Doses) (N[a]=15)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any adverse event	0	(0.0, 2.0)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 2.0)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)
Muscular weakness	0	(0.0, 2.0)	1 (0.5)	(0.0, 2.8)	0	(0.0, 10.6)	0	(0.0, 9.3)	0	(0.0, 21.8)

Note: MedDRA (v25.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any adverse event," n = number of subjects reporting at least 1 occurrence of any adverse event.
c. Exact 2-sided CI, based on the Clopper and Pearson method.
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(Database Snapshot Date: 28APR2023) Output File: ./nda2_unblinded/C4591001_CSR/adae_s130_sae_p3_d4

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SUPPLEMENTAL FIGURES

14.1 Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay - Reference Strain - NT50 – Phase 3 – BNT162b2-Experienced Subjects Without Evidence of Infection up to 1 Month After Booster Dose Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (Lower Dose) – Dose 3 Booster Evaluable Immunogenicity Population



Abbreviations: LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; RCDC = reverse cumulative distribution curve; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Subjects who had no serological or virological evidence (up to 1 month after receipt of the booster vaccination) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Dose 1 visit, 1-month post–Dose 2 visit, booster dose visit, 1-month post–booster visit and SARS-CoV-2 not detected by NAAT [nasal swab] at Dose 1 visit, Dose 2 visit, booster dose visit) and had a negative NAAT (nasal swab) at any unscheduled visit up to 1 month after booster vaccination were included in the analysis.

Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.

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PARTICIPANT NARRATIVES

Primary Reason for Narrative	Subject Number
Death	Subject PPD
	Subject PPD
	Subject PPD

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Safety-Related Subject Withdrawal

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Myocarditis/Pericarditis

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Ischemic Stroke

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Anaphylaxis

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Pregnancy

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Table of Abbreviations		
Category	**Abbreviation**	**Text**
Action - Subject	N	No action
	O	Other
	P	Drug withdrawn (study intervention discontinued)
	TC	Concomitant drug treatment given
	TCN	Concomitant nondrug treatment given
	W	Withdrawn from study
Toxicity Grade	1	Mild
	2	Moderate
	3	Severe
	4	Life-threatening
System Organ Class	BLOOD	Blood and lymphatic system disorders
	CARD	Cardiac disorders
	CONG	Congenital, familial and genetic disorders
	EAR	Ear and labyrinth disorders
	ENDO	Endocrine disorders
	EYE	Eye disorders
	GASTR	Gastrointestinal disorders
	GENRL	General disorders and administration site conditions
	HEPAT	Hepatobiliary disorders
	IMMUN	Immune system disorders
	INFEC	Infections and infestations
	INJ&P	Injury poisoning and procedural complications
	INV	Investigations
	METAB	Metabolism and nutrition disorders
	MUSC	Musculoskeletal and connective tissue disorders
	NEOPL	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
	NERV	Nervous system disorders
	PREG	Pregnancy, puerperium and perinatal conditions
	PSYCH	Psychiatric disorders
	RENAL	Renal and urinary disorders
	REPRO	Reproductive system and breast disorders

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Table of Abbreviations		
Category	**Abbreviation**	**Text**
	RESP	Respiratory, thoracic and mediastinal disorders
	SKIN	Skin and subcutaneous tissue disorders
	SOCCI	Social circumstances
	SURG	Surgical and medical procedures
	VASC	Vascular disorders

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	GASTR	Abdominal rigidity	PPD	PPD (34)		PPD (276)	PPD	243	2	TC	N
2	GASTR	Constipation		PPD (39)		PPD (276)	PPD	238	3	TC	N
3	GENRL	Death		PPD (276)		PPD (276)	PPD	1	4	W	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
4	BLOOD	Immune thrombocytopenia	PPD	PPD 243)		ONGOING			2	TC	N
5	MUSC	Muscle spasms		PPD 34)		PPD (276)	PPD	243	2	TC	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (PPD)	NOT RELATED/OTHER: Pain/spasms of abdominal/back area	2	13	N
2	Resolved (PPD)	NOT RELATED/OTHER: constipation	2	18	N
3	Fatal (PPD)	NOT RELATED/OTHER: death from natural causes possibly related to ITP	2	255	Y
4	Yes	NOT RELATED/OTHER: History of PPD	2	222	N
5	Resolved (PPD)	NOT RELATED/OTHER: spasms	2	13	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications				
Investigator Text	WHO Drug Preferred Term	Start Date	End Date	Route
PPD		PPD	PPD	PPD
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, an ≥75-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22). Concomitant medications received within 2 weeks prior to the subject's death included PPD On PPD (Day 243), the subject, with a history of PPD experienced a relapse. The subject was treated with protocol-prohibited medications of PPD It was reported that PPD had received the same treatment for PPD past medical history of PPD A complete blood count (CBC) performed on PPD showed a white blood cell count of 12.1×10^3/µL (normal range [NR]: 4.0-11.0×10^3/µL), red blood cell count of 3.51×10^6/µL (NR: 4.40-6.20×10^6/µL), hemoglobin of 10.8 g/dL (NR: 13.0-18.0 g/dL), hematocrit of 32% (NR: 40-52%), lymphocytes of 3% (NR: 15-45%), platelets of 44×10^3/µL (NR: 150-450×10^3/µL), neutrophils of 83% (NR: 45-75%), and monocytes of 12% (NR: 0-15%); eosinophils and basophils results were unknown. On PPD, the subject's primary care physician reviewed the CBC results and stopped PPD therapy, as the subject's platelet count had increased to 44,000. The subject died from natural causes on PPD (at PPD), 254 days after receiving Dose 2. The subject was found dead in PPD home by PPD. The coroner did not perform an autopsy and noted that the cause of death was due to natural causes. It was reported that the subject had PPD for several years and most recently in PPD when it was recommended to have additional cardiac testing, the subject declined (PPD last cardiac visit was on PPD). However, it was unknown if the subject died of PPD. The site did not receive the subject's death certificate. The ITP was ongoing at the time of the subject's death. In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per the investigator, the death was also not related to concomitant medications, but it was possibly related to ITP.

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

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Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (164)	PPD
VACCINATION 4	BNT162b2	PPD (183)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	GASTR	Abdominal compartment syndrome	PPD	PPD (309)		PPD (363)		55	4	TCN	Y
2	INFEC	Abdominal wall abscess		PPD (393)		PPD (412)		20	3	N	Y
3	RENAL	Acute kidney injury		PPD (337)		PPD (412)	PPD	76	3	TC	N
4	RESP	Acute respiratory distress syndrome		PPD (309)		PPD (412)	PPD	104	4	TCN	Y
5	CARD	Atrial fibrillation		PPD (311)		PPD (323)		13	2	TC	N
6	GENRL	Chills		PPD (3)	PPD	PPD (7)		5	2	N	N
7	MUSC	Flank pain		PPD (3)	PPD	PPD (7)		5	3	TC	N
8	GASTR	Gastrointestinal necrosis		PPD (309)		PPD (412)	PPD	104	3	TCN	N
9	HEPAT	Hepatic steatosis		PPD (307)		PPD (319)		13	2	TC	N
10	NERV	Metabolic encephalopathy		PPD (329)		PPD (412)	PPD	84	3	TC	N
11	GASTR	Pancreatitis necrotising		PPD (307)		PPD (412)	PPD	106	4	TCN	Y
12	INFEC	Sepsis		PPD (412)	PPD	PPD (412)	PPD	1	4	W	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
13	BLOOD	Thrombocytopenia	PPD	PPD (324)		PPD (335)		12	1	N	N
14	GASTR	Vomiting		PPD (3)		PPD (9)		7	3	TC	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (PPD)	NOT RELATED/OTHER: Acute pancreatitis	4	127	N
2	Resolved (PPD)	NOT RELATED/OTHER: bacterial infection	4	211	N
3	Resolved (PPD)	NOT RELATED/OTHER: Pancreatitis	4	155	N
4	Resolved (PPD)	NOT RELATED/OTHER: Acute Pancreatitis	4	127	N
5	Resolved (PPD)	NOT RELATED/OTHER: Pancreatitis	4	129	N
6	Resolved (PPD)	Study Treatment	1	3	N
7	Resolved (PPD)	Study Treatment	1	3	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
8	Resolved (PPD)	NOT RELATED/OTHER: Pancreatitis, abdominal abdominal compartment syndrome	4	127	N
9	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	125	N
10	Resolved (PPD)	NOT RELATED/OTHER: Pancreatitis	4	147	N
11	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	125	N
12	Fatal (PPD)	NOT RELATED/OTHER: bacterial infection	4	230	Y
13	Resolved (PPD)	NOT RELATED/OTHER: Pancreatitis	4	142	N
14	Resolved (PPD)	Study Treatment	1	3	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD
		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING I	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 164) and PPD (Day 183), respectively. Concomitant medications received within 2 weeks prior to the onset of the sepsis included PPD (all since unknown dates); PPD (from unknown date to PPD (from unknown date to PPD The subject developed sepsis on PPD 229 days after receiving Dose 4 (second dose of BNT162b2) and died on the same day. On PPD (Day 307), the subject presented to the emergency department with complaints of shortness of breath, decreased urination, and abdominal pain in the epigastric and periumbilical areas. Following examinations, PPD was diagnosed with necrotizing pancreatitis, along with urinary retention, acute renal failure, redundant colon, hyperkalemia, colon distention, and elevated liver function tests. On the same day (Day 307), the subject was hospitalized for necrotizing pancreatitis. On PPD (Day 308), the subject was transferred to the intensive care unit (ICU) in another facility. A diagnosis of necrotizing pancreatitis was confirmed, with secondary events of distributive shock, acute renal failure, acute hypercarbic and hypoxemic respiratory failure, hyperkalemia, hypocalcemia, and PPD An x-ray of the abdomen showed persistent abnormal distention of bowel, a computed tomography (CT) scan of the abdomen and pelvis showed pancreatitis, a transesophageal echocardiogram (echo) showed right ventricular thrombus and a transthoracic echo with bubble study showed suspect thrombus vs endocarditis, and an ultrasound lower extremity venous duplex bilateral showed no evidence of deep or superficial bilateral venous thrombosis.

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Narrative Comment
On PPD (Day 309), a CT scan of the abdomen/pelvis showed pancreatitis. The subject was diagnosed with abdominal compartment syndrome secondary to necrotizing pancreatitis and acute respiratory distress syndrome. A CT scan of the abdomen and pelvis on PPD revealed acute necrotizing pancreatitis with mild inflammatory change in the small bowel and volume overload change, including pleural effusions. The subject underwent formation of an ileostomy on PPD. A chest x-ray showed low lung volumes with stable bibasilar opacities. The site was informed of these events on PPD (Day 323); during this time, PPD had undergone the following treatment procedures: multiple recurrent abdominal washouts with packing and wound vacuum-assisted closure placement, subtotal colectomy, and decompressive laparotomy. Pathological results of PPD colon biopsy revealed marked ischemic changes and necrosis of the mucosa, along with transmural necrosis in some areas. At the time, the subject was intubated, requiring ventilation and a central line for medications. PPD condition was not stable, and PPD was listed as critically ill with an open abdomen. On PPD (Day 324), PPD underwent final closure of the abdomen. On PPD (Day 329), the subject was diagnosed with metabolic encephalopathy. PPD respiratory failure and renal failure improved, and PPD was extubated on PPD (Day 333). PPD received PPD On PPD, the subject was transferred to another hospital. PPD acute kidney injury was noted to have stabilized on the same day. PPD chest CT scan showed improving pancreatic fluid on PPD. Another chest CT scan taken on PPD showed improving thoracic fluid. PPD paroxysmal atrial fibrillation was stable, and necrotizing pancreatitis and acute respiratory distress syndrome were resolving. On PPD (Day 363), the subject's abdominal compartment syndrome was considered resolved. The subject's intra-abdominal abscess was positive for vancomycin-resistant enterococci (VRE), *Enterococcus*, and *Candida*; the abscess was considered resolved on PPD and PPD was discharged to a skilled nursing facility on PPD. On PPD (Day 393), the subject presented to the emergency department from the nursing facility with abdominal pain near drain sites and discharge from previous drain sites. The subject was hospitalized on the same day (Day 393) due to an abdominal wall abscess. On that day, laboratory tests showed leukocytosis with a white blood cell (WBC) count of 13.3 and creatinine of 0.6 (units and normal ranges [NR] not reported). A CT scan of the abdomen/pelvis showed decreased size of pancreatic pseudocyst, which was not drainable. The subject received treatment with PPD (Day 393), PPD .

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Narrative Comment
On PPD, PPD WBC was 9.1 (unit and NR not reported). The subject was treated with PPD On PPD, a CT scan of the abdomen/pelvis showed a pancreatic pseudocyst, which had decreased in size, and the superior mesenteric vein/splenic vein occlusion due to extrinsic compression from inflammatory peripancreatic fluid collections. PPD creatinine was 1.6. On the same day, PPD WBC count increased, and continued to increase until PPD. On PPD, a CT scan of the abdomen/pelvis showed decreased pancreatic fluid collection, small pleural effusion, and associated basilar atelectasis. On PPD, the subject tested positive for COVID-19. A chest x-ray showed bilateral interstitial opacities suggestive of COVID-related pneumonia; PPD was diagnosed with a secondary illness of COVID-19. A CT scan of the abdomen/pelvis with/without contrast revealed a small pleural effusion, and a small amount of pneumothorax, with right lower quadrant ostomy. An ultrasound revealed normal appearance of kidneys, without hydronephrosis. On the same day, the subject was moved to a surgical trauma ICU. At that time, PPD had abdominal pain near the drain sites with discharge from previous drain sites. PPD creatinine was 2.68 and arterial blood gas pCO_2 was 51, suggestive of hypercapnic respiratory failure. The subject was in the surgical trauma ICU from PPD to PPD, and was treated with PPD On PPD, the subject was transferred to a neuro-ICU for serotonin syndrome. On the same day, an electrocardiogram was consistent with sinus tachycardia and nonspecific ST-segment abnormalities. A chest x-ray showed small pleural fluid and several unchanged left rib fractures. On PPD, the subject was transferred back to the intermediate care floor unit. The subject started treatment with PPD On PPD a nasojejunal feeding tube was placed and an x-ray confirmed successful placement. The subject was discharged to the nursing facility on the same day. On PPD (Day 412), the subject died of sepsis in the emergency room. The sepsis was suspected to be secondary to the abdominal wall abscess. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the sepsis was related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the sepsis was not related to concomitant medications and was most likely due to progression of the subject's underlying infectious conditions.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Cardiac arrest	PPD	PPD (81)		PPD (84)		4	4	W	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Fatal (PPD)	NOT RELATED/OTHER: Heart attack. Occurred 2 months after last receipt of study agent	2	60	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 60-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22).

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Narrative Comment
Concomitant medications received within 2 weeks prior to the onset of the cardiac arrest included PPD The subject experienced cardiac arrest on PPD, 59 days after receiving Dose 2, and died of the event on PPD, 62 days after receiving Dose 2. On PPD (Day 81), the subject presented to the emergency room following an intubation prior to arrival after a cardiac arrest. It was reported by the nursing facility that the subject did not have a neurologic response other than occasional movements and could breathe only with the help of ventilator settings. PPD electrocardiogram was abnormal, with initial rhythm of pulseless electrical activity and ischemic changes. The downtime was reported as 15 minutes. On the same day (Day 81), a computed tomography scan of the head showed cerebral edema. Emergency department personnel spoke with cardiology personnel, who deferred an intervention, and targeted temperature management (TTM) was ordered. The laboratory results on PPD (Day 81) showed a blood chloride level of 124 mEq/L (normal range [NR]: 98-111 mEq/L), blood glucose of 393 mg/dL (NR: 70-99 mg/dL), blood potassium of 3.5 mEq/L (NR: 3.6-5.1 mEq/L), blood sodium of 155 mEq/L (NR: 135-145 mEq/L), carbon dioxide of 18 mmol/L (NR: 21-31 mmol/L), and glomerular filtration rate of 58 mL/min/1.73 m^2 (NR: >59 mL/min/1.73 m^2). Pressors were required, and the subject was admitted to the intensive care unit. On admission, the subject's potassium level was low at 2.8 mEq/L. PPD urine toxicology screening showed elevated PPD at 109 mg/dL (upper limit of normal: 9.9 mg/dL) and was positive for PPD. On PPD (Day 82), the subject was on TTM with high urine output overnight, which was concerning for diabetes insipidus. On the same day (Day 82), the subject's troponin I was high at 491 ng/L (NR: <15 ng/L), which was considered critical. The subject had a negative SARS-CoV-2 test result. On PPD (Day 83), the subject was rewarmed; magnetic resonance imaging showed anoxic brain injury with possible herniation, and an electroencephalogram showed absent brain activity. On PPD (Day 84), the subject was pronounced dead at PPD because of a cardiac arrest. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures, as the death occurred 2 months after receiving Dose 2. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was most likely associated with the subject's multiple underlying clinical conditions, including PPD and PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (106)	PPD
VACCINATION 4	BNT162b2	PPD (128)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (379)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	PPD	PPD (106)	PPD	PPD (107)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	2	N	N	Resolved (PPD)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 70-year-old PPD with a reported medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 21). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 106), PPD (Day 128), and PPD (Day 379), respectively. The subject died on an unspecified date. On PPD, the site updated the subject's disposition status for the study follow-up phase as "withdrawn" because of the death. This death event occurred outside the protocol-defined postvaccination safety reporting period and as such was reported only as an update to the subject's disposition status but not reported as an adverse event. No additional details will be provided for this event.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (414)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (533)		PPD (533)		1
2	INFEC	Skin infection		PPD (38)		PPD (233)		196

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	3	120	Y
2	2	TC	N	Resolved (PPD)	NOT RELATED/OTHER: skin infection	2	17	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (24)	PPD
VACCINATION 3	BNT162b2	PPD (144)	PPD
VACCINATION 4	BNT162b2	PPD (165)	PPD

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , a 60-year-old PPD with a reported medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 24).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 144) and PPD (Day 165), respectively.

The subject died on an unspecified date. On PPD , the site updated the subject's disposition status for the study follow-up phase as "withdrawn" because of the death. This death event occurred outside the protocol-defined postvaccination safety reporting period and as such was reported only as an update to the subject's disposition status but not reported as an adverse event. No additional details will be provided for this event.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (57)	PPD
VACCINATION 4	BNT162b2	PPD (78)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	PPD	PPD (79)	PPD	PPD (82)	PPD

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	1	N	N	Resolved (PPD)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD, a 70-year-old PPD with no reported medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 22).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 57) and PPD (Day 78), respectively.

The subject died on an unspecified date. On PPD, the site updated the subject's disposition status for the study follow-up phase as "withdrawn" because of the death. This death event occurred outside the protocol-defined postvaccination safety reporting period and as such was reported only as an update to the subject's disposition status but not reported as an adverse event. No additional details will be provided for this event.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD
VACCINATION 3	BNT162b2	PPD (149)	PPD
VACCINATION 4	BNT162b2	PPD (169)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Respiratory failure	PPD	PPD (512)		PPD (519)		8	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: DISEASE PROCESS	4	344	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 20). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 149) and PPD (Day 169), respectively. Concomitant medications received within 2 weeks prior to the onset of the respiratory failure included PPD The subject was diagnosed with respiratory failure (end-stage lung disease) on PPD, 343 days after receiving Dose 4 (second dose of BNT162b2), and died on PPD, 350 days after receiving the second dose of BNT162b2. On PPD (Day 512), the subject required an emergency room visit with subsequent hospitalization for evaluation of respiratory failure manifested as shortness of breath. PPD SARS-CoV-2 test result was negative and a chest x-ray revealed no acute process. On PPD, a computed tomography (CT) scan of the thorax revealed bronchial thickening in the lower lobes and bilateral peripheral patchy areas of infiltration consistent with areas of bronchopneumonia. On PPD, a chest x-ray revealed a new 29-mm mass-like infiltrate in the right upper lobe, just superior to right hilum, and a CT scan of the head showed no acute findings. Therapeutic measures were taken because of the respiratory failure. On PPD (Day 519), the subject experienced cardiac arrest and received cardiopulmonary resuscitation (CPR), PPD, and required ventilation. On the same day (Day 519), an abdominal x-ray showed a nonobstructive bowel gas pattern; a chest x-ray showed an endotracheal tube and an increasing airspace disease; blood examinations showed creatinine of 1.58 mg/dL (normal range [NR]: 0.70-1.30 mg/dL), lactic acid of 8.2 mmol/L (NR: 0.5-2.2 mmol/L), pH of 7.21 (NR: 7.35-7.45), urea of 48 mg/dL (NR: 7-25 mg/dL), and partial pressure of carbon dioxide (pCO_2) of 72 mmHg (NR: 35-45 mmHg); estimated glomerular filtration rate status assay was 53 mL/min (NR low: 60 mL/min); an echocardiogram showed small anterior pericardial effusion overlying the right ventricle. The subject was transitioned to hospice care. On that same day (Day 519), the subject died of disease progression, respiratory failure, and cardiac arrest. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the respiratory failure was related to BNT162b2 or concomitant medications. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was also not related to clinical trial procedures.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Death	PPD	PPD ()		PPD ()		

Adverse Events							
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	114	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a 50-year-old PPD with a reported medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22). On an unspecified date in PPD, the subject died of an unknown cause. It was unknown if an autopsy was performed. No additional details were reported. On PPD, the site updated the subject's disposition status for the study follow-up phase as "withdrawn" because of death. In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (24)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Myocardial infarction	PPD	PPD (226)		PPD (226)		1	4	W

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Fatal (PPD)	NOT RELATED/OTHER: possible underlying PPD	2	203	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , a 60-year-old PPD with a pertinent medical history of PPD ; since unknown date) and a family history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 24).

The subject experienced a myocardial infarction on PPD , 202 days after receiving Dose 2, and died on the same day.

The subject was feeling unwell, had indigestion, and stated that PPD was having a heart attack and collapsed on PPD (Day 226). PPD family witnessed the event and attempted cardiopulmonary resuscitation until the emergency medical services arrived. The subject was pronounced deceased on that same day (Day 226) at PPD home. The cause of death was reported as heart attack/myocardial infarction. An autopsy was not performed.

In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per the investigator, the myocardial infarction was possibly related to the subject's underlying PPD .

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (21)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Pulmonary embolism	PPD	PPD (277)		PPD (277)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TCN/WY	Y	Fatal (PPD)	NOT RELATED/OTHER: blood clot	2	257	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 30-year-old PPD with a pertinent medical history of PPD ; since unknown dates), PPD since unknown date), and a family history of PPD dates unknown), received Dose 1 on PPD and Dose 2 on PPD (Day 21). Concomitant medications received within 2 weeks prior to the onset of the pulmonary thromboembolism included PPD (all since unknown dates). The subject experienced a pulmonary thromboembolism on PPD , 256 days after receiving Dose 2, and died on the same day. On PPD , the subject was feeling unwell, contacted PPD , and complained of abdominal pain, diarrhea, and blood in stool. The subject's PPD reported to the site that the subject visited a healthcare clinic on PPD for a swollen foot and was prescribed PPD Per the PPD , the

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Narrative Comment
subject had an allergic reaction to the PPD which caused the bloody diarrhea. The subject had a history of PPD On PPD (Day 277), the subject went to an urgent care clinic (UCC) for leg pain and on evaluation, PPD blood pressure was 115/78 mmHg, pulse was 110 beats/min, weight was PPD lb, height was PPD feet PPD inches, and body mass index was PPD. Per UCC records provided to the site on PPD, the subject's chief complaint was gradual swelling of PPD right lower leg. On evaluation at the UCC, nonpitting edema (2+) in the lower extremity to the level of the proximal thigh was noted, along with diffuse enlargement of the right inguinal lymph nodes with moderate tenderness; the left inguinal lymph nodes showed no enlargement or tenderness. The discharge diagnosis was right-side lumbago with sciatica and edema. It was reported that the sciatica always caused the subject's leg to swell with tight muscles. At the UCC, DVT was ruled out. A venous Doppler was ordered for the right lower extremity and was scheduled to be performed on PPD. In addition, the UCC records noted a family history of PPD (dates unknown). Upon questioning the PPD, the PPD reported that the subject was tested for clotting disorders in the past, but tests were negative, and the subject had no prior history of blood clots. After leaving the UCC at approximately PPD PM Central Time, the subject called PPD and complained of breathing difficulty. PPD talked with PPD PPD on the phone until PPD returned to the PPD. While on the phone, the subject collapsed in the PPD The PPD found the subject lying on the floor after collapsing and assisted PPD The subject was unconscious; the PPD aroused PPD briefly and after an unspecified amount of time, the subject regained consciousness. The subject's PPD could hear PPD yelling that PPD couldn't breathe, and for the PPD to retrieve PPD The subject was administered a dose of PPD by the PPD. Emergency medical services were contacted, and the subject was transported to the local emergency room. During transport, the subject went into cardiac arrest and was unable to be resuscitated. PPD was pronounced dead at the emergency room on PPD (Day 277). The subject's PPD confirmed that, to PPD knowledge, the subject did not recently travel (no long car rides or airplane rides) or experience trauma. The cause of death was reported as cardiac arrest, an autopsy was performed, and it was determined that an additional cause of death was thromboembolism. On PPD, an autopsy report noted the following: "There was a red fibrous clot that bulges upon dissection of the right pulmonary artery. A segment of the thrombus extends across the branch between the right and left pulmonary artery into the left lung vasculature. The right lower leg was approximately 3/4 to 1 inch greater in diameter than the left." In the opinion of the investigator, there was no reasonable possibility that the pulmonary thromboembolism was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per the investigator, the event was related to the concomitant medication PPD but not related to other concomitant medications. Per Pfizer, the event was not related to concomitant medications but rather it was considered more likely associated with the subject's underlying medical conditions.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (21)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	CARD	Coronary artery disease	PPD	PPD (28)		ONGOING			3	TCN	Y
2	NERV	Haemorrhagic stroke		PPD (197)		PPD (200)		4	4	TCN/W	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Yes	NOT RELATED/OTHER: Believed related to chronic conditions including PPD	2	8	N
2	Fatal (PPD)	NOT RELATED/OTHER: Unknown	2	177	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, and a family history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 21). Concomitant medications received within 2 weeks prior to the onset of the hemorrhagic stroke included PPD The subject was diagnosed with a hemorrhagic stroke on PPD, 176 days after receiving Dose 2, and died on PPD, 179 days after receiving Dose 2.

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Narrative Comment
On PPD (Day 28), the subject's routine cardiac stress test result was abnormal, and PPD was diagnosed with and hospitalized for coronary artery disease (CAD). The subject underwent a cardiac bypass surgery on PPD and was discharged home on PPD. On an unspecified date in PPD, the subject started treatment with PPD at an unknown dose level for CAD. On PPD (Day 197), the subject was found unconscious by PPD family in PPD home and was taken to the emergency room (ER). During a telephone call with PPD family 2 days before that, the subject complained of a headache with confusion. In the ER (Day 197), the subject was found to be minimally responsive with a Glasgow Coma Scale score of 5 and was intubated for airway protection. PPD also had hypertensive emergency with a systolic blood pressure of 220 mmHg and was started on PPD. The subject was subsequently diagnosed with nontraumatic subcortical intracerebral hemorrhage with intraventricular hemorrhage that resulted in a stroke and likely herniation. The physical examination indicated fixed, blown right 5-mm pupil, 3-mm left pupil minimally reactive, weak corneal reflex on the right, and no corneal reflex on the left. The hemorrhagic stroke was life-threatening and required inpatient hospitalization for 4 days. Per the hospital records, the subject was coagulopathic and was on PPD. Per the history and physical written notes of PPD (Day 197), the subject had coagulopathy secondary to anticoagulation and the plan was to reverse it with prothrombin complex concentrate (PCC), but there was no medication list that showed whether PCC was used or not. Furthermore, the PPD stop date was presumed to be on PPD (Day 197), but there was no clear documentation of the stop date in the subject's medical records. Laboratory results showed mildly decreased hemoglobin and hematocrit and normal platelets (values not provided). There were no results available for the prothrombin time, partial thromboplastin time, or international normalized ratio. Imaging studies provided in records included only a computed tomography (CT) scan of the neck, which showed mild degenerative changes but no acute abnormality. Medical records further indicated extensive brain damage, including subcortical intracerebral hemorrhage, intraventricular hemorrhage, cerebral edema, obstructive hydrocephalus, compression of the brain, cerebral herniation, hemiparesis, hemiplegia, dysphagia following intracerebral hemorrhage, acute encephalopathy, and coma. A head CT scan showed stroke. The stroke appeared to be due to PPD in conjunction with a hypercoagulable state caused by PPD use. Per the family's knowledge of the subject's PPD, PPD was issued a "PPD" order with no surgical intervention. PPD was compassionately extubated and died a few hours later on PPD (Day 200). The causes of death were reported as hemorrhagic stroke and disease progression. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the hemorrhagic stroke was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per the investigator, the event was likely related to PPD use, and possibly PPD. Per Pfizer, the event was due to the progression of the subject's underlying condition, which was uncontrolled, in conjunction with a hypercoagulable state caused by PPD use.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (23)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Chest pain	PPD	PPD (198)		ONGOING		
2	GENRL	Death		PPD (265)		PPD (265)		1
3	MUSC	Pain in extremity		PPD (28)		PPD (29)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Yes	NOT RELATED/OTHER: Unknown	2	176	N
2	4	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	243	Y
3	1	N	N	Resolved (PPD)	Study Treatment	2	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 60-year-old PPD with a pertinent medical history of PPD (both since unknown dates) PPD received Dose 1 on PPD and Dose 2 on PPD (Day 23). Concomitant medications received within 2 weeks prior to the death included PPD The subject died of an unknown cause on PPD , 242 days after receiving Dose 2. On PPD (Day 198), the subject developed shooting left chest pain; the causality of the event was not identified, and the outcome was not resolved. The subject saw a pulmonologist and a computed tomography (CT) scan done on PPD (Day 235) showed normal results. On PPD , the

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Narrative Comment
subject was hospitalized with severe diarrhea (16 stools on the same day) and abdominal pain. PPD reported some dark stools. PPD also reported a moderate increase in PPD intake. On the same day, PPD laboratory examination revealed a heart rate (HR) of 120, blood pressure (BP) of 118/51, and blood workup showed low hemoglobin of 5.8 g/dL, white blood cell (WBC) count of 3100, platelet count of 71,000, sodium of 122 mEq/L, and bicarbonate of 15 mEq/L (units not reported for HR, BP, WBC, and platelets; normal ranges [NR] were not reported). Further investigations showed blood urea nitrogen of 18 mg/dL, creatinine of 1.12 mg/dL, total bilirubin of 1.2 g/dL, and serum lactate of 11.1 mmol/L (NR not reported). Tests were consistent with transaminitis. PPD received PPD for persistent lactic acidosis and hypoglycemia; PPD also received packed red blood cells. On an unspecified date in PPD, a test result for infectious mononucleosis was positive. On an unspecified date in PPD, an abdominal CT scan showed a small pericardial and left pleural effusion along with marked splenomegaly and diverticulosis without bowel inflammation, and a chest CT scan showed mediastinal adenopathy. It was suspected that the splenomegaly was secondary to the hepatic disease due to PPD. There were no signs of gastrointestinal bleeding seen on endoscopy. Hematology workup for pancytopenia could not be completed due to progressive multiorgan failure, profound and persistent hypoglycemia, and metabolic acidosis. It was unknown if a COVID test was done. The subject was transferred to hospice care on PPD, and PPD died of an unknown cause on PPD (Day 265). An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Biliary cancer metastatic	PPD	PPD (57)		PPD (108)		52	4
2	NEOPL	Metastases to liver		PPD (57)		PPD (108)		52	4

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Unknown	2	36	Y
2	W	Y	Fatal (PPD)	NOT RELATED/OTHER: metastatic biliary cancer	2	36	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD , a 70-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22). The subject was diagnosed with metastatic biliary cancer with metastases to the liver on PPD , 35 days after receiving Dose 2, and died of the events on PPD , 86 days after receiving Dose 2. The subject experienced abdominal discomfort on PPD (4 days before receiving Dose 2), and magnetic resonance imaging done on an unspecified date showed gallstones and hepatic densities of an unknown cause. On PPD , an ultrasound-guided core biopsy and liver biopsy revealed a poorly differentiated carcinoma in the liver, which led to a diagnosis of biliary cancer with metastases to the liver on PPD (Day 57). On PPD , a positron emission tomography scan revealed no other organ involvement besides the liver. The subject had oncology consultations on PPD . The subject received a treatment of PPD (no further information reported). The subject had no reported predisposing factors and died on PPD (Day 108) because of the disease progression of biliary carcinoma metastatic to the liver. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the metastatic biliary cancer with metastases to the liver was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (24)	PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Acute left ventricular failure	PPD	PPD (50)		PPD (52)		3	3	TC
2	CARD	Cardiac failure congestive		PPD (92)		PPD (111)		20	4	TC/W
3	METAB	Hypokalaemia		PPD (50)		PPD (52)		3	3	TC

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (PPD)	NOT RELATED/OTHER: Not related to drug or non-drug treatments	2	27	N
2	Y	Fatal (PPD)	NOT RELATED/OTHER: Not related to drug or non-drug treatment	2	69	Y
3	N	Resolved (PPD)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	27	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , a 50-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 24).

Concomitant medications received within 2 weeks prior to the onset of the congestive cardiac failure included PPD

On PPD (Day 50), the subject presented to the emergency room (ER) with severe hypokalemia (potassium values not provided) and was diagnosed with acute left ventricular failure (New York Heart Association Class 4 acute on chronic systolic heart failure), resulting in hospitalization. Hypokalemia was considered likely to be secondary to the need for aggressive diuresis with PPD (unspecified start dates). The subject's magnesium and potassium levels were restored. On PPD (Day 52), the acute left ventricular failure and hypokalemia resolved, and the subject was discharged from the hospital.

The subject was diagnosed with congestive cardiac failure on PPD, 68 days after receiving Dose 2, and died of the event on PPD, 87 days after receiving Dose 2.

On PPD (Day 92), the subject's ongoing history of PPD worsened because of end-stage heart failure. The subject went to the ER and was diagnosed with congestive cardiac failure that resulted in hospitalization. A subsequent chest x-ray showed stable cardiac enlargement with a faint infiltrate and/or subsegmental atelectasis at the right lung base; however, there was no consolidation or edema observed. The venous/lower-extremity

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Doppler performed on PPD showed no evidence of acute deep vein thrombosis. A peripherally inserted central catheter line was placed for PPD Per the cardiologist, the subject was only minimally responsive to aggressive medical therapy, including PPD because of idiopathic cardiomyopathy and severe left ventricular systolic dysfunction coupled with acute on chronic combined systolic and diastolic heart failure. Per the discharge summary, the subject was not a candidate for any advanced cardiac therapies. On PPD, the automatic implantable cardioverter defibrillator was turned off. On PPD, influenza and SARS-CoV-2 test results were negative. On the same day, the subject was discharged to an inpatient hospice care facility. On PPD (Day 111), the subject died of congestive cardiac failure (stage IV) and disease progression. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the congestive cardiac failure was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Acute respiratory failure	PPD	PPD (124)		PPD (156)		33	4
2	INFEC	COVID-19		PPD (124)		PPD (156)		33	4

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Diagnosis of COVID-19	2	103	Y
2	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Viral Infection	2	103	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22). Concomitant medications received within 2 weeks prior to the onset of the acute respiratory failure and COVID-19 illness included PPD The subject was diagnosed with acute respiratory failure and COVID-19 illness on PPD, 102 days after receiving Dose 2, and died of the events on PPD, 134 days after receiving Dose 2. On PPD (Day 125), the subject completed a telehealth potential COVID-19 illness visit with a positive central laboratory COVID-19 test result, and tested positive for COVID-19 at an outside testing site on PPD (Day 126). The subject's family informed the site that on PPD (Day 130), the subject presented to the hospital via emergency medical services with shortness of breath, productive cough, headache, fever, myalgia, lack of taste, decreased appetite, and 2 syncopal episodes. According to the subject's medical records, upon hospital admission, the subject was afebrile with a respiratory rate of 22 breaths/min. The subject was noted to be hypoxic with blood saturation levels in the 80s (%), with improvement on supplemental oxygen; PPD oxygen saturation was 95% on 3 L of supplemental oxygen via nasal cannula. The subject was diagnosed with acute hypoxic respiratory failure due to COVID-19 with an onset date of PPD (Day 124). PPD was treated with PPD. The subject remained on oxygen therapy, and was additionally treated with PPD. On PPD, the laboratory test results showed hemoglobin of 10.2, potassium of 3.1, calcium of 8.1, C-reactive protein of 2.8, and fibrinogen of 530 (units and normal ranges [NRs] not available). A computed tomography angiogram of the chest with contrast revealed multifocal pneumonia, left upper lobe and right hilar/suprahilar postradiation changes, and emphysema with no evidence of large or central pulmonary artery embolus. On PPD, the laboratory test results showed leukocytes of 10.6 K/µL (NR: 4.0-10.5 K/µL) and neutrophils of 9.1 K/µL (NR: 1.7-7.7 K/µL). On PPD, the subject was moved to hospice care because of deterioration in PPD health from acute hypoxic respiratory failure caused by COVID-19. On PPD, the subject's family informed the site that the subject had died on PPD (Day 156) because of acute hypoxic respiratory failure caused by COVID-19. An autopsy was not performed. The subject had COVID-19 illness per study protocol criteria. In the opinion of the investigator, there was no reasonable possibility that the acute respiratory failure and COVID-19 were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (23)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (377)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Glioblastoma	PPD	PPD (512)	PPD	PPD (554)	PPD	43

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Brain Tumor	3	136	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD, Dose 2 on PPD (Day 23), and Dose 3 on PPD (Day 377). The subject was diagnosed with a right temporoparietal glioblastoma on PPD, 135 days after receiving Dose 3, and died of the event on PPD, 177 days after receiving Dose 3. The glioblastoma was diagnosed by a computed tomography scan on PPD (Day 512) and was confirmed by a stereotactic biopsy on PPD. Upon consultation with the physician, the subject opted to not start treatment, and PPD was transitioned to hospice care. PPD died of glioblastoma on PPD (Day 554). In the opinion of the investigator, there was no reasonable possibility that the glioblastoma was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD
VACCINATION 3	BNT162b2	PPD (153)	PPD
VACCINATION 4	BNT162b2	PPD (180)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (400)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Acute respiratory failure	PPD	PPD (546)		PPD (582)	PPD	37

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Death	5	147	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD a 60-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 20).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 153), PPD (Day 180), and PPD (Day 400), respectively.

The subject was diagnosed with acute respiratory failure on PPD, 146 days after receiving Dose 5 (third dose of BNT162b2), and died of the event on PPD, 182 days after receiving the third dose of BNT162b2.

The acute respiratory failure required an emergency room visit and subsequent hospitalization for 36 days. An autopsy was not performed.

In the opinion of the investigator, there was no reasonable possibility that the acute respiratory failure was related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (155)	PPD
VACCINATION 4	BNT162b2	PPD (176)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD	PPD	PPD (208)		PPD (208)		1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD.	4	33	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INJ&P	Injury	PPD	PPD (112)		PPD (112)		1	4	W
2	INJ&P	PPD		PPD (112)		PPD (112)		1	4	W

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	2	91	Y
2	Y	Fatal (PPD)	NOT RELATED/CONCOMITANT NON-DRUG TREATMENT	2	91	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 60-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 22). Concomitant medications received within 2 weeks prior to the onset of the traumatic injuries from PPD The subject sustained traumatic injuries and died in PPD on PPD , 90 days after receiving Dose 2. The subject was the PPD . The outcome of the events was fatal. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the traumatic injuries from the PPD were related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	VASC	Arteriosclerosis	PPD	PPD (90)		PPD (90)		1	4
2	CARD	Hypertensive heart disease		PPD (90)		PPD (90)		1	4
3	GENRL	Injection site pain		PPD (1)	PPD	PPD (3)	PPD	3	1
4	GENRL	Injection site pain		PPD (20)	PPD	PPD (22)		3	2

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
5	GENRL	Pyrexia	PPD	PPD (21)	PPD	PPD (21)	PPD	1	1
6	INJ&P	Contusion		PPD (1)	PPD	PPD (13)	PPD	13	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: cardiovascular disease	2	71	Y
2	W	Y	Fatal (PPD)	NOT RELATED/OTHER: cardiovascular disease	2	71	Y
3	N	N	Resolved (PPD)	Study Treatment	1	1	N
4	N	N	Resolved (PPD)	Study Treatment	2	1	N
5	TC	N	Resolved (PPD)	Study Treatment	2	2	N
6	N	N	Resolved (PPD)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, an 79-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 20). Concomitant medications received within 2 weeks prior to the onset of arteriosclerosis and hypertensive heart disease included PPD for hypertension. The subject experienced arteriosclerosis and hypertensive heart disease on PPD, 70 days after receiving Dose 2, and died on the same day. The subject, with a history of PPD, lost consciousness on PPD (Day 90). PPD family witnessed the event and attempted resuscitation, but it was unsuccessful. The subject was not taken to the emergency room or physician's office, and PPD died on the same day (Day 90). The subject had regular follow-ups with PPD primary care physician, and there were no new complications or events reported prior to the subject's death. The cause of death was disease progression (arteriosclerosis and hypertensive heart disease). An autopsy was not performed.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
In the opinion of the investigator, there was no reasonable possibility that the arteriosclerosis and hypertensive heart disease were related to the study intervention, concomitant medications, or clinical trial procedures, but rather they were related to cardiovascular disease. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (134)	PPD
VACCINATION 4	BNT162b2	PPD (155)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (435)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	CARD	Cardiac disorder	PPD	PPD (543)		ONGOING			4	W	Y
2	GENRL	PPD		PPD (543)		PPD (543)		1	4	W	Y
3	GENRL	Injection site pain		PPD (156)	PPD	PPD (156)	PPD	1	1	N	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Yes	NOT RELATED/OTHER: PPD	5	109	Y
2	Fatal (PPD)	NOT RELATED/OTHER: cardiac event	5	109	Y
3	Resolved (PPD)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 134), PPD (Day 155), and PPD (Day 435), respectively. Concomitant medications received within 2 weeks prior to the onset of the cardiac disorder and PPD included PPD. The subject experienced a cardiac disorder and was involved in an PPD resulting in death on PPD, 108 days after receiving Dose 5 (third dose of BNT162b2). On PPD (Day 543), the subject died because of an PPD that could have been caused by a cardiac disorder. No other information about the timing and sequence of events was available. It was unknown if a postmortem evaluation was done. The investigator suspected that the cardiac disorder was an acute cardiac ischemic event but did not have records or verbal reports to confirm. It was not reported if an autopsy was performed. All information on the subject's death was provided by the subject's PPD and the site did not have access to any further records. Therefore, the site could not confirm definitively that the cardiac event was a cause of death. In the opinion of the investigator, there was no reasonable possibility that the cardiac disorder and PPD were related to BNT162b2; the suspected risk factors for the cardiac disorder were the subject's medical history of PPD. Pfizer concurred with the investigator's causality assessment. Per the investigator, the PPD was related to the cardiac disorder.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	Not Reported	PPD	

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (127)	PPD
VACCINATION 4	BNT162b2	PPD (148)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Coronary artery disease	PPD	PPD (402)		PPD (406)		5	4
2	NERV	Headache		PPD (127)	PPD	PPD (128)	PPD	2	1
3	GENRL	Injection site pain		PPD (127)	PPD	PPD (128)	PPD	2	1
4	GENRL	Injection site pain		PPD (148)	PPD	PPD (150)		3	1

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	4	255	Y
2	TC	N	Resolved (PPD)	Study Treatment	3	1	N
3	TC	N	Resolved (PPD)	Study Treatment	3	1	N
4	N	N	Resolved (PPD)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD
		PPD

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD, a 60-year-old PPD (race not reported) with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 127) and PPD (Day 148), respectively.

Concomitant medications received within 2 weeks prior to the onset of the coronary artery disease (CAD) included PPD

The subject was diagnosed with CAD on PPD, 254 days after receiving Dose 4 (second dose of BNT162b2), and died of the event on PPD, 258 days after receiving the second dose of BNT162b2.

The subject reported to PPD primary care physician (PCP) exertional chest pain as well as dyspnea on exertion that started around PPD, and the subject was referred to a cardiologist. On PPD, the subject's cardiac pharmacologic stress test result was abnormal, and a myocardial perfusion scan

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Narrative Comment
showed a large-sized severe fixed defect in the mid to apical anterior, inferior, and septal wall with diffuse wall motion abnormalities. The subject received the nonstudy PPD on PPD for SARS-CoV-2 prophylaxis, but the site was not notified. The subject was evaluated at the physician's office for CAD. On PPD (Day 402), the subject visited the hospital and underwent cardiac catheterization, which showed total occlusion of the left anterior descending artery and confirmed the diagnosis of CAD. A cardiac stent was placed successfully on the same day (Day 402). Therapeutic measures were taken because of the CAD and the subject was discharged. The hospital stay was 1 day. It was reported that the plan was to follow-up with the subject's PCP in a month and to administer PPD The subject died on PPD (Day 406). The reported cause of death was disease progression and CAD. It was not reported if an autopsy was performed. The site was unable to reach the subject's family to follow up and get more details. In the opinion of the investigator, there was no reasonable possibility that the CAD was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per the investigator, the event was related to PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Breast cancer metastatic	PPD	PPD (79)		ONGOING		
2	GENRL	Death		PPD (291)		PPD (291)		1

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
3	GASTR	Mouth ulceration	PPD	PPD (27)		PPD (29)		3
4	GASTR	Stomatitis		PPD (27)		PPD (29)		3

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC/W	Y	Yes	NOT RELATED/OTHER: unknown	2	58	Y
2	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unk	2	270	Y
3	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: unk	2	6	N
4	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: unk	2	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , a 50-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22).

The subject was diagnosed with metastatic breast cancer on PPD, 57 days after receiving Dose 2.

The subject received PPD (3 unspecified treatments) from PPD to PPD for breast cancer.

The subject died of an unknown cause on PPD, 269 days after receiving Dose 2.

On receiving a compliance alert regarding the subject's e-diary, the clinical research coordinator googled the subject's name to find the alternate contact information and the search results yielded the subject's obituary details. It was unknown if an autopsy was performed. The subject was withdrawn from the study on PPD (Day 291) because of the death and metastatic breast cancer, which was ongoing at the time of the subject's death. No further details were available.

In the opinion of the investigator, there was no reasonable possibility that the metastatic breast cancer and death were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the metastatic breast cancer provided a most likely explanation for the subject's death.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD
VACCINATION 3	BNT162b2	PPD (162)	PPD
VACCINATION 4	BNT162b2	PPD (187)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (416)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Haemorrhage intracranial	PPD	PPD (737)		PPD (751)		15

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	5	322	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , a 70-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 20).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 162), PPD (Day 187), and PPD (Day 416), respectively.

Concomitant medications received within 2 weeks prior to the onset of the intracranial hemorrhage included PPD

The subject was diagnosed with an intracranial hemorrhage on PPD , 321 days after receiving Dose 5 (third dose of BNT162b2), and died of the event on PPD , 335 days after receiving the third dose of BNT162b2.

The subject's medical records stated that the subject called 911 on an unspecified date with a complaint of high blood pressure, which PPD could not lower. On PPD (Day 737), the subject was hospitalized with a diagnosis of intracranial hemorrhage. Surgery was discussed but the physicians decided not to perform the surgery. On PPD (Day 751), the subject died from the intracranial hemorrhage. An autopsy was not performed.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
In the opinion of the investigator, there was no reasonable possibility that the intracranial hemorrhage was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (21)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Acute myocardial infarction	PPD	PPD (231)		PPD (238)		8
2	RESP	Haemoptysis		PPD (231)		PPD (238)		8
3	GASTR	Melaena		PPD (231)		PPD (238)		8

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	211	Y
2	3	N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	211	N
3	3	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	211	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 21). Concomitant medications received within 2 weeks prior to the onset of the acute myocardial infarction included PPD

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Narrative Comment
The subject was diagnosed with an acute myocardial infarction on PPD, 210 days after receiving Dose 2, and died of the event on PPD, 217 days after receiving Dose 2. On PPD, the subject underwent laboratory tests and procedures, which included blood cultures with no growth at 5 days; negative *Mycoplasma pneumoniae* antibodies; and a single view chest x-ray showing bilateral patchy airspace opacity consistent with multifocal pneumonia and small bilateral pleural effusions. On PPD (Day 231), the subject presented to the emergency room with complaints of worsening dyspnea over the past 3-4 weeks. PPD had no nausea, vomiting, or chest pains, but PPD had hemoptysis, melena, and worsening lower extremity edema. PPD was treated with PPD and was transferred to another hospital for further evaluation. A chest computed tomography (CT) angiogram scan showed multifocal pneumonia with large bilateral pleural effusions. An echocardiogram showed an ejection fraction (EF) of 20–25% with severe global hypokinesis, mild mitral annular calcification, moderate mitral valve regurgitation, moderately calcified aortic cusps, and mild aortic valve insufficiency. Laboratory examinations showed a negative SARS-CoV-2 virus test, negative urine analysis, stool positive for occult blood, and fifth generation troponin T level of 688 ng/L (normal range [NR]: <20 ng/L). On PPD, a cardiac catheterization showed 95% proximal anterior descending coronary artery, circumflex proximal subtotal occlusion, right coronary artery 100%, EF of 20–30% with severe global hypokinesis, ischemic cardiomyopathy, elevated filling pressures, and severe pulmonary hypertension. The subject was found to have congestive heart failure, and PPD was diagnosed with acute myocardial infarction (non-ST elevation) with severe triple-vessel coronary artery disease. On PPD, a posteroanterior and lateral chest x-ray revealed interval resolution of underlying central vascular congestion, multifocal infiltrates, and small bilateral effusions. On PPD, the subject experienced an episode of hemoptysis with melena, marked by an acute drop in hemoglobin. A CT angiogram of the chest and abdomen showed focal consolidation without active bleeding. PPD hemoglobin continued to drop, reaching 7.1 g/dL (NR: 14.0-18.0 g/dL) despite receiving 1 unit of blood. Other laboratory tests included point of care testing with pH of 7.366 (NR: 7.35-7.45), partial pressure of carbon dioxide of 28.2 mmHg (NR: 35-45 mmHg), partial pressure of oxygen of 114 mmHg (NR: 70-90 mmHg), bicarbonate of 16.2 mmol/L (NR: 22-26 mmol/L), total carbon dioxide of 17 mmol/L (NR: 22-29 mmol/L), potassium of 6.2 mEq/L (NR: 3.5-5.0 mEq/L), chloride of 92 mmol/L (NR: 96-108 mmol/L), sodium of 129 mEq/L (NR: 133-145 mEq/L), creatinine of 2.4 mg/dL (NR: 0.5-1.2 mg/dL), hematocrit of 21% (NR: 42-52%), ionized calcium of 0.99 mmol/L (NR: 1.10-1.35 mmol/L), glucose of 126 mg/dL (NR: 70-100 mg/dL), lactate of 15.49 mmol/L (NR: 0.5-2.2 mmol/L), white blood cell count of $14.72\times10^3/\mu L$ (NR: 4.10-12.20$\times10^3/\mu L$), red blood cells of $2.42\times10^6/\mu L$ (NR: 4.40-5.50$\times10^6/\mu L$), mean cell volume of 107.9 fL (NR: 77.6-97.4 fL), mean corpuscular hemoglobin of 32.6 pg (NR: 25.9-32.7 pg), mean corpuscular hemoglobin concentration of 30.3 g/dL (NR: 31.5-35.4 g/dL), red cell distribution width of 15.7% (NR: 12.3-15.9%), platelet count of $120\times10^3/\mu L$ (NR: 137-352$\times10^3/\mu L$), mean platelet volume of 12.1 fL (NR: 9.6-13.3 fL), absolute neutrophils of $14.20\times10^3/\mu L$ (NR: 1.50-7.90$\times10^3/\mu L$), absolute lymphocytes of $0.13\times10^3/\mu L$ (NR: 1.10-3.40$\times10^3/\mu L$), absolute monocytes of $0.25\times10^3/\mu L$ (NR:

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Narrative Comment
0.30-1.10 ×10^3/µL), absolute eosinophils of 0.00×10^3/µL (NR: 0.00-0.50×10^3/µL), absolute basophils of 0.13×10^3/µL (NR: 0.00-0.30×10^3/µL), prothrombin time of 23.4 seconds (NR: 12.5-15.5 seconds), international normalized ratio of 2.0 (NR: 0.9-1.2), activated partial thromboplastin time of 32.5 seconds (NR: 27-39 seconds), plasma lactic acid of 23.2 mmol/L (NR: 0.5-2.2 mmol/L), total bilirubin of 1.6 mg/dL (NR: <1.0 mg/dL), total protein of 5.1 g/dL (NR: 6.4-8.3 g/dL), and aspartate aminotransferase of 278 enzyme (Enz) U/L (NR: <39 EnzU/L). A CT angiogram of the chest showed a mildly prominent thoracic aorta at 4.1 cm without significant abnormalities in the pericardium and heart. There was no large central embolus in pulmonary arteries and no pneumothorax; moderate to large bilateral pleural effusions and patchy consolidation in both lungs were noted. A CT angiogram of the abdomen showed high grade stenosis and diffuse patchy, soft, calcified plaque throughout the arterial system, resulting in luminal narrowing with calcification of left and right renal arteries, and a significant narrowing of bilateral renal arteries. The liver appeared shrunken and cirrhotic with biliary cholelithiasis and moderate ascites in bowel and peritoneum, without hemorrhage. A CT angiogram of the pelvis revealed severe, chronic multilevel compression deformities in the lumbar spine with 80-90% loss of height of L2 and L5. On PPD (Day 238), the subject developed hypotension. PPD subsequently developed multiple organ failure secondary to hypovolemic and cardiogenic shock. The subject was intubated and started on treatment with an unspecified PPD A portable x-ray after intubation showed a mild increase in bilateral interstitial and alveolar prominence, progressive consolidation in lungs (right upper lobe), and increasing prominent pulmonary vascularity. Subsequently, the subject became unresponsive, PPD potassium levels were significantly elevated. PPD was treated with PPD No marked interval change was noted on an anteroposterior chest x-ray (supine). On Day 238, the laboratory analysis revealed the following results: blood magnesium of 2.4 mg/dL (NR: 1.6-2.5 mg/dL), blood sodium of 137 mmol/L (NR: 133-145 mmol/L), potassium of 5.8 mmol/L (NR: 3.5-5.0 mmol/L), chloride of 92 mmol/L (NR: 96-108 mmol/L), carbon dioxide of 7 mmol/L (NR: 22-29 mmol/L), blood urea nitrogen (BUN) of 65 mg/dL (NR: 8-23 mg/dL), creatinine of 2.4 mg/dL (NR: 0.7-1.2 mg/dL), glucose of 91 mg/dL (NR: 70-100 mg/dL), calcium of 8.8 mg/dL (NR: 8.8-10.2 mg/dL), anion gap of 38 (NR: 7-17), calculated osmolality of 292 mOsm/kg, BUN/creatinine ratio of 27 (NR: 5-28), glomerular filtration rate of 27 mL/min/1.73 m^2 (NR: >60 mL/min/1.73 m^2), albumin of 2.3 g/dL (NR: 3.5-5.2 g/dL), alkaline phosphatase of 90 EnzU/L (NR: 39-117 EnzU/L), and alanine aminotransferase of 170 EnzU/L (NR: <42 EnzU/L). The subject had a PPD order and PPD died of an acute myocardial infarction (disease progression) on the same day (Day 238) at PPD. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the acute myocardial infraction was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Chronic obstructive pulmonary disease	PPD	PPD (283)	PPD	PPD (283)	PPD	1

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	262	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22). Concomitant medications received within 2 weeks prior to the onset of the chronic obstructive pulmonary disease (COPD) included PPD The subject was diagnosed with COPD on PPD, 261 days after receiving Dose 2, and died on the same day. The cause of death was COPD. Per the study site, the subject did not have a previous diagnosis of COPD and there were no relevant tests performed or medications given. An autopsy was not performed. No further information was available. In the opinion of the investigator, there was no reasonable possibility that the COPD was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	NERV	Basal ganglia haemorrhage	PPD	PPD (210)		PPD (225)		16	4	TC/TCN/W
2	PSYCH	PPD		PPD (210)		PPD (225)		16	3	N
3	VASC	Hypertensive urgency		PPD (210)		ONGOING			3	TC
4	NERV	Seizure		PPD (210)		PPD (210)		1	3	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Fatal (PPD)	NOT RELATED/OTHER: hypertensive crisis	2	190	
2	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	190	N
3	N	Yes	NOT RELATED/OTHER: possible exacerbation by PPD	2	190	N
4	N	Resolved (PPD)	NOT RELATED/OTHER: cerebral hemorrhage	2	190	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a 50-year-old PPD with a pertinent medical history of PPD (since an unknown date), received Dose 1 on PPD and Dose 2 on PPD (Day 21). Concomitant medications received within 2 weeks prior to the onset of the basal ganglia hemorrhage included PPD (since an unknown date) PPD. The subject was diagnosed with right basal ganglia hemorrhage with intraventricular extension on PPD, 189 days after receiving Dose 2, and died of the event on PPD, 204 days after receiving Dose 2. On PPD (Day 210), the subject experienced a seizure and collapsed in front of PPD. When PPD arrived at the emergency room, PPD blood pressure was 223/115 (units not reported). PPD was diagnosed with hypertensive urgency and treated with a PPD. The PPD upon admission was positive for PPD A computed tomography (CT) scan showed a 3.6 cm right basal ganglia hemorrhage with a 6 mm right to left midline shift, possibly due to the uncontrolled PPD. PPD did not show signs of trauma. A COVID-19 test was negative. Another CT scan on the same day was significant for right basal ganglia hemorrhage with intraventricular extension. Subsequently, PPD showed nonreactive and asymmetric pupils. PPD was unable to track with PPD eyes or follow commands. PPD showed response to pain, but it was intermittent posturing. A ventricular drain was inserted, and the seizure was considered resolved on the same day (Day 210). PPD developed concurrent aspiration pneumonia and received unspecified treatment for the event. On PPD, the subject, who had been intubated, had a PPD order. On PPD, the subject was compassionately extubated, and on PPD, PPD was transferred to hospice care.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
On PPD (Day 225), the subject died of non-traumatic intracerebral hemorrhage in the subcortical hemisphere (basal ganglia hemorrhage). An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the basal ganglia hemorrhage was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a hypertensive crisis. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (-1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (144)	PPD
VACCINATION 4	BNT162b2	PPD (164)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (437)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD		PPD (582)	PPD	PPD (582)	PPD	1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	5	146	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (161)	PPD
VACCINATION 4	BNT162b2	PPD (180)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (414)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Chills	PPD	PPD (181)	PPD	PPD (182)	PPD	2	1
2	GENRL	Fatigue		PPD (181)	PPD	PPD (183)		3	1
3	INFEC	Fungal skin infection		PPD (15)		PPD (76)		62	1
4	GENRL	Injection site pain		PPD (180)	PPD	PPD (182)		3	1

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
5	GENRL	Injection site pain	PPD	PPD (161)	PPD	PPD (164)	PPD	4	1
6	GENRL	Pyrexia		PPD (181)	PPD	PPD (182)	PPD	2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	Study Treatment	4	2	N
2	N	N	Resolved (PPD)	Study Treatment	4	2	N
3	TC	N	Resolved (PPD)	NOT RELATED/OTHER: fungal skin infection	1	15	N
4	N	N	Resolved (PPD)	Study Treatment	4	1	N
5	TC	N	Resolved (PPD)	Study Treatment	3	1	N
6	TC	N	Resolved (PPD)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD , a 30-year-old PPD with a reported medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 161), PPD (Day 180), and PPD (Day 414), respectively. The subject died on an unspecified date. On PPD, the site updated the subject's disposition status for the study follow-up phase as withdrawn because of death. This death event occurred outside the protocol-defined post-vaccination safety reporting period, and as such was reported only as an update to the subject's disposition status but not reported as an adverse event. No additional details will be provided for this event.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (19)	PPD
VACCINATION 3	BNT162b2	PPD (151)	PPD
VACCINATION 4	BNT162b2	PPD (172)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Coronary artery disease	PPD	PPD (368)		PPD ()		
2	INFEC	Postoperative wound infection		PPD (411)		PPD (435)		25

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Resolved (PPD)	NOT RELATED/OTHER: UNK	4	197	N
2	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: UNK	4	240	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 19). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 151) and PPD (Day 172), respectively. Concomitant medications received within 2 weeks prior to the onset of the postoperative wound infection included PPD The subject experienced a postoperative wound infection on PPD, 239 days after receiving Dose 4 (second dose of BNT162b2), and died of the event on PPD, 263 days after receiving the second dose of BNT162b2. On PPD (Day 368), the subject was diagnosed with coronary artery disease and underwent coronary artery bypass graft surgery on the same day. Almost a month after the surgery, PPD was hospitalized for a postoperative wound infection. During this hospitalization, PPD developed unspecified complications of the postoperative wound infection and died of the event on PPD (Day 435). It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the postoperative wound infection was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (21)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Pneumonia aspiration	PPD	PPD (121)		PPD (131)		11	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: VOMIT ASPIRATION	2	101	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD , a 70-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 21). Concomitant medications received within 2 weeks prior to the onset of the aspiration pneumonia included PPD The subject was diagnosed with aspiration pneumonia on PPD, 100 days after receiving Dose 2, and died of the event on PPD, 110 days after receiving Dose 2. On PPD (Day 121), the subject was hospitalized after PPD aspirated PPD own vomit. PPD remained hospitalized until PPD death, on PPD (Day 131). It was unknown if a COVID-19 test was performed during the hospitalization. Treatment given during the hospital stay was unknown. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the aspiration pneumonia was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to the aspiration of vomit. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Peritonitis	PPD	PPD (461)		PPD (461)		1

Adverse Events							
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: UNK	2	442	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 70-year-old PPD with a reported medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 20). The subject received a nonstudy vaccine PPD on PPD . The subject developed acute peritonitis on PPD , 441 days after receiving Dose 2, and died on the same day. The subject's PPD and PPD attempted to reach PPD unsuccessfully for 24 hours, and PPD was later found dead at home by PPD . Per the death certificate, the subject died of acute peritonitis on PPD (Day 461). An autopsy was performed, but the results were not provided. In the opinion of the investigator, there was no reasonable possibility that the acute peritonitis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (399)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	INV	Blood lactic acid increased	PPD	PPD (310)		PPD (523)		214	2	N
2	INV	Fibrin D dimer increased		PPD (309)		PPD (523)		215	2	N
3	NEOPL	Triple negative breast cancer		PPD (316)		PPD (523)		208	4	TC/W

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Resolved (PPD)	NOT RELATED/OTHER: metastatic triple negative breast cancer	2	289	N
2	N	Resolved (PPD)	NOT RELATED/OTHER: metastatic triple negative breast cancer	2	288	N
3	Y	Fatal (PPD)	NOT RELATED/OTHER: previous history of PPD	2	295	Y

Prohibited Concomitant Medications				
Investigator Text	WHO Drug Preferred Term	Start Date	End Date	Route
PPD			ONGOING	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD , an ≥75-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22). Concomitant medications received within 2 weeks prior to the onset of metastatic triple negative breast cancer included PPD The subject was diagnosed with metastatic triple negative breast cancer on PPD , 294 days after receiving Dose 2. The subject with an ongoing history of PPD presented to the emergency department on PPD (Day 309) with complaints of shortness of breath. Laboratory tests showed D-dimer of 1830 ng/mL (NR: ≤500 ng/mL) and lactic acid of 3.2 and 2.0 mmol/L (NR: 0.7-2.1 mmol/L). A computed tomography (CT) pulmonary angiogram scan did not show pulmonary embolism but revealed multiple hepatic masses, and metastatic disease was suspected. Per the investigator, the increased blood lactic acid and fibrin D-dimer were related to the metastatic triple negative breast cancer. On PPD (Day 310), blood lactic acid had decreased to 1.3 mmol/L; on the same day, additional blood lactic acid values were reported to be 1.7 mmol/L and 2.6 mmol/L. On PPD (Day 316), the subject underwent a CT needle biopsy of the liver, which was positive for carcinoma. The diagnosis was consistent with metastatic triple negative breast cancer. PPD started treatment with PPD ; prohibited medication) on PPD . On PPD (Day 399), the subject received Dose 3 of BNT162b2. Subsequently, the site reached out to the subject due to noncompliance with the e-diary but received no response. The subject's family member notified the site about the subject's death. It was reported that the subject died of metastatic triple negative breast cancer on PPD , 124 days after receiving Dose 3. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the metastatic triple negative breast cancer was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to PPD history of PPD Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Myocardial infarction	PPD	PPD (16)		PPD (16)		1

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	P/W	Y	Fatal (PPD)	NOT RELATED/OTHER: disease progression	1	16	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	DEATH
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD , a 60-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD .
Concomitant medications received within 2 weeks prior to the onset of the myocardial infarction included PPD
The subject experienced a myocardial infarction in PPD sleep on PPD , 15 days after receiving Dose 1, and died on the same day.
The cause of death was myocardial infarction. An autopsy was not performed.
In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to disease progression. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was most likely coincidental and associated with underlying conditions of PPD from PPD .

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (21)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (371)		PPD (371)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Fatal PPD	2	351	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 70-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 21).
The subject was involved in PPD on PPD, 350 days after receiving Dose 2, and died on the same day.
The cause of death was PPD. An autopsy was not performed.
In the opinion of the investigator, there was no reasonable possibility that the PPD was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)

Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Duodenal perforation	PPD	PPD (271)		PPD (293)		23	4
2	METAB	Hyperlipidaemia		PPD (185)		ONGOING			1
3	VASC	Hypertension		PPD (183)		ONGOING			1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: INCIDENTAL FINDING	2	250	Y
2	TC	N	Yes	NOT RELATED/OTHER: NEW MEDICAL CONDITION	2	164	N
3	TC	N	Yes	NOT RELATED/OTHER: PROGRESSION OF DISEASE	2	162	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 70-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 22). Concomitant medications received within 2 weeks prior to the onset of the duodenal perforation included PPD for hypertension, PPD for hyperlipidemia. The subject was diagnosed with a duodenal perforation on PPD, 249 days after receiving Dose 2, and died of the event on PPD, 271 days after receiving Dose 2. On PPD, the subject underwent a robotic assisted laparoscopic radical prostatectomy and was discharged home the next day. However, on PPD (Day 271), the subject presented to the emergency department with severe abdominal pain with distension and was hospitalized. A computed tomography (CT) scan of the abdomen and pelvis revealed intra-abdominal free air and mild ascites. PPD C-reactive protein level was 45.4 mg/dL (normal range [NR] high: 0.9 mg/dL). A SARS-CoV-2 test was negative. PPD was diagnosed with a duodenal perforation. On PPD, the subject was admitted to the surgical service. PPD underwent an exploratory laparotomy, that was converted to an open laparotomy with findings of severe duodenal ulcer with spillage into the peritoneum. PPD remained admitted for severe perforated duodenal ulcer, peritonitis, and resultant sepsis, and PPD had recurrent intra-abdominal hemorrhage after the Billroth II procedure. On the same day, PPD underwent a repeat surgery for stump leakage and closure of the stump, kocherization of the duodenum and retrograde duodenoduodenostomy tube placement, and nasogastric (NG) tube placement. An abdominal x-ray confirmed the placement of NG tube tip in the stomach. On PPD, the subject underwent placement of a peripherally inserted central catheter for intravenous therapy. On PPD, an angiogram showed no evidence of central pulmonary embolism (evaluation limited due to motion artifact and contrast mixing), moderate left pleural effusion, and adjacent compressive atelectasis (increased from the previous examination). Tests revealed elevated troponin I of 0.57 ng/mL (NR: <0.04 ng/mL) and hemoglobin of 10 (unit not reported). Owing to the increased troponin levels, cardiology was consulted, and it was suspected that the elevation was likely secondary to severe illness: peritonitis/sepsis, severe anemia, hypotension. PPD received transfusions to maintain the hemoglobin at 10. On PPD, examinations showed an interval increase in density and volume of a moderate amount of hemoperitoneum, mainly along the perihepatic region, right paracolic gutter, and peri-gastric region. A CT angiogram showed no signs of active contrast extravasation. On PPD, the subject underwent another exploratory laparotomy; PPD abdomen was left open following the procedure. Abdominal fluid cultures were obtained, which were positive for carbapenem-resistant *Enterobacter cloacae* and vancomycin-resistant *Enterococcus faecium*. The subject was started on treatment with PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
On PPD, urology findings indicated acute kidney injury with a glomerular filtration rate that dropped from an initial >60 mL to 49 mL/min/1.73 m^2 (NR: >60 mL/min/1.73 m^2).
On PPD, the abdomen was closed from the exploratory laparotomy procedure.
On PPD, the subject was hemorrhaging after a spike in blood pressure with sanguineous output from all the abdominal drains. PPD received 2 units of packed red blood cells.
On PPD (Day 293), the subject experienced respiratory failure. PPD troponin-I was elevated to 4.54 ng/mL. PPD died of duodenal perforation on the same day (Day 293). It was unknown if an autopsy was performed.
In the opinion of the investigator, there was no reasonable possibility that the duodenal perforation was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (155)	PPD
VACCINATION 4	BNT162b2	PPD (176)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (425)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	Arthropod bite	PPD	PPD (325)		PPD (362)		38	2	TC	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
2	INJ&P	Arthropod bite	PPD	PPD (372)		PPD (380)		9	2	TC	N
3	CARD	Cardiac failure congestive		PPD (0)		PPD (777)			4	W	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	150	N
2	Resolved (PPD)	NOT RELATED/OTHER: Insects	4	197	N
3	Fatal (PPD)	NOT RELATED/OTHER: New diagnosis of Congestive heart Failure	5	288	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 23). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 155), PPD (Day 176), and PPD (Day 425), respectively. Concomitant medications received within 2 weeks prior to the onset of the congestive cardiac failure included PPD The subject was diagnosed with congestive cardiac failure on an unspecified date in PPD, approximately 287 days after receiving Dose 5 (third dose of BNT162b2), and died from the event on PPD, 352 days after receiving the third dose of BNT162b2. The subject visited the emergency room and received treatment with unspecified medications for congestive cardiac failure. On PPD (Day 777), the subject died of congestive cardiac failure, myocardial infarction, and liver failure. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the congestive cardiac failure was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was a coincidental medical condition associated with the subject's age and medical history.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (24)	PPD
VACCINATION 3	BNT162b2	PPD (173)	PPD
VACCINATION 4	BNT162b2	PPD (193)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	Toxicity to various agents	PPD	PPD (297)		PPD (300)	PPD	4	4

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	4	105	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Myocardial infarction	PPD	PPD (56)		PPD (56)		1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	2	37	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 50-year-old PPD with a reported medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 20). Concomitant medications within 2 weeks prior to the onset of the myocardial infarction included PPD

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Narrative Comment
The subject experienced a myocardial infarction on PPD, 36 days after receiving Dose 2, and died on the same day. The subject was scheduled for a visit on PPD but did not show up for PPD appointment. The family was contacted, and they reported that the subject was found deceased in PPD home on PPD (Day 56) and had likely died 3 days prior on PPD. A family member had spoken with the subject on PPD and the subject told PPD family member that PPD had just gotten out of the shower and was going to lie down because PPD had "stomach pains." This was the final conversation with the subject before PPD died. An autopsy was not performed. The death certificate and toxicology report were received on PPD and the date of death was PPD (Day 56) per state regulations; the cause of death was reported as myocardial infarction due to PPD and disease progression. It was reported that the toxicology report was negative. In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to PPD. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (164)	PPD
VACCINATION 4	BNT162b2	PPD (186)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (418)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	IMMUN	Haemophagocytic lymphohistiocytosis	PPD	PPD (692)		ONGOING			4
2	MUSC	Musculoskeletal chest pain		PPD (419)		PPD (430)		12	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal ()	NOT RELATED/OTHER: concomitant disease	5	275	Y
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: muscle pain due to working out	5	2	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 50-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 164), PPD (Day 186), and PPD (Day 418), respectively. Concomitant medication received within 2 weeks prior to the onset of the hemophagocytic lymphohistiocytosis included PPD The subject was diagnosed with hemophagocytic lymphohistiocytosis on PPD, 274 days after receiving Dose 5 (third dose of BNT162b2), and died of the event on PPD. The subject was feeling poorly with presence of nausea and vomiting upon consuming solids or liquids. PPD also had a poor oral intake. PPD did not report hematemesis or abdominal pain. PPD symptoms worsened and PPD experienced alternating sweating and chills, along with generalized malaise and myalgias. PPD became progressively weaker. PPD also showed intermittent headaches without photophobia, neck pain, or stiffness. Over the weekend, PPD symptoms became severe, and PPD presented to an urgent care clinic with suspected dehydration on PPD (Day 692) and was admitted on the same day. PPD laboratory examinations upon presentation showed: white blood cell count of $0.6\times10^3/\mu L$, absolute neutrophil count of $0.1\times10^3/\mu L$, and fever of 39.4°C. PPD was sent to the emergency room. PPD reported one episode of diarrhea on Day 692. PPD did not report ear or sinus pain, sore throat, or cough. PPD had recently (on PPD) undergone nerve decompression surgery of the right ulnar nerve; however, PPD did not experience pain, erythema, swelling, or edema at the surgical site, nor did PPD report melena, dysuria, hemoptysis, or hematuria. PPD had no pain in the chest, abdomen, or pleuritic region. Examination showed blood pressure of 138/80, SpO2 of 98%, heart rate of 102, and respiration rate of 18 (normal ranges [NR] and units not reported). PPD physical examination was unremarkable. PPD chest x-ray was clear, and PPD tested negative for flu and COVID-19; the urinalysis was negative. Owing to PPD dehydration and volume depletion, PPD received PPD. PPD also received PPD Laboratory examinations showed increased international normalized ratio level, glucose, blood urea nitrogen, creatinine, total bilirubin, aspartate aminotransferase (AST), and alanine aminotransferase (ALT), along with low levels of absolute lymphocytes, sodium, chloride, platelets, and a low hematocrit. PPD urine was dark yellow in color with an elevated specific gravity. An initial diagnosis of neutropenic fever was made. PPD laboratory tests included: ALT of 212 IU/L, AST of 256 IU/L, blood bilirubin of 1.4 mg/dL, blood chloride of 90 mmol/L, blood creatinine of 24 mg/dL, blood sodium of 127 mmol/L, and lymphocyte count of $0.5\times10^3/mm^3$ (NR not reported). PPD was diagnosed with hemophagocytic lymphohistiocytosis. On PPD, the subject was intubated and required placement of a central venous line.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
On PPD, the subject died in the hospital. The reported cause of death was hemophagocytic lymphohistiocytosis. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the hemophagocytic lymphohistiocytosis was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (30)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INFEC	Abdominal abscess	PPD	PPD (212)	PPD	ONGOING			3	TCN
2	GASTR	Acute abdomen		PPD (212)	PPD	ONGOING			4	TC/TCN/W
3	CARD	Acute myocardial infarction		PPD (217)	PPD	ONGOING			3	TC
4	CARD	Cardiac arrest		PPD (225)	PPD	PPD (225)	PPD	1	4	TC/TCN
5	GENRL	Complication associated with device		PPD (213)	PPD	PPD (213)	PPD	1	3	TCN
6	INJ&P	Contusion		PPD (57)	PPD	ONGOING			1	N
7	INJ&P	Fall		PPD (28)	PPD	PPD (28)	PPD	1	2	N
8	INJ&P	Fall		PPD (57)	PPD	PPD (57)	PPD	1	1	N
9	GENRL	Multiple organ dysfunction syndrome		PPD (225)	PPD	ONGOING			4	TC/TCN
10	MUSC	Musculoskeletal stiffness		PPD (25)	PPD	PPD (28)	PPD	4	1	N
11	MUSC	Rotator cuff syndrome		PPD (28)	PPD	ONGOING			2	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
12	INFEC	Sepsis	PPD	PPD (225)	PPD	ONGOING			3	TC/TCN
13	INJ&P	Skin abrasion		PPD (57)	PPD	ONGOING			1	N

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Yes	NOT RELATED/OTHER: Acute Abdomen	2	183	N
2	Y	Fatal ()	NOT RELATED/OTHER: Procedural Complication-erosion of the adjustable gastric band	2	183	Y
3	N	Yes	NOT RELATED/OTHER: Multisystem failure and Cardiovascular Disease	2	188	N
4	Y	Resolved (PPD)	NOT RELATED/OTHER: Multiple system failure	2	196	N
5	N	Resolved (PPD)	NOT RELATED/OTHER: Misadventure	2	184	N
6	N	Yes	NOT RELATED/OTHER: Fall	2	28	N
7	N	Resolved (PPD)	NOT RELATED/OTHER: Injury	1	28	N
8	N	Resolved (PPD)	NOT RELATED/OTHER: Injury	2	28	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
9	Y	Yes	NOT RELATED/OTHER: Sepsis	2	196	N
10	N	Resolved (PPD)	NOT RELATED/OTHER: ergonomic injury from sleeping wrong	1	25	N
11	N	Yes	NOT RELATED/OTHER: Orthopedic	1	28	N
12	N	Yes	NOT RELATED/OTHER: Abdominal Abcess	2	196	N
13	N	Yes	NOT RELATED/OTHER: Injury	2	28	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a ≥75-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 30). Concomitant medications received within 2 weeks prior to the onset of an acute abdomen included PPD The subject was diagnosed with an acute abdomen on PPD, 182 days after receiving Dose 2 and died of the event on PPD. On PPD (Day 212), the subject presented to the emergency room with abdominal bloating, pain, and nausea. The subject was tachycardic and became hypoxic at 88%. An evaluation showed tenderness with distention and guarding in the abdomen. The subject was treated with PPD since Day 212) along with other unspecified PPD. On the same day (Day 212), laboratory data included: differential complete blood count, which showed giant platelets and platelet clumps; glucose of 168, sodium of 32, chloride of 93, calcium of 8.5, and albumin of 2.8 (units and normal ranges not provided). The subject also underwent an ultrasound with unknown results. The primary infection site was intraabdominal. A culture was obtained with unknown results and a COVID-19 test was negative. On the same day (Day 212), the subject was hospitalized for intragastric erosion of LAGB and intraabdominal abscesses (open drain). The intragastric erosion of gastric band occurred on PPD (Day 213) and the subject underwent a diagnostic laparoscopy with open drainage of multiple drain intraabdominal abscesses, removal of LAGB and port, gastrorrhaphy, and appendectomy. On PPD (Day 217), PPD experienced a non-ST segment elevation myocardial infarction and was started on PPD (since Day 212), along with PPD. On PPD, PPD underwent an interventional radiologist guided nasogastric tube placement with an episode of bilious emesis. On PPD (Day 225), COVID-19 testing remained negative. On the same day (Day 225), PPD suffered cardiac arrest with return of spontaneous circulation (ROSC) after one cycle of compressions and PPD. ROSC was achieved with compressions. PPD was given for adrenergic effect (since Day 225). The subject was intubated and returned to the surgical intensive care unit for further care. On Day 225, the subject developed acute respiratory distress syndrome and was started on PPD (since Day 225) as muscle relaxer with prone position, but PPD progressed to multiorgan failure. On PPD, COVID-19 testing was negative. On PPD, the subject's condition continued to worsen, and the subject was transitioned to comfort care. The subject died in the hospital on the same day at PPD PM, and the causes of death were acute abdomen (primary) and multiorgan failure (secondary). An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the acute abdomen was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was considered related to the procedural complication - erosion of the adjustable gastric band. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Death	PPD	PPD (702)		PPD (702)		1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Sudden Death No IP Received	2	681	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a 40-year-old PPD with a reported medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22). The subject died of an unknown cause on PPD, 680 days after receiving Dose 2. It was reported that the site had been trying to get in touch with the subject regarding e-diary compliance. Site was able to get in contact with the subject's PPD, who informed the site that the subject passed away in PPD sleep on PPD (Day 702) and the cause of death was unknown. Per alternate contact, an autopsy was performed but was in the 90-day waiting period for toxicology and autopsy report. It was reported that the subject declined placebo crossover and never received any BNT162b2 in the study. In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (153)	PPD
VACCINATION 4	BNT162b2	PPD (176)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Adenocarcinoma	PPD	PPD ()		PPD (461)			2
2	CARD	Cardiac failure congestive		PPD (214)		PPD (220)		7	3
3	INFEC	Cellulitis		PPD (198)		PPD (461)		264	1
4	RESP	Chronic obstructive pulmonary disease		PPD (141)		PPD (461)		321	1
5	INFEC	Urinary tract infection		PPD (139)		PPD (153)		15	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Cancer	4	81	Y
2	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: Congestive Heart failure	4	39	N
3	TC	N	Resolved (PPD)	NOT RELATED/OTHER: PPD scratch	4	23	N
4	TC	N	Resolved (PPD)	NOT RELATED/OTHER: COPD	2	120	N
5	TC	N	Resolved (PPD)	NOT RELATED/OTHER: UTI	2	118	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	REPEAT SCREENING 3	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a ≥75-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the received the first and second doses of BNT162b2 on PPD (Day 153) and PPD (Day 176), respectively. Concomitant medications received within 2 weeks prior to the onset of adenocarcinoma included PPD The subject was diagnosed with adenocarcinoma with high grade dysplasia on an unspecified date in PPD, approximately 80 days after receiving Dose 4 (second dose of BNT162b2), and died of the event on PPD, 285 days after receiving the second dose of BNT162b2. The subject reported weight loss, nausea, and intermittent vomiting since PPD. On PPD, PPD went to see PPD doctor, who ordered a biopsy on PPD duodenum to rule out intestinal conditions; the subject underwent a tissue biopsy on the same day, and the results showed cancerous cells. PPD was scheduled for further follow-up with a gastroenterologist. On PPD (Day 461), the subject passed away after progression of metastatic duodenal cancer. Medical records noted the diagnosis as adenocarcinoma with high grade dysplasia. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the adenocarcinoma was related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the adenocarcinoma was not related to concomitant medications.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (24)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	RENAL	Acute kidney injury	PPD	PPD (74)		ONGOING			2	TCN
2	CARD	Atrial fibrillation		PPD (74)		ONGOING			2	TC
3	INFEC	Emphysematous cholecystitis		PPD (74)		PPD (144)		71	4	TC/TCN/W
4	MUSC	Muscular weakness		PPD (68)		ONGOING			2	N
5	MUSC	Rhabdomyolysis		PPD (73)		PPD (84)		12	2	TCN
6	INFEC	Sepsis		PPD (74)		PPD (144)		71	4	TC/TCN/W

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Yes	NOT RELATED/OTHER: Dehydration	2	51	N
2	N	Yes	NOT RELATED/OTHER: CAD	2	51	N
3	Y	Fatal (PPD)	NOT RELATED/OTHER: bacteria	2	51	Y
4	N	Yes	NOT RELATED/OTHER: sepsis	2	45	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	N	Resolved (PPD)	NOT RELATED/OTHER: dehydration	2	50	N
6	Y	Fatal (PPD)	NOT RELATED/OTHER: Klebsiella Oxytoca, Escherichia coli, Klebsiella pneumonia	2	51	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD
		PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , a ≥75-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 24).

Concomitant medications received within 2 weeks prior to the onset of the emphysematous cholecystitis and sepsis included PPD

The subject was diagnosed with emphysematous cholecystitis and sepsis on PPD , 50 days after receiving Dose 2, and died of the events on PPD , 120 days after receiving Dose 2.

On PPD (Day 68), the subject experienced muscular weakness in the left lower extremity and was subsequently diagnosed with rhabdomyolysis on PPD (Day 73). On PPD (Day 73), the subject was admitted to the hospital with weakness in the left lower extremity after being bedbound for 4 days. The subject could wiggle PPD toes but was unable to lift PPD left lower extremity. The laboratory results on PPD (Day 73) included a creatine kinase level of 2849 U/L (normal range [NR]: 39-308 U/L), creatinine of 1.97 mg/dL (NR: 0.60-1.30 mg/dL), consistent with acute renal failure, brain natriuretic peptide (BNP) of 403 pg/mL (NR: 0 -100 pg/mL), white blood cell (WBC) count of 16.3 × 10^3/mm^3 (NR: 4.5-10.5 × 10^3/mm^3), and blood glucose of 379 and 342 (units and NR not reported), and the subject's blood pressure (BP) measurements were 134/74 mmHg, 135/68 mmHg,

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Narrative Comment
136/63 mmHg, and 134/77 mmHg. On PPD (Day 74), the subject was hospitalized, and the laboratory tests included troponin of 14.13 ng/mL (NR: 0.00-0.04 ng/mL), consistent with a new non–ST-segment elevation myocardial infarction, and lactic acid of 2.8 mmol/L (NR: 0.4-2.0 mmol/L). On Day 74, the subject was diagnosed with sepsis, emphysematous cholecystitis, acute kidney injury, dehydration, and atrial fibrillation with rapid ventricular response. A gallbladder drain was inserted for the acute emphysematous cholecystitis. A blood culture on Day 74 showed no aerobic or anaerobic growth for 5 days. The subject's BP ranged from 67/30 mmHg to 188/72 mmHg, and the glucose values ranged from 134 to 346 (units and NR not reported). On PPD, the blood culture was positive for *Klebsiella oxytoca, Escherichia coli*, and *Klebsiella pneumoniae*, and PPD blood glucose levels ranged from 321-358 (units and NR not reported). On PPD and PPD, the subject's BP was between 90/57 mmHg and 104/72 mmHg, respectively. On PPD, the laboratory tests included blood glucose ranging from 213 to 280 (units and NR not reported), creatinine of 1.63 mg/dL, creatine kinase of 92 U/L, BNP of 586 pg/mL, WBC count of 7.9 × 10^3/mm^3, and troponin of 1.74 ng/mL. On the same day, the subject received PPD . The subject's BP fluctuated from 94/58 mmHg to 118/72 mmHg from PPD to PPD. On PPD (Day 84), repeat laboratory test results showed creatinine of 0.99 mg/dL, glucose of 134 and 163, and WBC count of 6.3 × 10^3/mm^3. The subject was treated with PPD (unspecified dates). On PPD (Day 84), the subject was discharged to a skilled nursing facility. The rhabdomyolysis resolved on the same day (Day 84). The subject received PPD at the facility. A SARS-CoV-2 polymerase chain reaction test on Day 84 was negative during hospitalization. On PPD (Day 144), the subject died of the emphysematous cholecystitis. It was reported that the subject was on life support and the family requested that the subject be withdrawn from life support, as the subject's condition was not getting better, and the physician informed the family that there was no real hope for recovery. It was unknown if an autopsy was performed, and the reported cause of death was disease progression (acute emphysematous cholecystitis and sepsis). The events atrial fibrillation, muscular weakness, and acute kidney injury were ongoing at the time of the subject's death. In the opinion of the investigator, there was no reasonable possibility that the emphysematous cholecystitis and sepsis were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	COVID-19	PPD	PPD (93)		PPD (104)		12
2	GENRL	Multiple organ dysfunction syndrome		PPD (93)		PPD (104)		12

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: COVID-19	2	72	Y
2	4	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: COVID-19	2	72	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
PPD		PPD	PPD	

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 70-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 22).

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Narrative Comment
Concomitant medications received within 2 weeks prior to the onset of the COVID-19 infection and multiple organ dysfunction syndrome included PPD. On PPD, the subject received a nonstudy vaccine PPD through PPD employer. The site was first informed of this vaccination by the subject's PPD on PPD. The subject was diagnosed with COVID-19 infection and multiple organ dysfunction syndrome on PPD, 71 days after receiving Dose 2. The subject experienced shortness of breath, fever, cough, fatigue, and muscle aches "a day or so after" exposure to COVID-19 on PPD. On PPD (Day 93), the subject received PPD from PPD primary care physician. Later the same day (Day 93), the subject presented to the emergency department with weakness, dyspnea, nausea, and diarrhea and was subsequently hospitalized with COVID-19. On the same day (Day 93), the subject's laboratory tests included: a positive SARS-CoV-2 test, sodium of 134 mmol/L (normal range [NR]: 137-145 mmol/L), chloride of 97 mmol/L (NR: 98-107 mmol/L), glucose of 121 mg/dL (NR: 74-99 mg/dL), aspartate aminotransferase of 78 (NR: 17-59, unit not provided), alanine aminotransferase of 51 (normal high: 50, unit not provided), C-reactive protein of 191.2 mg/dL (normal high: 10 mg/dL), total protein of 8.5 g/dL (NR: 6.3-8.2 g/dL), D-dimer quantitative of 1.21 µg/mL fibrinogen equivalent units (normal high: 0.50 µg/mL), red blood cell count of 5.86 M/mm^3 (NR: 4.20-5.70 M/mm^3), hemoglobin of 17.8 g/dL (NR: 13-17 g/dL), and hematocrit of 53.1% (NR: 40%-50%). The chest x-ray done on that same day (Day 93) was consistent with bilateral multifocal viral pneumonia. The subject was treated with PPD. On PPD, the subject was treated at bedside for acute hypoxemic respiratory failure with a left radial arterial line placed, and PPD was intubated and sedated. After being placed on a ventilator, PPD health status continued to deteriorate, resulting in multiple organ dysfunction syndrome. On PPD, PPD suffered acute renal failure. Acute hypoxic respiratory failure and acute renal failure were considered because of the COVID-19. On PPD (Day 104), the subject's family opted for "PPD" status. On PPD, the site learned that the subject had died on PPD (Day 104), and it was unknown if an autopsy was performed. It was reported that the subject also experienced shock, nose bleeding, PPD. The cause of death was reported as disease progression, multiple organ dysfunction syndrome, and COVID-19 infection. The subject's vaccine status was unblinded on PPD. In the opinion of the investigator, there was no reasonable possibility that the COVID-19 infection and multiple organ dysfunction syndrome were related to the study intervention, concomitant medications, or clinical trial procedures. Multiple organ dysfunction syndrome was considered related to COVID-19. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (448)	PPD

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	NEOPL	Adenocarcinoma pancreas	PPD	PPD (469)		PPD (517)		49	4	TCN/W	Y
2	VASC	Aneurysm		PPD (469)		ONGOING			1	TCN	Y
3	VASC	Aortic aneurysm		PPD (469)		ONGOING			1	TCN	Y
4	VASC	Arteriosclerosis		PPD (469)		PPD (517)		49	2	N	N
5	HEPAT	Biliary obstruction		PPD (469)		ONGOING			4	TC/TCN	Y
6	HEPAT	Jaundice cholestatic		PPD (469)		ONGOING			1	TCN	Y
7	BLOOD	Splenic vein thrombosis		PPD (469)		ONGOING			1	TCN	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Fatal (PPD)	NOT RELATED/OTHER: Adenocarcinoma of the pancreas	3	22	Y
2	Yes	NOT RELATED/OTHER: common iliac aneurysm due to arthrosclerosis	3	22	N
3	Yes	NOT RELATED/OTHER: abdominal aortic aneurysm due to arthrosclerosis	3	22	N
4	Resolved (PPD)	NOT RELATED/OTHER: vascular atherosclerosis	3	22	N
5	Yes	NOT RELATED/OTHER: acute bile duct obstruction	3	22	N
6	Yes	NOT RELATED/OTHER: common bile duct obstruction	3	22	N
7	Yes	NOT RELATED/OTHER: splenic vein thrombosis idiopathic	3	22	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a ≥75-year-old PPD with no pertinent medical history, received Dose 1 on PPD, Dose 2 on PPD (Day 20), and Dose 3 on PPD (Day 448). Concomitant medications received within 2 weeks prior to the onset of adenocarcinoma of the pancreas included PPD The subject was diagnosed with adenocarcinoma of the pancreas on PPD, 21 days after receiving Dose 3, and died of the event on PPD, 69 days after receiving Dose 3.

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Narrative Comment
The subject stated that for the last few months, PPD had a poor appetite and had been losing weight. Initially, PPD took PPD for presumed muscle spasm/shoulder arthritis but noticed that PPD was becoming progressively jaundiced with more cramping abdominal pain. The subject's laboratory reports from PPD were normal, but PPD laboratory tests reported on an unknown date in the week of PPD presentation showed bilirubin of 9 and elevated alkaline phosphatase (ALP) of 1k+ (units and normal ranges not provided). An ultrasound showed a distended gallbladder with common bile duct dilation of 1.9 cm. PPD was referred to the hospital for further workup, where PPD was admitted on PPD (Day 469). PPD was seen in consultation by vascular surgery due to evidence for portal vein obstruction related to external compression from a pancreatic mass and abdominal aortic aneurysm. It was recommended to hold anticoagulation pending further testing for hyperbilirubinemia/obstructive jaundice and a pancreatic mass. A magnetic resonance imaging (MRI)/magnetic resonance cholangiopancreatography (MRCP) confirmed a pancreatic head mass, and the subject consulted oncology for concern of pancreatic cancer or cholangiocarcinoma. Arrangements were planned for endoscopic ultrasound (EUS)/endoscopic retrograde cholangiopancreatography (ERCP), but these could not be arranged at this hospital and the subject was transferred to another hospital for expedited EUS/ERCP. PPD liver function tests remained elevated throughout PPD hospitalization. On the same day (Day 469), relevant tests included total bilirubin of 12.3 mg/dL (normal range [NR]: 0.2-1.0 mg/dL), ALP of 1019 U/L (NR: 45-117 U/L), aspartate aminotransferase of 157 U/L (NR: 15-37 U/L), alanine amino transferase of 179 U/L (NR: 16-61 U/L), and carbohydrate antigen 19-9 was 3786 (NR not provided). On PPD, a computed tomography (CT) scan of the abdomen/pelvis with contrast showed intra and extrahepatic biliary dilatation with caliber change to soft tissue fullness in the region of the pancreatic head (raising concern for a pancreatic mass), diffuse gallbladder distension with wall thickening and edema (superimposed acute cholecystitis was not excluded), infrarenal abdominal aortic aneurysm with mural thrombus as well as aneurysm of bilateral common iliac arteries, and probable splenic vein thrombosis with paraesophageal varices and small ascites in the abdomen/pelvis. Additionally, wall thickening and edema of the rectum was noted, and a clinical correlation was recommended to exclude proctitis. On the same day, an MRI of the liver without contrast showed a pancreatic mass measuring approximately 2.5 to 3 cm that was suspected to be obstructing the common bile duct in the head of the pancreas. Severe intrahepatic bile duct dilation was noted. The portal vein appeared occluded as it passed through the pancreas, suggesting malignant occlusion. Marked dilation of the gallbladder with gallbladder wall edema was also noted. An MRCP done on PPD showed a large infiltrative mass measuring 6.8×3.3 cm centered within the pancreatic tail, which was highly concerning for pancreatic malignancy and favored adenocarcinoma. The mass occluded the superior mesenteric and splenic vein junction along with the portions of the proximal main portal vein. The mass contacted the superior mesenteric artery by less than 180 degrees and closely approximated the common hepatic artery with possible invasion. There was malignant structuring of the common bile duct with severe diffuse dilation (mildly improved from prior examinations) and areas of markedly heterogeneous cystic change within the liver (mainly involving segments 2 and 3) related to severe intrahepatic biliary dilation. No discrete mass was identified; however, continued imaging surveillance was suggested. Small bilateral pleural effusions and aortic atherosclerosis with a fusiform infrarenal abdominal aortic aneurysm measuring 5.5 cm were also noted. The subject underwent paracentesis (results not provided). On PPD, an ERCP showed bile duct obstruction from a large extrinsic mass, and PPD underwent placement of a 10 mm × 6 cm coated metal stent.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
On PPD, a CT scan of chest/abdomen/pelvis showed noncalcified pulmonary nodules within the right (sub-centimeter) and left (measuring 5.5 mm) lower lobes, representing noncalcified granuloma versus metastatic disease in this clinical setting. Enlarged necrotic mediastinal lymph nodes (up to 1.9 cm) consistent with metastatic lymphadenopathy were seen, as were small to moderate bilateral pleural effusions with bibasilar compressive atelectasis or infiltrates, mild subpleural scarring within the lower lobes, and mild linear atelectasis or scarring within the lingula. A 5.2 cm ill-defined mass of the body of the pancreas (compatible with the subject's history of PPD) encasing the splenic artery and adjoining the common hepatic artery and superior mesenteric artery was noted. Superior mesenteric vein and splenic vein occlusion was also noted, requiring interval placement of biliary stent within the common duct. Associated pneumobilia, intrahepatic and extrahepatic biliary ductal dilatation as noted in the previous examination (dated PPD), severe distention of the gallbladder with focal gallbladder wall calcifications consistent with porcelain gallbladder, a 5.4 cm infrarenal abdominal aortic aneurysm, anasarca and moderate to large abdominal and pelvic ascites, and bilateral renal cysts were noted. A follow-up CT of the chest in 3-6 months was recommended. On PPD, an esophagogastroduodenoscopy/EUS showed a metastatic pancreatic mass (T3N1Mx), and a fine-needle aspiration was performed (pathology results pending). The preliminary examination was suggestive of adenocarcinoma. On PPD, pathology report confirmed adenocarcinoma of the pancreas, and the subject was diagnosed with pancreatic adenocarcinoma, arteriosclerosis, common iliac aneurysm, abdominal aortic aneurysm, biliary obstruction, cholestatic jaundice, and splenic vein thrombosis with an onset date of PPD (Day 469). It was reported that the subject was not a surgical candidate. After discussion about the diagnosis, prognosis, and treatment options, the subject opted for hospice care. On PPD (Day 517), the subject died of adenocarcinoma of the pancreas with metastasis to mediastinum (disease progression). It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the adenocarcinoma was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (24)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (442)	PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	NEOPL	Acute myeloid leukaemia	PPD	PPD (485)		PPD (511)		27	4	W

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Fatal (PPD)	NOT RELATED/OTHER: New onset of leukemia of unknown type	3	44	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD, a≥75-year-old PPD with no pertinent medical history, received Dose 1 on PPD, Dose 2 on PPD (Day 24), and Dose 3 on PPD (Day 442).

Concomitant medications received within 2 weeks prior to the onset of acute myeloid leukemia (AML) included PPD

The subject was diagnosed with AML on PPD, 43 days after receiving Dose 3, and died of the event on PPD, 69 days after receiving Dose 3.

The subject had increasing fatigue and dyspnea for 2-3 weeks, which prompted a visit to PPD primary care physician. On an unspecified date, the primary care physician ran laboratory tests, which showed a white blood cell count of 1.2, hemoglobin of 10.0, mean cell volume of 109, platelet count of 154, 1% nucleated red blood cells, absolute neutrophil count of 400, and an absolute lymphocyte count of 800 (units and normal ranges not provided). These labs were indicative of pancytopenia with macrocytic anemia. The subject was referred to an oncologist, who suggested a bone marrow biopsy to diagnose the etiology of the pancytopenia. On PPD (Day 485), a bone marrow biopsy was done, and the subject was diagnosed with AML. On PPD, the subject was contacted to inquire about symptoms reported in PPD e-diary, and PPD informed the coordinator that PPD had a "sore throat" that the doctor attributed to PPD new diagnosis of leukemia.

On PPD (Day 511), the subject passed away. Per death certificate, the reported cause of death was AML. An autopsy was not performed.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
In the opinion of the investigator, there was no reasonable possibility that the AML was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (169)	PPD
VACCINATION 4	BNT162b2	PPD (189)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Pulmonary fibrosis	PPD	PPD (399)		PPD (399)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: pulmonary fibrosis	4	211	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 60-year-old PPD with no reported medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 169) and PPD (Day 189), respectively. The subject was diagnosed with pulmonary fibrosis on PPD, 210 days after receiving Dose 4 (second dose of BNT162b2) and died on the same day. The cause of death was pulmonary fibrosis, which required an emergency room visit. Further details could not be obtained. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the pulmonary fibrosis was related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (428)	PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Acute myocardial infarction	PPD	PPD (664)		PPD (664)		1	4	W
2	METAB	Hypercholesterolaemia		PPD (410)		ONGOING			1	TC
3	INFEC	Prostate infection		PPD (13)		PPD (20)		8	2	TC
4	INV	Prostatic specific antigen increased		PPD (13)		PPD (20)		8	1	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Fatal (PPD)	NOT RELATED/OTHER: coronary artery disease	3	237	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	N	Yes	NOT RELATED/OTHER: New onset high cholesterol	2	389	N
3	N	Resolved (PPD)	NOT RELATED/OTHER: Idiopathic	1	13	N
4	N	Resolved (PPD)	NOT RELATED/OTHER: PROGRESSION OF KNOWN DISEASE	1	13	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , a 70-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD , Dose 2 on PPD (Day 22), and Dose 3 on PPD (Day 428).

Concomitant medications received within 2 weeks prior to the onset of the acute myocardial infarction included PPD for hypercholesterolemia.

The subject was diagnosed with an acute myocardial infarction on PPD , 236 days after receiving Dose 3, and died on the same day.

The cause of death was acute myocardial infarction, and PPD was in PPD home country at the time of death. PPD was not taken to the hospital. An autopsy was not performed. Further information was not available.

In the opinion of the investigator, there was no reasonable possibility that the acute myocardial infarction was related to the study intervention or clinical trial procedures, but rather it was related to coronary artery disease. Pfizer concurred with the investigator's causality assessment. Per the investigator, the event was also not related to the concomitant medications. Per Pfizer, the subject's old age and the underlying diseases of PPD were high-risk factors for the event.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (113)	PPD
VACCINATION 4	BNT162b2	PPD (136)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (380)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Pancreatic carcinoma	PPD	PPD ()		PPD (643)		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Idiopathic	5	68	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
PPD		PPD	ONGOING	

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 113), PPD (Day 136), and PPD (Day 380), respectively. Concomitant medications received within 2 weeks prior to the onset of the pancreatic carcinoma included PPD The subject was diagnosed with pancreatic carcinoma in PPD, approximately 67 days after receiving Dose 5 (third dose of BNT162b2), and died of the event on PPD, 263 days after receiving the third dose of BNT162b2. On an unspecified date, the subject visited their physician with abdominal pain. A computed axial tomography scan was done in PPD and the findings were consistent with pancreatic carcinoma. The tumor was reported to be inoperable due to blood vessels in the specific region, and the subject started protocol-prohibited PPD in PPD (further specifics not reported). PPD started treatment with PPD for pain and PPD for nausea. Subsequently, PPD opted for hospice care. On PPD (Day 643), while in hospice, the subject died of pancreatic carcinoma (disease progression). An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the pancreatic carcinoma was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (24)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	COVID-19	PPD	PPD (91)		ONGOING		
2	CARD	Cardiac arrest		PPD (93)		PPD (93)		1
3	CARD	Coronary artery disease		PPD (93)		PPD (93)	PPD	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	N	Y	Yes	NOT RELATED/OTHER: COVID-19	2	68	N
2	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	70	Y
3	4	N	Y	Resolved (PPD)	NOT RELATED/OTHER: cardiac arrest	2	70	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 24). Concomitant medications received within 2 weeks prior to the onset of the cardiac arrest included PPD The subject experienced cardiac arrest on PPD, 69 days after receiving Dose 2, and died on the same day. The subject attended a COVID-19 illness visit on PPD for cough first occurring on PPD (Day 91), and a self-swab was positive. A local COVID-19 illness test result on PPD (Day 93) was also positive. The site was trying to contact the subject to unblind PPD for this study and, after an online search, it was discovered that the subject had died on PPD (Day 93). On PPD (Day 93), the subject visited PPD primary care physician with cough, fatigue, muscle/body aches, diarrhea, nasal congestion, and a runny nose. The subject was advised to self-isolate, increase fluids and rest, take PPD, and consider taking vitamin D and vitamin C to boost PPD immune system. The subject was reported to have experienced cardiac arrest; it was unknown if cardiopulmonary resuscitation was attempted. The subject had cardiac arrest due to progression of PPD, which led to death on the same day (Day 93). The death certificate indicated the cause of death as cardiac arrest due to progression of PPD, PPD, and COVID-19. It was also reported that the coronary artery disease and PPD did not worsen after receiving study intervention. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the cardiac arrest was associated with subject's underlying PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (44)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Metastases to lung	PPD	PPD (176)		PPD (186)		11	4
2	NEOPL	Pancreatic carcinoma metastatic		PPD (176)		PPD (186)		11	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Metastases to the lungs	2	133	Y
2	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Pancreatic Cancer	2	133	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Narrative Comment
Subject PPD, an ≥75-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 44). Concomitant medications received within 2 weeks prior to the onset of the metastatic pancreatic cancer with metastases to the lungs included PPD The subject was diagnosed with metastatic pancreatic cancer with metastases to the lungs on PPD, 132 days after receiving Dose 2, and died of the events on PPD, 142 days after receiving Dose 2. On PPD, the subject was hospitalized because of pancreatic cancer with metastases to the lungs. The site was not aware of any preexisting neoplasm. No disease-specific treatment was reported. The subject was discharged from the hospital on PPD. On PPD (Day 186), the subject died at home because of metastasis to the lungs and disease progression. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the metastatic pancreatic cancer and metastasis to the lungs were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (109)	PPD
VACCINATION 4	BNT162b2	PPD (130)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Acute respiratory failure	PPD	PPD (332)		PPD (332)		1	4
2	RESP	Chronic obstructive pulmonary disease		PPD (332)		ONGOING			4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Acute on chronic respiratory failure	4	203	Y
2	W	Y	Yes	NOT RELATED/OTHER: COPD	4	203	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment

Subject PPD, an ≥75-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 21).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 109) and PPD (Day 130), respectively.

Concomitant medications received within 2 weeks prior to the onset of the chronic obstructive pulmonary disease (COPD) and acute respiratory failure included PPD

The subject developed COPD and acute on chronic respiratory failure on PPD, 202 days after receiving Dose 4 (second dose of BNT162b2) and died of acute on chronic respiratory failure on the same day.

An autopsy was not performed. The COPD was ongoing at the time of death.

In the opinion of the investigator, there was no reasonable possibility that the COPD and acute on chronic respiratory failure were related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (202)	PPD
VACCINATION 4	BNT162b2	PPD (225)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INFEC	Diabetic foot infection	PPD	PPD (166)	PPD	PPD (198)		33	3	TC/TCN	Y
2	VASC	Hypertension		PPD (194)	PPD	PPD (282)		89	2	TC	N
3	CARD	Myocardial infarction		PPD (282)		PPD (282)		1	4	W	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (PPD)	NOT RELATED/OTHER: Secondary to PPD	2	144	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	Resolved (PPD)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	172	N
3	Fatal (PPD)	NOT RELATED/OTHER: Hypoglycemia (Medical history PPD)	4	58	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 50-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 23). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 202) and PPD (Day 225), respectively. Concomitant medications received within 2 weeks prior to the onset of the myocardial infarction included PPD for hypertension, PPD for pain PPD. The subject experienced a myocardial infarction on PPD, 57 days after receiving Dose 4 (second dose of BNT162b2), and died on the same day. On PPD (Day 166), the subject developed a diabetic foot infection in the right little toe, which required an emergency room visit on PPD (Day 194) and subsequent hospitalization. On PPD (Day 194), the subject developed hypertension due to unspecified concomitant drug treatment, and treatment with PPD was initiated. On PPD (Day 198), PPD, and the diabetic foot infection was considered resolved. PPD stay in the hospital was for 30 days. On PPD (Day 282), the subject was found dead in PPD home by PPD friend. PPD was pronounced dead on arrival to the emergency room. The subject's PPD reported hypoglycemia and myocardial infarction as the possible causes of death. The site reported that the subject did not report any prior hypoglycemic episodes while on PPD. Per the death certificate, the cause of death was myocardial infarction. An autopsy was not performed. The hypertension was ongoing at the time of death. In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per the investigator, the event was possibly related to the underlying hypoglycemia (medical history: PPD).

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (30)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Chronic obstructive pulmonary disease	PPD	PPD (99)		PPD (99)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: history of PPD	2	70	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD , a 60-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 30).
Concomitant medications received within 2 weeks prior to the onset of the worsening of COPD PPD
The subject experienced worsening of COPD on PPD , 69 days after receiving Dose 2, and died on the same day.
The subject had known but stable PPD disease at enrollment. On PPD , the subject's PPD informed the site that the subject had died on PPD (Day 99) because of worsening of COPD. Relevant tests were unknown. PPD died under hospice care at home. An autopsy was not performed.
In the opinion of the investigator, there was no reasonable possibility that the worsening of COPD was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (135)	PPD
VACCINATION 4	BNT162b2	PPD (154)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (463)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	SOCCI	PPD	PPD	PPD (598)		PPD (598)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	5	136	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NERV	Dementia Alzheimer's type	PPD	PPD (136)		PPD (147)		12

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Dementia	2	115	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , an ≥75-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 22).

The subject was diagnosed with worsening of dementia (Alzheimer's) on PPD , 114 days after receiving Dose 2, and died of the event on PPD , 125 days after receiving Dose 2.

According to the subject's PPD , the subject stopped eating and drinking on PPD (Day 136). All concomitant medications were discontinued from PPD (Day 136) onwards. On PPD (Day 147), the subject died at home and the cause of death was worsening of dementia (Alzheimer's). The subject had no symptoms of COVID-19 at the time of PPD death. An autopsy was not performed.

In the opinion of the investigator, there was no reasonable possibility that the worsening of dementia (Alzheimer's) was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (422)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Aortic rupture	PPD	PPD (556)		PPD (556)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: aortic aneurysm	3	135	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD, Dose 2 on PPD (Day 22), and Dose 3 on PPD (Day 422). Concomitant medication received within 2 weeks prior to the onset of the aortic rupture included PPD The subject developed an aortic rupture on PPD, 134 days after receiving Dose 3, and died on the same day. On PPD (Day 556), the subject was hospitalized for a ruptured aortic aneurysm. The subject was transferred to another hospital and died the same day. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the aortic rupture was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was also not related to the concomitant medication.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (23)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Bladder cancer	PPD	PPD (247)		PPD (408)	PPD	162

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	W	Y	Fatal (PPD)	NOT RELATED/OTHER: cancer	2	225	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, an ≥75-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 23). The subject was diagnosed with bladder cancer on PPD, 224 days after receiving Dose 2, and died of the event on PPD, 385 days after receiving Dose 2. On PPD (Day 247), the subject was diagnosed with bladder cancer. The subject refused chemotherapy and was not hospitalized since PPD wanted to spend PPD remaining time at home. PPD cancer spread to other organs, and PPD died at home on PPD (Day 408) at PPD AM. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the bladder cancer was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (24)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	VASC	Arteriosclerosis	PPD	PPD (217)	PPD	PPD (217)	PPD	1	4	W	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
2	GASTR	Gastrointestinal haemorrhage	PPD	PPD (217)	PPD	PPD (217)	PPD	1	4	W	Y
3	NERV	Restless legs syndrome		PPD (99)		ONGOING			1	TC	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Fatal (PPD)	NOT RELATED/OTHER: PPD	2	194	Y
2	Fatal (PPD)	NOT RELATED/OTHER: PPD and Atherosclerotic cardiovascular Disease	2	194	Y
3	Yes	NOT RELATED/OTHER: cardiovascular disease	2	76	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 24). Concomitant medications received within 2 weeks prior to the onset of the arteriosclerosis and gastrointestinal (GI) hemorrhage included PPD and restless leg syndrome. The subject was diagnosed with arteriosclerosis and GI hemorrhage on PPD, 193 days after receiving Dose 2, and died on the same day. On PPD, the subject went for PPD dialysis appointment. When PPD arrived at the facility, PPD was feeling unwell, so PPD decided to return home. The subject never made it back and it took 3 days for the PPD to locate PPD, which was PPD The subject was found on PPD (Day 217) by PPD. The subject was PPD and was unresponsive. The medical team reported that PPD had died 3 days ago. The subject's body was taken to a funeral home where an autopsy was performed. The summary of the forensic report was as follows: "Autopsy report on PPD. Cause of death was GI hemorrhage associated with PPD and atherosclerotic cardiovascular disease. Manner of death was natural. Date of death was on PPD (Day 217) at PPD Central Standard Time. Internal examination: head - no contusion, no fracture, no hemorrhage, free of atherosclerosis and aneurysms. Neck - normal. Body cavities - normal. Cardiovascular - the aorta had marked atherosclerosis. Lung - normal. Liver, gallbladder, and pancreas - normal. Hemic and lymphatic systems - normal. Genitourinary system - normal. Endocrine system - normal. Digestive system - the lumen of jejunum, ileum, colon, and rectum were distended by liquid blood, which was leading through the anus. There was no hemorrhage in the duodenum. The mucosal surfaces had adherent blood; no lesions were identified. Musculoskeletal system - normal. Toxicology report was negative." In the opinion of the investigator, there was no reasonable possibility that the arteriosclerosis and GI hemorrhage were related to the study intervention, concomitant medications, or clinical trial procedures, but rather they were related to PPD and atherosclerotic cardiovascular disease. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the underlying PPD provides plausible explanations for the event.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Acute respiratory failure	PPD	PPD (82)		PPD (102)		21	4
2	INFEC	COVID-19		PPD (80)		PPD (102)		23	4
3	INFEC	Pneumonia		PPD (80)		PPD (102)		23	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: COVID-19 Pneumonia	2	61	Y
2	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: COVID-19	2	59	Y
3	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: COVID-19 Infection	2	59	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22). The subject developed a COVID-19 infection and pneumonia on PPD, 58 days after receiving Dose 2. On PPD (Day 80), the subject experienced acute shortness of breath, and PPD family called emergency medical services. On arrival, the subject complained of respiratory symptoms, which PPD had been experiencing for the past 3 to 4 days. PPD stated that since the start of PPD respiratory symptoms, PPD oxygen levels declined; PPD had intermittent fevers, diffuse body aches, and left-sided abdominal pain. In the emergency room, PPD oxygen saturation was 82% on room air, which improved with 4 L of oxygen via nasal cannula. On the same day (Day 80), the subject underwent laboratory tests and procedures, which showed blood urea nitrogen (BUN) of 16 mg/dL (normal range [NR]: 7-22 mg/dL), creatinine of 0.76 mg/dL (NR: 0.50-1.40 mg/dL), white blood cell (WBC) count of 9.2 K/cmm (NR: 3.7-10.4 K/cmm), hemoglobin (Hgb) of 12.5 g/dL (NR: 12.0-16.0 g/dL), hematocrit (Hct) of 36.6% (NR: 36.0%-48.0%), platelet count of 272 K/cmm (NR: 133-450 K/cmm), and troponin less than 0.02 ng/mL (NR: 0.00-0.40 ng/mL); a SARS-CoV-2 nucleic acid amplification test was positive; an electrocardiogram (ECG) showed sinus rhythm but could not rule out anterior infection; chest x-ray showed bilateral pneumonia; computed tomography scan of abdomen with pelvis showed extensive ground-glass pulmonary opacities in the lungs consistent with the given history of COVID-19 infection. On the same day (Day 80), the subject was admitted to the intensive care unit. The subject developed acute hypoxemic respiratory failure on PPD, 60 days after receiving Dose 2. On PPD, troponin was less than 0.02 ng/mL, ECG showed sinus bradycardia, and D-dimer was 0.64 µg/mL (NR not provided). On PPD, a chest x-ray showed severe viral pneumonia. On PPD, a chest x-ray showed mildly improved opacities in the lower lobes, with no definite pneumothorax. On PPD, a chest x-ray showed resolution of the right pneumothorax and decrease in size of the trace left apical pneumothorax. On PPD, creatine kinase-MB was high at 9.3 ng/mL (NR: 0.5-3.6 ng/mL) and troponin was less than 0.02 ng/mL. On PPD, oxygen saturation was 98.4% (NR: 95.0%-100.0%). On PPD, oxygen saturation was 93.5% and on PPD, the WBC count was 18.0 K/cmm, Hgb was 8.8 g/dL, Hct was 28.7%, and platelet count was 177 K/cmm. On PPD, creatinine was 2.43 mg/dL, BUN was 73 mg/dL, WBC count was 13.6 K/cmm, Hgb was 8.4 g/dL, Hct was 26.7%, and platelet count was 163 K/cmm. On PPD, creatinine was 3.72 mg/dL and BUN was 97 mg/dL. On PPD, oxygen saturation was 83.3%, WBC count was 10.3 K/cmm, Hgb was 7.2 g/dL, Hct was 22.6%, platelet count was 151 K/cmm, creatinine was 4.61 mg/dL, and BUN was 109 mg/dL. SARS-CoV-2 tests were positive on PPD and PPD during hospitalization. During the hospitalization, the subject was treated with PPD. The subject had a long course with COVID-19 illness; PPD condition did not improve, and PPD was compassionately extubated. On PPD, the subject's PPD informed the site of PPD untimely death, which occurred on PPD (Day 102). An autopsy was not performed, and the causes of death were reported as COVID-19, pneumonia, and acute hypoxemic respiratory failure.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
In the opinion of the investigator, there was no reasonable possibility that the COVID-19 infection, pneumonia, and acute hypoxemic respiratory failure were related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Cerebrovascular accident	PPD	PPD (314)		PPD (316)	PPD	3
2	GASTR	Gastritis		PPD (309)		PPD (316)	PPD	8

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	295	Y
2	3	TC	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	290	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 50-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 20). Concomitant medications received within 2 weeks prior to the onset of the cerebrovascular accident (CVA) included PPD The subject was diagnosed with CVA on PPD, 294 days after receiving Dose 2, and died of the event on PPD, 296 days after receiving Dose 2. On PPD, the subject, who was PPD, presented to the emergency room at PPD with abdominal pain lasting 3 days. PPD was treated PPD. PPD was diagnosed with gastritis (onset PPD [Day 309]) and was discharged on PPD at PPD. On PPD (Day 314), the subject had a massive stroke (CVA), and PPD was hospitalized after PPD was found unresponsive; it was reported that PPD had been PPD for 3 days. Upon hospitalization, PPD was intubated. A brain computed tomography revealed a large left-sided infarct with subacute midline shift. PPD was minimally reactive to pain on the first day of hospitalization and became unresponsive on the second night. A brain nuclear perfusion test showed no flow, and the time of death was PPD on PPD (Day 316). On PPD, the family identified the body. The cause of the subject's death was CVA. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the CVA was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (24)	PPD
VACCINATION 3	BNT162b2	PPD (176)	PPD
VACCINATION 4	BNT162b2	PPD (198)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (425)	PPD

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Death	PPD	PPD ()		PPD ()		
2	INV	Hepatic enzyme increased		PPD (35)		PPD (56)		22

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	W	Y	Fatal PPD)	NOT RELATED/OTHER: unknown	5	290	Y
2	3	N	Y	Resolved (PPD)	NOT RELATED/OTHER: UNKNOWN	2	12	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

Subject Summary

Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 60-year-old PPD with a reported medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 24). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 176), PPD (Day 198), and PPD (Day 425), respectively. Concomitant medications received within 2 weeks prior to the subject's death included PPD The subject died on an unspecified date in PPD, at least 289 days after receiving Dose 5 (third dose of BNT162b2). On PPD, the site had tried to contact the subject for the protocol amendment 20 update, but the subject's phone number was disconnected. The site contacted the subject's friend, who reported that the subject passed away about 2 and a half months ago but did not have the exact date or cause of the death. It was unknown if an autopsy was performed. The site did not have any other alternative contact for the subject to collect further information. On PPD, the site updated the subject's disposition status for the study follow-up phase as "withdrawn" because of the death. In the opinion of the investigator, there was no reasonable possibility that the death was related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (23)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	SKIN	Actinic keratosis	PPD	PPD (65)		PPD (65)		1	2
2	EAR	Cerumen impaction		PPD (31)		PPD (31)		1	1
3	INFEC	Septic shock		PPD (115)	PPD	PPD (120)	PPD	6	4
4	SKIN	Skin lesion		PPD (65)		PPD (71)		7	2
5	NEOPL	Squamous cell carcinoma of skin		PPD (71)		PPD (71)		1	2

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: ketatosis	2	43	N
2	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: cerumen impaction	2	9	N
3	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Gallbladder Failure	2	93	Y
4	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: squamous cell carcinoma	2	43	N
5	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: skin lesion	2	49	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , an≥75-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 23).

Concomitant medications received within 2 weeks prior to the onset of the septic shock included PPD

The subject developed septic shock on PPD , 92 days after receiving Dose 2, and died of the event on PPD , 97 days after receiving Dose 2.

On PPD (Day 115), the subject had 4 episodes of emesis. On PPD , the subject had 2 episodes of emesis and came to the emergency room, with abdominal pain in the lower quadrant along with nausea. PPD described the pain as throbbing and aching, which was localized in PPD lower abdominal area with tenderness in the right upper quadrant. The subject denied fever, chills, bloody emesis, bloody stool, or rectal pain, and PPD was hospitalized for care. The subject received a nasogastric tube and a dose of PPD . On PPD , a chest x-ray was unremarkable, computed tomography (CT) scan of the abdomen showed acute mild small-bowel obstruction due to formed stool, heterogeneously enhanced solid left renal mass, and colonic diverticulitis, and an ultrasound examination of the biliary duct on the same day confirmed cholelithiasis. On the same day, laboratory tests showed high levels of lactic acid: 2.4 mmol/L (normal range [NR]: 0.7-1.9 mmol/L) and creatinine: 1.4 mg/dL (NR: 0.52-1.04 mg/dL). Emergency surgery was required because of the abdominal pain with acidosis and suspected acute renal failure. During surgery, it was found that the subject had dark bloody fluid in the abdomen and a distended inflamed pre-gangrenous gallbladder, with a twisted loop of small bowel in the pelvis that could not be released. It was decided to

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Narrative Comment
remove the gallbladder. On the same day, postoperatively, the subject was transferred to the intensive care unit and intubated. PPD was diagnosed with septic shock and was treated with PPD On PPD, the subject's chest x-ray showed bibasilar atelectasis with mild edema and/or infiltrates, and a CT scan of the abdomen showed a small-bowel obstruction and distended gallbladder with gallstones. On the same day, the subject's creatinine was high at 3.13 mg/dL. On PPD, the subject's chest x-ray showed development of subcutaneous emphysema, and abdominal x-ray showed paucity of bowel gas. While the subject was in the hospital, PPD condition continued to decline; PPD was tachycardic, hypotensive, and in atrial fibrillation with rapid ventricular response and developed severe metabolic acidosis. During the hospitalization, the subject was treated with PPD . Even after the treatment, the subject's condition declined and PPD family decided to withdraw care, and the subject was extubated. On PPD, the subject's creatinine was high at 4.31 mg/dL, blood lactic acid was high at 9.4 mmol/L, and the glomerular filtration rate was 8 mL/min/1.73 m^2 (NR not reported). On PPD (Day 120), at PPD AM, the subject died of septic shock. An autopsy was not performed. There was no indication in the hospital records that the subject had a COVID-19 test. In the opinion of the investigator, there was no reasonable possibility that the septic shock was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per the investigator, the septic shock was related to gallbladder failure.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (148)	PPD
VACCINATION 4	BNT162b2	PPD (169)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	RENAL	Acute kidney injury	PPD	PPD (288)		PPD (299)		12	3	TC/TCN	Y
2	NERV	Cerebrovascular accident		PPD (417)	PPD	PPD (427)		11	4	TC/W	Y
3	NERV	Cerebrovascular accident		PPD (185)		PPD (207)		23	3	N	Y
4	NERV	Cerebrovascular accident		PPD (418)	PPD	PPD (427)		10	3	TC	Y
5	INJ&P	Subdural haematoma		PPD (389)		PPD (427)		39	3	TC	N
6	RENAL	Urinary retention		PPD (270)		PPD (427)		158	2	TCN	N
7	INFEC	Urinary tract infection		PPD (417)		PPD (427)		11	2	TC	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (PPD)	NOT RELATED/OTHER: hx of PPD	4	120	N
2	Fatal (PPD)	NOT RELATED/OTHER: Unknown	4	249	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	Resolved (PPD)	NOT RELATED/OTHER: unknown at this time	4	17	N
4	Fatal (PPD)	NOT RELATED/OTHER: Unknown	4	250	Y
5	Resolved (PPD)	NOT RELATED/OTHER: Stroke	4	224	N
6	Resolved (PPD)	NOT RELATED/OTHER: medical history of PPD	4	102	N
7	Resolved (PPD)	NOT RELATED/OTHER: Unknown	4	249	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , an >75-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 148) and PPD (Day 169), respectively. Concomitant medications received within 2 weeks prior to the onset of the cerebrovascular accident (CVA) (acute CVA and right posterior cerebral artery [PCA] stroke) included PPD

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Narrative Comment
PPD The subject experienced a CVA on PPD and another on PPD, 248 days and 249 days after receiving Dose 4 (second dose of BNT162b2), respectively, and died of the event on PPD, 258 days after receiving the second dose of BNT162b2. On PPD (Day 389), the subject experienced a traumatic subdural hematoma resulting in hospitalization. After discharge, since PPD, PPD had been in a rehabilitation facility; PPD was able to ambulate. On PPD (Day 417), the subject's PPD visited PPD and found PPD asleep. After allowing the subject to sleep for some time, the subject's PPD tried to wake PPD up around PPD PM, but the subject was difficult to arouse. The subject was taken to the emergency room for altered mental status. PPD did not have a recent history of fall, fevers, or chills. A laboratory workup was consistent with a urinary tract infection (UTI). A chest x-ray revealed pulmonary edema. No acute intracranial process was noted on a head computed tomography (CT) scan without contrast. PPD was admitted for further management. The diagnosis was UTI and pulmonary edema with a possibility of acute CVA. The *Candida* cystitis was treated with PPD, and the subject was also started on PPD. On the same day (Day 417), blood tests showed a white blood cell count of $6.69\times10^3/\mu L$, platelets of $213\times10^3/\mu L$, and a high neutrophil count of 80.7%. PPD international normalized ratio was 1.08 ng/mL, potassium level was 4 mmol/L, glucose level was 102 mg/dL, troponin I was 0.017 (unit not reported) (normal range [NR] not reported for all). A brain/head CT scan without contrast showed a very faint area of low attenuation within the right thalamus versus the left, noted only on a single image (thought to be artifact); the ventricular shunt catheter placement was stable, and ventricles were stable in size. An old encephalomalacia was seen in the right frontoparietal region. In the area of the previous subdural hematoma, chronic hygromas were noted along the flax. Pulmonary vascular congestion and hazy bibasilar airspace disease suggestive of volume overload were seen on a chest x-ray on Day 417. An echocardiogram showed an ejection fraction of 60-65% with grade 1 diastolic dysfunction. On PPD (Day 418), the subject experienced another CVA with a right PCA stroke. On PPD, an MRI of the brain without contrast showed a large distribution posterior cerebral artery level infarction with persistent inter-hemispheric hemorrhage. A head CT scan without contrast showed continued evolution of the right PCA and right cerebellar infarctions. Hemorrhagic signal was not excluded in the middle cranial fossa in areas related to lower density on the head CT scan. A shunt catheter was noted. A small amount of potential residual left intraventricular hemorrhage was also noted. An interval improvement in the hydrocephalus and an unchanged subdural hemorrhage were seen. A bilateral carotid Doppler duplex ultrasound revealed estimated <50% stenosis of the right internal carotid artery and >70% stenosis of the left internal carotid artery by velocities.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
On PPD, a brain magnetic resonance imaging (MRI) was ordered for possible acute ischemia, but it was cancelled due to the programmable ventriculoperitoneal shunt, which would have to be reprogrammed after the MRI (and nobody in the facility could do so). PPD altered mental status had improved earlier in the day. On the evening of PPD, the subject became minimally responsive and lethargic. During hospital stay, PPD showed an acute change in mental status with increased obtundation, worsening right gaze deviation, and differing pupil sizes from right to left. A head CT scan without contrast was ordered and stroke alert was activated. The head CT scan revealed a huge acute right cerebral hemisphere, right occipital, and right thalamus infarct with mild mass effect on the fourth ventricle. A CT angiogram scan of the head showed complete occlusion of right PCA, not amenable to mechanical thrombectomy. Immediate neurosurgery evaluation was recommended, and PPD was transferred to another facility. Owing to a poor prognosis, PPD family opted for comfort care, and PPD was discharged to hospice. On PPD (Day 427), the subject died of the CVA. It was not reported if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the CVA (acute CVA and right PCA stroke) was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was also not related to concomitant medications, but rather it was associated with subject's underlying contributory factors, including advanced old age, PPD .

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (25)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RENAL	Acute kidney injury	PPD	PPD (144)	PPD	PPD (151)	PPD	8	3
2	CARD	Atrial fibrillation		PPD (127)		PPD (129)		3	3
3	CARD	Atrial fibrillation		PPD (144)		PPD (218)		75	3
4	CARD	Cardiac failure congestive		PPD (114)		PPD (218)		105	2
5	CARD	Mitral valve incompetence		PPD (144)		PPD (218)		75	3
6	INV	Troponin increased		PPD (144)		PPD (151)		8	3

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: PPD heart disease	2	120	N
2	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	103	N
3	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	120	Y
4	TC	N	Resolved (PPD)	NOT RELATED/OTHER: fluid retention	2	90	N
5	N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	120	N
6	N	N	Resolved (PPD)	NOT RELATED/OTHER: persistent afib	2	120	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , a ≥75-year-old PPD with a pertinent medical history of PPD PPD), received Dose 1 on PPD and Dose 2 on PPD (Day 25).

Concomitant medications received within 2 weeks prior to the onset of the atrial fibrillation included PPD

The subject experienced atrial fibrillation on PPD , 119 days after receiving Dose 2, and died of the event on PPD 193 days after receiving Dose 2.

On PPD (Day 127), the subject experienced a new onset atrial fibrillation. The subject was scheduled to undergo a cardioversion on PPD (Day 144). During cardioversion, PPD condition worsened. PPD heart rate dropped to 20 beats/min. PPD was treated with PPD Following administration, PPD returned to PPD previous atrial fibrillation with a controlled ventricular response with heart rate between 80-90 beats/min. PPD was shifted to the intensive care unit. PPD laboratory examinations on Day 144 showed that PPD was negative for COVID-19 and had a critical troponin level of 0.055 ng/mL (normal range [NR] not provided). Severe mitral valve regurgitation was noted on a transesophageal echocardiogram, and a chest x-ray showed mild central vascular congestion and low lung volumes. PPD was stable at that time. On PPD , laboratory tests results showed a troponin level of 0.081 ng/mL (critical), creatinine level of 3.22 mg/dL (high), blood urea nitrogen level of 68 mg/dL (high), and potassium level of 7.4 mmol/L (critical) (NR not reported for all). A bilateral renal ultrasound showed normal sonographic evaluation of kidneys with free fluid ascites. PPD

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Narrative Comment
was diagnosed with hyperkalemia and acute renal failure. PPD was treated with PPD, but it induced hypotension. PPD also received PPD for treatment of atrial fibrillation. Installation of a pacemaker was to be considered after the subject became sufficiently stable. The subject's discharge date was not available. An autopsy was not performed. On PPD (Day 218), the subject died of persistent atrial fibrillation. In the opinion of the investigator, there was no reasonable possibility that the atrial fibrillation was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (23)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (409)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	INFEC	Bacterial sepsis	PPD	PPD (29)		PPD (41)		13	3
2	NERV	Dizziness		PPD (166)		ONGOING			2
3	INJ&P	Fall		PPD (166)		PPD (166)		1	2
4	NEOPL	Neoplasm malignant		PPD (733)		PPD (733)		1	4
5	INFEC	Urinary tract infection		PPD (29)		PPD (41)		13	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: unspecified organism	2	7	N
2	TC	Y	Yes	NOT RELATED/OTHER: NOT KNOWN AT THIS TIME	2	144	N
3	N	N	Resolved (PPD)	NOT RELATED/OTHER: dizziness	2	144	N
4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Unknown	3	325	Y
5	TCITCN	Y	Resolved (PPD)	NOT RELATED/OTHER: Escherichia coli	2	7	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, an ≥75-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD, Dose 2 on PPD (Day 23), and Dose 3 on PPD (Day 409). The subject was diagnosed with an unspecified malignant neoplasm on PPD, 324 days after receiving Dose 3, and died at home on the same day. The site learned about the subject's death from an online obituary after failing to reach PPD. The reported cause of death was cancer. It was unknown if an autopsy was performed. The site was unaware of the subject's cancer and was unable to obtain any further information as it did not have other contact information for the subject. In the opinion of the investigator, there was no reasonable possibility that the malignant neoplasm was related to the study intervention or clinical trial procedures. Pfizer concurrent with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (111)	PPD
VACCINATION 4	BNT162b2	PPD (132)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (457)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	PPD	PPD	PPD (557)		PPD (557)		1	4
2	INJ&P			PPD (557)		PPD (557)		1	4
3	GENRL	Pain		PPD (132)	PPD	PPD (133)		2	2

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
4	GENRL	Pyrexia	PPD	PPD (132)	PPD	PPD (133)		2	2
5	GENRL	Injection site pain		PPD (132)	PPD	PPD (133)		2	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	5	101	Y
2	W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	5	101	Y
3	N	N	Resolved (PPD)	Study Treatment	4	1	N
4	N	N	Resolved (PPD)	Study Treatment	4	1	N
5	N	N	Resolved (PPD)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Death	PPD	PPD (266)		PPD (266)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: UNKNOWN	2	247	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD , a 50-year-old PPD with a reported medical history of PPD (dates unknown for all); PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 20). Concomitant medications received within 2 weeks prior to the subject's death included PPD . The subject died of an unknown cause on PPD , 246 days after receiving Dose 2. On PPD (Day 266), the subject was PPD and PPD detected a heartbeat between PPD and PPD . The subject was found dead at approximately PPD by PPD , and the emergency services confirmed PPD death. PPD had blood work done on that day, but the result was unknown. Previously, a week prior to PPD death, the subject had a physical examination and blood work done; PPD was in great health per PPD physician, and PPD blood work was reported to be fine. PPD had cataract surgery a couple of weeks before and had intentionally lost considerable weight in the past 3-4 years. The subject had no history of COVID-19 illness, and PPD death was reported to be sudden and unexpected. An autopsy was not performed because there was no suspicion of drug overdose or foul play. In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the subject's multiple underlying medical conditions including PPD might have contributed to the fatal event.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (444)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Acute myocardial infarction	PPD	PPD (593)		PPD (593)	PPD	1	4	N	Y
2	NERV	Haemorrhagic stroke		PPD (593)		PPD (593)	PPD	1	4	W	Y
3	INFEC	Septic endocarditis		PPD (593)		PPD (593)	PPD	1	4	N	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Fatal (PPD)	NOT RELATED/OTHER: Hemorrhagic stroke, Mx history, severe sepsis.	3	150	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	Fatal (PPD)	NOT RELATED/OTHER: hemorriahagic stroke	3	150	Y
3	Fatal (PPD)	NOT RELATED/OTHER: Mx history of PPD	3	150	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , a 70-year-old PPD , with a pertinent medical history of PPD , received Dose 1 on PPD , Dose 2 on PPD (Day 22), and Dose 3 on PPD (Day 444).

Concomitant medications received within 2 weeks prior to the onset of the septic endocarditis, hemorrhagic stroke, and acute myocardial infarction included PPD

The subject experienced severe septic endocarditis, hemorrhagic stroke, and acute myocardial infarction (non-ST-elevation) on PPD , 149 days after receiving Dose 3, and died on the same day.

The information about the subject's death was conveyed by PPD when the site called to discuss e-diary noncompliance. Relevant tests were unknown. An autopsy was not performed.

In the opinion of the investigator, there was no reasonable possibility that the septic endocarditis, hemorrhagic stroke, and acute myocardial infarction were related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per the investigator, the acute myocardial infarction was related to the hemorrhagic stroke, underlying medical history, and severe sepsis; the septic endocarditis was related to the medical history of PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (29)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Cardio-respiratory arrest	PPD	PPD (402)		PPD (402)		1	4	W	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Fatal (PPD)	NOT RELATED/OTHER: Cardiopulmonary arrest, no other details to report.	2	374	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a ≥75-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 29). The subject experienced cardio-respiratory arrest on PPD, 373 days after receiving Dose 2, and died on the same day. An autopsy was not performed.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Narrative Comment
In the opinion of the investigator, there was no reasonable possibility that the cardio-respiratory arrest was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (183)	PPD
VACCINATION 4	BNT162b2	PPD (204)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Acute myocardial infarction	PPD	PPD (267)	PPD	PPD (267)	PPD	1	4

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Underlying diseases	4	64	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 60-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 21). On PPD , the subject's blood calcium was 3662 (unit and reference range not provided), and a cardiac perfusion scan performed on PPD was negative. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 183) and PPD (Day 204), respectively. Concomitant medications received within 2 weeks prior to the onset of the acute myocardial infarction included PPD The subject suffered an acute myocardial infarction on PPD , 63 days after receiving Dose 4 (second dose of BNT162b2), and died on the same day. On PPD (Day 267), while at home, the subject woke up and went to the bathroom. After returning to PPD bed, PPD laid down on PPD side and suffered an acute myocardial infarction (at PPD). The subject was transported to the emergency room where resuscitation was unsuccessful, and PPD was declared dead. The cause of death was acute myocardial infarction (progression of underlying disease). An autopsy was not performed.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Narrative Comment
In the opinion of the investigator, there was no reasonable possibility that the acute myocardial infarction was related to BNT162b2, concomitant medications, or clinical trial procedures but rather it was related to the underlying diseases. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was associated with the subject's underlying contributory factors, including PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (24)	PPD
VACCINATION 3	BNT162b2	PPD (212)	PPD
VACCINATION 4	BNT162b2	PPD (231)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Death	PPD	PPD (316)		PPD ()			4
2	METAB	Hyperkalaemia		PPD (191)		PPD (204)		14	2
3	METAB	Obesity		PPD (204)		PPD (316)		113	2
4	INFEC	Urinary tract infection		PPD (191)		PPD (199)		9	2

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Unknown cause of death	4	86	Y
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: Unknown	2	168	N
3	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: Obesity	2	181	N
4	TC	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	168	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 60-year-old PPD with a reported medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 24). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 212) and PPD (Day 231), respectively. The subject died of an unknown cause on PPD , 85 days after receiving Dose 4 (second dose of BNT162b2). This subject, with an ongoing history of PPD decided to undergo gastric bypass revision surgery after multiple unsuccessful attempts to lose weight. The procedure was performed successfully without any complications, and the subject was in the hospital for 2 days (PPD to PPD) for postoperative care. On PPD (Day 316), the subject died of unknown non-COVID-19 related causes. The PPD was ongoing at the time of death. It was unknown if an autopsy was performed. No additional details were provided for this event as the subject's family declined to provide any further information. In the opinion of the investigator, there was no reasonable possibility that the death was related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the subject's multiple comorbidities should be considered as an alternative explanation for the subject's demise.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Arteriosclerosis	PPD	PPD (63)		PPD (63)		1
2	CARD	Hypertensive heart disease		PPD (63)		PPD (63)		1

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	42	Y
2	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Unknown	2	42	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD , a 60-year-old PPD with a pertinent medical history of PPD to unknown date), received Dose 1 on PPD and Dose 2 on PPD (Day 22). Concomitant medications received within 2 weeks prior to the onset of the hypertensive heart disease and arteriosclerosis included PPD The subject died on PPD, 41 days after receiving Dose 2. An autopsy determined the causes of death as hypertensive heart disease and arteriosclerosis. Of note, the subject had risk factors of PPD , which put PPD at high risk for cardiac/acute myocardial infarction death. The events did not require a visit to the emergency room. In the opinion of the investigator, there was no reasonable possibility that the hypertensive heart disease and arteriosclerosis were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NERV	Dementia Alzheimer's type	PPD	PPD (233)		PPD (233)		1	4	W	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Fatal (PPD)	NOT RELATED/OTHER: rapid onset/progression of Alzheimer and Dementia	2	212	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a ~~75~~-year-old PPD with a pertinent medical history of PPD (both since unknown dates), received Dose 1 on PPD and Dose 2 on PPD (Day 22). The subject experienced progression of Alzheimer's disease and dementia on PPD, 211 days after receiving Dose 2, and died on the same day. The information about the subject's death was reported to the site by PPD friend. The site confirmed the diagnosis of Alzheimer's disease via an obituary, and the subject's medical records from hospice confirmed the medical history of PPD. No additional details were provided, and the subject's family declined to provide any further information. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the progression of Alzheimer's disease and dementia was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (23)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (415)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	RESP	Acute respiratory failure	PPD	PPD (603)		ONGOING			4	TC	Y
2	INV	Biopsy skin		PPD (513)	PPD	PPD (513)		1	1	TCN	N
3	GENRL	Chills		PPD (38)		PPD (39)	PPD	2	1	N	N
4	HEPAT	Cholelithiasis		PPD (3)		PPD (85)		83	2	TCN	N
5	SKIN	Dermal cyst		PPD (46)		PPD (46)		1	2	TCN	N
6	INFEC	Diverticulitis		PPD (47)		PPD (47)		1	1	N	N
7	INJ&P	Fall		PPD (603)		PPD (603)		1	4	N	Y
8	MUSC	Myalgia		PPD (38)		PPD (39)		2	1	N	N
9	GASTR	Nausea		PPD (38)		PPD (39)		2	1	N	N
10	VASC	Neurogenic shock		PPD (603)		PPD (605)		3	4	TC/W	Y
11	RESP	Pulmonary embolism		PPD (603)		ONGOING			4	TC	Y
12	MUSC	Rhabdomyolysis		PPD (603)		PPD (605)		3	3	TC	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
13	INFEC	Sepsis	PPD	PPD (603)		ONGOING			4	TC	Y
14	INJ&P	Spinal cord injury		PPD (603)		PPD (605)		3	4	TC/W	Y
15	MUSC	Spondylitis		PPD (3)		PPD (435)		433	1	N	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Yes	NOT RELATED/OTHER: trauma	3	189	N
2	Resolved (PPD)	NOT RELATED/OTHER: unk	3	99	N
3	Resolved (PPD)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	16	N
4	Resolved (PPD)	NOT RELATED/OTHER: FOUND DURING IMAGING EVENT	1	3	N
5	Resolved (PPD)	NOT RELATED/OTHER: RECURRENT SEBACEOUS CYST	2	24	N
6	Resolved (PPD)	NOT RELATED/OTHER: INCIDENTAL FINDING	2	25	N
7	Resolved (PPD)	NOT RELATED/OTHER: unknown	3	189	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
8	Resolved (PPD)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	16	N
9	Resolved (PPD)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	16	N
10	Fatal (PPD)	NOT RELATED/OTHER: trauma	3	189	Y
11	Yes	NOT RELATED/OTHER: trauma	3	189	N
12	Resolved (PPD)	NOT RELATED/OTHER: TRAUMA	3	189	N
13	Yes	NOT RELATED/OTHER: TRAUMA	3	189	N
14	Fatal (PPD)	NOT RELATED/OTHER: unknown at this time	3	189	Y
15	Resolved (PPD)	NOT RELATED/OTHER: PLANNED IMAGING EVENT SCHEDULED PRIOR TO SCREENING PPD	1	3	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD
		PPD
		PPD
		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a ≥75-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD, Dose 2 on PPD (Day 23), and Dose 3 on PPD (Day 415). Concomitant medications received within 2 weeks prior to the onset of the spinal cord injury and neurogenic shock included PPD The subject experienced a spinal cord injury and neurogenic shock on PPD, 188 days after receiving Dose 3, and died of the events on PPD, 190 days after receiving Dose 3. On PPD (Day 603), the subject fell in the PPD and suffered a spinal cord injury. Approximately 10 hours later, the subject's PPD, and a fall was suspected. On the same day (Day 603), the subject was taken to the emergency room and was subsequently hospitalized. Upon assessment in the hospital, PPD was found to have multiple wounds on PPD face, chest, left thigh, right knee, and was unable to move PPD upper and lower extremities spontaneously. The subject also developed a pulmonary embolism, acute respiratory failure, rhabdomyolysis, and sepsis on the same day (Day 603). The subject's vital signs showed a body temperature of 29°C, heart rate of 45 beats/min, oxygen saturation of 77% on room air, and PPD was hypotensive (blood pressure readings not reported). The subject's venous blood gas results showed a pH of 7.14 (normal range [NR]: 7.32-7.43), partial pressure of oxygen of 60 mmHg (NR: 35-40 mmHg), partial pressure of carbon dioxide of 85 mmHg (NR: 40-50 mmHg), and bicarbonate of 30 mmol/L (NR: 20-30 mmol/L). PPD was intubated, a central venous catheter was placed, and "PPD was started for warming." The subject received PPD for sedation, PPD. The subject continued to show extreme blood pressure instability throughout PPD admission. The subject's admission laboratory test results included a white blood cell (WBC) count of 13.2 K/mm^3 (NR: 3.8-9.9 K/mm^3), a red blood cell count of 5.53 M/mm^3 (NR: 3.90-5.20 M/mm^3), hemoglobin of 16.4 g/dL (NR: 11.9-15.5 g/dL), hematocrit of 48.6% (NR: 35.6%-45.5%), platelets of 184 K/mm^3 (NR: 150-400 K/mm^3), ethanol of <10 (NR: ≤10), potassium of 5.3 mmol/L (NR: 3.3-4.9 mmol/L), sodium of 142 mmol/L (NR: 135-145 mmol/L), chloride of 108 mmol/L (NR: 97-110 mmol/L), blood urea nitrogen of 29 mmol/L (NR: 8-25 mmol/L), creatinine of 0.47 mg/dL (NR: 0.60-1.10 mg/dL), estimated glomerular filtration rate of 74 mL/min/1.73 m^2 (NR: 90-130 mL/min/1.73 m^2), alanine aminotransferase of 150 U/L (NR: 7-45 U/L), aspartate aminotransferase of 466 U/L (NR: 10-45 U/L), and creatine phosphokinase of 9194 U/L (NR: 200-300 U/L). The subject's arterial blood gas results showed a pH of 7.36 (NR: 7.35-7.45), partial oxygen of 311 mmHg (NR: 83-108 mmHg), partial carbon dioxide of 36 mmHg (NR: 35-45 mmHg), and bicarbonate of 21 mmol/L (NR: 20-30 mmol/L). The subject's urine drug screen result was unremarkable. After 4 hours, repeat laboratory test results showed a WBC count of 32.3 K/mm^3 (NR: 3.8-9.9 K/mm^3), lactate of 6.0 mmol/L (NR: 0.7-2.0 mmol/L), and troponin of 62 ng/L (NR: ≤17 ng/L).

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
A computed tomography (CT) angiogram scan of the head and neck showed bilateral anterior maxillary fractures with overlying hematoma, an anterior cartilaginous septal hematoma, and a diffuse idiopathic skeletal hyperostosis. A CT scan of the chest, abdomen, and pelvis with contrast showed a lobar pulmonary embolism of the right pulmonary artery. On an unknown date, a nasopharyngeal swab was collected for multiple test components, which showed negative results for influenza (A and B), respiratory syncytial virus, COVID-19, coronavirus (229E, HKU1, NL63, and OC43), adenovirus, rhinovirus/enterovirus, parainfluenza virus (1, 2, 3, and 4), *Chlamydia pneumoniae*, *Mycoplasma pneumoniae*, and pertussis. The subject experienced shock requiring fluid resuscitation. The primary complication associated with rhabdomyolysis was acute kidney injury; however, PPD creatinine never exceeded 1.6 mg/dL (NR: 0.6-1.1 mg/dL). On an unknown date, the subject had elevated muscle enzymes, and renal function had moderately declined without any requirement of additional therapies. On PPD, a venous duplex imaging showed bilateral acute deep vein thrombosis in the lower extremities. A magnetic resonance imaging (MRI) of the total spine showed low signal at C3-C4, likely representing cord edema and contusion. An edema with discontinuity of bridging anterior osteophytes at C3-C4 and C5-C6 likely represented a fracture. Hyperintense signal in the C3-C4 intervertebral disc was concerning for disc rupture. Superior to this, there was T1 and T2 hyperintense fluid in the ventral epidural space, representing a 3-mm epidural hematoma. Posterior to C4, the posterior longitudinal ligament was thinned and had T2 hyperintense signal, which was concerning for injury. There was also disruption of the nuchal ligament at the level of C1-C2. The MRI determined that there was a severe cervical spine injury. After discussing the goals of care with the subject's family, the subject was transitioned to comfort care with a 'PPD' order. On PPD (Day 605), the subject died from the spinal cord injury and neurogenic shock. The pulmonary embolism, acute respiratory failure, rhabdomyolysis, and sepsis were ongoing at the time of the subject's death. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the spinal cord injury and neurogenic shock were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per the investigator, the neurogenic shock was related to trauma (fall). Per Pfizer, the spinal cord injury was related to the fall.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_CSR_Safety_Narrative/profile. (Database Snapshot Date: 07MAR2023) Date of Generation: 13APR2023 (10:53)

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (24)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Cardiac arrest	PPD	PPD (96)		PPD (96)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Unknown	2	73	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 24). Concomitant medications received within 2 weeks prior to the cardiac arrest included PPD The subject suffered a cardiac arrest on PPD, 72 days after receiving Dose 2, and died on the same day. On PPD (Day 96), the subject's PPD notified the site that the subject had died in PPD sleep because of immediate cardiopulmonary arrest. The subject's PPD reported that the night before PPD death, PPD had taken an unspecified PPD for PPD PPD;

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Narrative Comment
these medications were previously used by the subject (dates unknown). No symptoms or illnesses leading to the subject's death were reported. The subject was not seen in the hospital. The coroner was called to pronounce death; an autopsy was not performed. On PPD, the subject's PPD stated that the cause of death on the death certificate was cardiac arrest (also described as cardiopulmonary arrest). In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the subject's underlying PPD might be the more likely explanations for the cardiac arrest.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (204)	PPD
VACCINATION 4	BNT162b2	PPD (225)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	Injury	PPD	PPD (573)		PPD (573)		1
2	INJ&P	PPD		PPD (573)		PPD (573)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	4	349	Y
2	4	W	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	4	349	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Narrative Comment
Subject PPD, a 30-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 204) and PPD (Day 225), respectively. The subject experienced a traumatic injury due to PPD on PPD, 348 days after receiving Dose 4 (the second dose of BNT162b2), and died on the same day. On PPD (Day 573), the subject was involved in PPD. The subject was pronounced dead at the PPD. The subject's PPD stated that PPD might have suffered a seizure. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the traumatic injury due to PPD was related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	EYE	Blindness unilateral	PPD	PPD (86)		ONGOING		
2	NEOPL	Lung cancer metastatic		PPD (86)		PPD (132)		47

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	N	Y	Yes	NOT RELATED/OTHER: UNKNOWN	2	67	N
2	4	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: UNKNOWN	2	67	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a 50-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 20). The subject was diagnosed with metastatic lung cancer on PPD, 66 days after receiving Dose 2, and died of the event on PPD, 112 days after receiving Dose 2. On PPD (Day 86), the subject went to an urgent care clinic because of blurred vision and was sent to the emergency room. The subject was treated with PPD On an unspecified date in PPD, 2 magnetic resonance imaging scans (1 with dye), 2 computed tomography scans (1 with dye), and a bronchial test (unspecified) were performed. The doctors reported a diagnosis of metastatic lung cancer that had spread to the abdomen and brain; the subject also had lost vision in PPD left eye (unilateral blindness) with the onset date of PPD (Day 86).

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
On PPD (Day 132), the subject died of the metastatic lung cancer. The unilateral blindness was ongoing at the time of the subject's death. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the metastatic lung cancer was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Death	PPD	PPD (672)		PPD (672)		1
2	VASC	Hypertension		PPD (1)	PPD	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Unknown	2	651	Y
2	2	TC	N	Yes	NOT RELATED/OTHER: unknown	.	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, an ≥75-year-old PPD with a reported medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22). The subject died of an unknown cause on PPD, 650 days after receiving Dose 2. The information about the subject's death was conveyed by PPD when the site called to inquire about a missed visit. No additional information was provided. An autopsy was not performed because of the subject's age.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention. Pfizer concurred with the investigator's causality assessment. Per the investigator, the event was unrelated to clinical trial procedures.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Cardio-respiratory arrest	PPD	PPD (107)	PPD	PPD (107)		1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: underlying PPD	2	86	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 50 -year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 22). The subject experienced cardiopulmonary arrest on PPD , 85 days after receiving Dose 2, and died on the same day. On PPD (Day 107), the subject PPD . PPD PPD went down to check on PPD since it had been a while and found that the subject was sitting cross-legged, leaning forward, and was blue in the face. On PPD at PPD , the subject's PPD called the study site to report the subject's death, which occurred at PPD on PPD (Day 107). The cause of death was cardiopulmonary arrest. An autopsy was performed; however, the results were not available.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
In the opinion of the investigator, there was no reasonable possibility that the cardiopulmonary arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per the investigator, the event was related to the subject's underlying PPD.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (165)	PPD
VACCINATION 4	BNT162b2	PPD (186)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (473)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD
		PPD

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 70-year-old PPD with a reported medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 165), PPD (Day 186), and PPD (Day 473), respectively. The subject died on an unspecified date. On PPD , the site updated the subject's disposition status for the study follow-up phase as "withdrawn" because of the death. This death event occurred outside the protocol-defined postvaccination safety reporting period and, as such, was reported only as an update to the subject's disposition status and not as an adverse event. No additional details will be provided for this event.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Myocardial infarction	PPD	PPD (89)		PPD (90)		2	4
2	INFEC	Pneumonia		PPD (90)		PPD (121)	PPD	32	4

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Y	Resolved (PPD)	NOT RELATED/OTHER: failed cardiac stent	2	70	N
2	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: infection	2	71	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 20). Concomitant medications received within 2 weeks prior to the onset of the pneumonia included PPD. On PPD (Day 89), the subject suffered a myocardial infarction due to failure of a cardiac stent. The subject was hospitalized, and the failed stent was removed and replaced. On PPD (Day 90), the myocardial infarction was considered resolved. After the stent replacement procedure, the subject developed pneumonia on PPD, 70 days after receiving Dose 2, and discharged against medical advice on PPD. The site reported that it was not COVID-19 pneumonia, as the subject's COVID-19 test result (date unspecified) was negative. The subject died of pneumonia at PPD on PPD, 101 days after receiving Dose 2. On an unknown date, the site contacted the subject regarding a missed e-diary entry, during which the subject's PPD informed the site about the subject's death. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the pneumonia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (153)	PPD
VACCINATION 4	BNT162b2	PPD (175)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	PPD		PPD (248)	PPD	PPD (248)	PPD	1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	4	74	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

==========

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (21)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Myocardial infarction	PPD	PPD (149)		PPD (149)		1

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	2	129	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a ≥75-year-old PPD with a pertinent medical history of PPD (since an unknown date); PPD (all on unknown dates), received Dose 1 on PPD and Dose 2 on PPD (Day 21). Concomitant medications received within 2 weeks prior to the onset of the myocardial infarction included PPD The subject experienced a myocardial infarction on PPD, 128 days after receiving Dose 2, and died on the same day. On PPD, the subject visited PPD doctor and it was reported that PPD was feeling well at this time. It was reported that the subject did not have any side effects after receiving Dose 1 and Dose 2. On PPD, the family spoke to the subject for the last time. The site received a call from the subject's PPD reporting that PPD had died on PPD (Day 149); the subject's PPD. When the subject's PPD arrived, PPD found that there was a PPD PPD skin was mottled, bruised, and rigid. The emergency medical technician noted no lacerations that could cause the pool of blood and estimated that PPD might have died 3 to 5 days before PPD body was found. The cause of death was reported as myocardial infarction per the medical examiner. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per the investigator, the event was related to the subject's PPD.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (21)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Death	PPD	PPD (579)		PPD (579)		1	4
2	INJ&P	Fall		PPD ()		PPD ()			2
3	MUSC	Rotator cuff syndrome		PPD ()		PPD ()			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: UNK waiting on death certificate	2	559	Y
2	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: UNK	2	47	N
3	TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: mechanical fall	2	47	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 40-year-old PPD with a reported medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 21). Concomitant medication received within 2 weeks prior to the subject's death included PPD The subject died on PPD, 558 days after receiving Dose 2. On an unknown date in PPD, the subject fell and suffered a rotator cuff syndrome, and had it repaired. On an unknown date in PPD, the rotator cuff syndrome was considered resolved. The subject was having a balance problem, and during the night of PPD and PPD (Day 579) when PPD woke up to take PPD; PPD tripped, fell, hit PPD head, and died. The subject's death information was reported by PPD to the site. The reported cause of death was unknown. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (24)	PPD
VACCINATION 3	BNT162b2	PPD (122)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	VASC	Aortic stenosis	PPD	PPD (137)		PPD (145)		9	3
2	CARD	Cardio-respiratory arrest		PPD (147)	PPD	PPD (147)	PPD	1	4

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Y	Resolved (PPD)	NOT RELATED/OTHER: atherosclerosis	3	16	N
2	W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	3	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Withdrawn	OPEN LABEL TREATMENT	PPD	DEATH
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , an ≥75-year-old PPD with a pertinent medical history of PPD to an unknown date), PPD received Dose 1 on PPD and Dose 2 on PPD (Day 24). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first dose of BNT162b2 on PPD (Day 122). Concomitant medication received within 2 weeks prior to the onset of the cardiopulmonary arrest included PPD The subject suffered cardiopulmonary arrest on PPD, 25 days after receiving Dose 3 (the first dose of BNT162b2), and died on the same day. The subject's PPD reported that the subject suffered shortness of breath and was taken to the emergency room on PPD (Day 137). Subsequently, the subject was hospitalized on the same day (Day 137) because of the worsening aortic stenosis. Per the investigator, the worsening aortic stenosis was related to atherosclerosis. The subject underwent an angiogram, and a stent insertion was recommended. The worsening aortic stenosis was considered resolved on PPD (Day 145), and the subject was discharged from the hospital on the same day. The subject had lain down for a nap on PPD (Day 147) and never woke up. The subject's PPD was unaware of the cause of death. PPD also reported that the stent insertion was not completed during the

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
hospitalization, as the cardiologist did not feel it was an urgent need. Later, on PPD, a death certificate received from the subject's primary care physician stated that the immediate cause of death was cardiopulmonary arrest secondary to a PPD. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the cardiopulmonary arrest was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (159)	PPD
VACCINATION 4	BNT162b2	PPD (180)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (441)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Adenocarcinoma pancreas	PPD	PPD ()		PPD (562)	PPD		3
2	CARD	Cardiac failure congestive		PPD (558)		PPD (562)	PPD	5	3
3	CARD	Cardio-respiratory arrest		PPD (562)		PPD (562)	PPD	1	3
4	INFEC	Pneumonia		PPD (558)		PPD (562)	PPD	5	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Cancer	5	50	Y
2	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Heart Failure	5	118	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	5	122	Y
4	TC	Y	Fatal (PPD)	NOT RELATED/OTHER: Respiratory Bacterial Infection	5	118	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , a 70-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 23).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 159), PPD (Day 180), and PPD (Day 441), respectively.

The subject was diagnosed with pancreatic adenocarcinoma in PPD , approximately 49 days after receiving Dose 5 (the third dose of BNT162b2) and congestive cardiac failure and pneumonia, both on PPD , 117 days after receiving the third dose of BNT162b2.

On an unknown date in PPD , the subject was under outpatient evaluation for pancreatic adenocarcinoma. On PPD (Day 558), the subject presented to the emergency room with complaints of shortness of breath and abdominal pain. The subject was hospitalized and treated with oxygen via nasal cannula for hypoxia. During the hospitalization, the subject was diagnosed with bilateral pneumonia (respiratory bacterial infection) leading to decompensation of congestive heart failure and atrial fibrillation. On the same day (Day 558), the laboratory test results showed blood creatinine of 0.55 mg/dL, blood sodium of 127 mmol/L (normal ranges [NR] not provided for all), hemoglobin of 12.7 (NR and units not provided), and a white blood cell count of $13.9\times10^3/mm^3$ (NR not provided). A computed tomography (CT) scan of the thorax showed moderate compressive atelectatic changes in both

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Narrative Comment
lower lobes with superimposed mild consolidation at the left lung base and moderate bilateral pulmonary embolism with no evidence of central pulmonary embolism. On an unknown date, the subject's laboratory test results showed elevated blood lactic acid, hypotension, and leukocytosis. A CT scan and chest x-ray showed lateral infiltrates and moderate bilateral pleural effusion. Sepsis was suspected, and the subject was treated with PPD On PPD, the subject's laboratory test results showed low lymphocytes of 4%, a high neutrophil count of $13.76\times10^3/mm^3$, and a high neutrophil percentage of 80% (NR not provided for all). The subject's condition did not improve, and PPD agreed on palliative care. The subject suffered cardiorespiratory arrest on PPD, 121 days after receiving the third dose of BNT162b2, and died on the same day. The reported causes of death were decompensated congestive cardiac failure, worsening pancreatic adenocarcinoma, cardiorespiratory arrest, and pneumonia. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the pancreatic adenocarcinoma, congestive cardiac failure, cardiorespiratory arrest, and pneumonia were related to BNT162b2. Pfizer concurred with the investigator's causality assessment and further stated that the events were not related to clinical trial procedures.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (174)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PSYCH	PPD	PPD	PPD (178)	PPD	PPD (178)	PPD	1
2	NERV	Hypoaesthesia		PPD (31)		PPD (31)		1

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	3	5	Y
2	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: muscle strain	2	9	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	OPEN LABEL TREATMENT	PPD	DEATH
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Cardiac arrest	PPD	PPD (52)	PPD	PPD (52)	PPD	1
2	GENRL	Injection site pain		PPD (23)	PPD	PPD (24)	PPD	2
3	GENRL	Injection site pain		PPD (1)		PPD (1)	PPD	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: cardiac related	2	31	Y
2	1	N	N	Resolved (PPD)	Study Treatment	2	2	N
3	1	N	N	Resolved (PPD)	Study Treatment	1	1	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	DEATH
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD , a ≥75-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22). Concomitant medication received within 2 weeks prior to the cardiac arrest included PPD (since an unknown date) PPD . The subject suffered cardiac arrest on PPD , 30 days after receiving Dose 2, and died on the same day. On PPD (Day 52), the subject collapsed PPD . The subject was unresponsive, and cardiopulmonary resuscitation was performed. An ambulance was called, and the emergency medical services found the subject to have ventricular tachycardia (heart rate not reported) followed by ventricular fibrillation. Two rounds of defibrillation with PPD were done. Chest compressions were performed, and PPD PPD were administered. An echocardiogram performed at bedside revealed cardiac standstill. Resuscitation efforts were terminated, and the subject died on the same day (Day 52) because of the cardiac arrest. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (195)	PPD
VACCINATION 4	BNT162b2	PPD (216)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (512)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	MUSC	Back pain	PPD	PPD (6)	PPD	PPD (6)	PPD	1	1	N	N
2	GENRL	Death		PPD (552)		PPD (552)		1	4	W	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
3	GASTR	Inguinal hernia	PPD	PPD ()		PPD (552)			1	N	N
4	GENRL	Vaccination site pain		PPD (196)	PPD	PPD (198)	PPD	3	1	N	N
5	GASTR	Nausea		PPD (195)	PPD	PPD (195)	PPD	1	1	N	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (PPD)	NOT RELATED/OTHER: Subject reports low back pain after doing strenuous activity	1	6	N
2	Fatal (PPD)	NOT RELATED/OTHER: Incidental death due to natural causes	5	41	Y
3	Resolved (PPD)	NOT RELATED/OTHER: Due to PPD	4	170	N
4	Resolved (PPD)	Study Treatment	3	2	N
5	Resolved (PPD)	Study Treatment	3	1	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD , a 70-year-old PPD with a reported medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 21).
In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 195), PPD (Day 216), and PPD (Day 512), respectively.
Concomitant medications received within 2 weeks prior to the subject's death included PPD for increased blood cholesterol. The subject additionally received an PPD a nonstudy vaccine, on PPD
The subject died due to natural causes on PPD , 40 days after receiving Dose 5 (the third dose of BNT162b2).
The subject's PPD found PPD dead at PPD home and reported the death to the site. An autopsy was not performed.
In the opinion of the investigator, there was no reasonable possibility that the death was related to BNT162b2. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Cardiac arrest	PPD	PPD (138)		PPD (138)	PPD	1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Underlying Comorbidities	2	117	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22). Concomitant medications received within 2 weeks prior to the cardiac arrest included PPD The subject suffered cardiac arrest on PPD, 116 days after receiving Dose 2, and died on the same day. On PPD (Day 138), the subject experienced seizure-like activity and collapsed; PPD was taken to the emergency room (ER) in cardiac arrest with bystander cardiopulmonary resuscitation (CPR) and electrical muscle stimulation (EMS) CPR. The subject was initially found to be in ventricular tachycardic arrest (as reported) on initial rhythm by EMS, and PPD received PPD along with subsequent CPR attempts. Per emergency medical services, PPD received PPD. The subject was in asystole before arrival at the ER, and PPD was unresponsive upon physical examination. PPD was defibrillated with 200 J of biphasic electricity but continued to be in pulseless electrical activity and pulseless ventricular fibrillation. Despite appropriate CPR, the subject's carbon dioxide (as reported) continued to drop, and a bedside echocardiogram showed no cardiac activity with complete cardiac standstill. Resuscitative efforts were ceased because of the significantly decreased probability of regaining spontaneous circulation. The subject died of cardiac arrest on PPD (Day 138) at PPD. An autopsy was not performed. Of further note, the subject had reported "sniffles" on PPD, which was not considered to be serious, and had a blood test on an unspecified date that showed COVID-19 antibodies. In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to the subject's underlying comorbidities. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs – Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (174)	PPD
VACCINATION 4	BNT162b2	PPD (195)	PPD

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	RENAL	Acute kidney injury	PPD	PPD (366)		ONGOING			3	TC	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
2	CARD	Aortic valve incompetence	PPD	PPD (44)		ONGOING			2	N	Y
3	CARD	Cardiac arrest		PPD (388)		PPD (388)		1	4	W	Y
4	GENRL	Injection site pain		PPD (175)	PPD	PPD (176)	PPD	2	1	N	N
5	INFEC	Kidney infection		PPD (366)		ONGOING			3	TC/TCN	Y
6	INFEC	Renal abscess		PPD ()		ONGOING			3	N	N
7	INFEC	Subcutaneous abscess		PPD ()		PPD ()			2	TC	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Yes	NOT RELATED/OTHER: Incidental Medical Diagnosis	4	172	N
2	Yes	NOT RELATED/OTHER: pre-existing medical history	2	23	N
3	Fatal (PPD)	NOT RELATED/OTHER: Subject with significant PPD related medical history	4	194	Y
4	Resolved (PPD)	Study Treatment	3	2	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	Yes	NOT RELATED/OTHER: Incidental Medical Diagnosis	4	172	N
6	Yes	NOT RELATED/OTHER: SAE of acute kidney infection	4	154	N
7	Resolved (PPD)	NOT RELATED/OTHER: MRSA infection	2	84	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , a 70-year-old PPD with a pertinent medical history of PPD ; and methicillin-resistant *Staphylococcus aureus* following an axilla abscess PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 22).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 174) and PPD (Day 195), respectively.

Concomitant medications received within 2 weeks prior to the cardiac arrest included PPD

The subject suffered cardiac arrest on PPD , 193 days after receiving Dose 4 (the second dose of BNT162b2), and died on the same day.

On PPD (Day 366), the subject was admitted to the hospital with an acute kidney injury (AKI), possibly due to intravenous contrast use. PPD had a large subdiaphragmatic fluid density collection in the right kidney and underwent interventional radiology-guided drain placement. The culture results were

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Narrative Comment
positive for methicillin-resistant *S aureus,* and PPD was treated with PPD. PPD underwent surgical drainage of the renal abscess. A transesophageal echocardiogram ruled out cardiac seeding by *S aureus*. PPD developed pneumonia and was treated with PPD. On the morning of PPD (Day 388), the subject was unresponsive, and cardiopulmonary resuscitation was initiated. PPD received PPD without return of spontaneous circulation. PPD died on the same day with ongoing anemia, AKI, leukocytosis, and hyponatremia. The reported cause of death was cardiac arrest. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to BNT162b2, concomitant medications, or clinical trial procedures, but rather it was related to the subject's underlying PPD history. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was associated with severe infectious conditions and the subject's underlying PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (183)	PPD
VACCINATION 4	BNT162b2	PPD (202)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (624)		PPD (624)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Massive Trauma	4	423	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD, a ≤24-year-old PPD with no reported medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 21).

In accordance with the protocol allowance, the subject's PPD agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 183) and PPD (Day 202), respectively.

The subject was involved in PPD on PPD, 422 days after receiving Dose 4 (the second dose of BNT162b2), and died on the same day.

On PPD (Day 624), the subject was PPD. The subject was found dead at the PPD. The reported cause of death was PPD. It was unknown if an autopsy was performed.

In the opinion of the investigator, there was no reasonable possibility that the PPD was related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (142)	PPD
VACCINATION 4	BNT162b2	PPD (161)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Amyotrophic lateral sclerosis	PPD	PPD ()		PPD (337)			4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Cause not determined	4	143	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 50-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 142) and PPD (Day 161), respectively. Concomitant medications received within 2 weeks prior to the worsening ALS included PPD for bulbar ALS. The subject's bulbar ALS worsened in PPD, approximately 142 days after receiving Dose 4 (the second dose of BNT162b2), and the subject died of the event on PPD, 176 days after receiving the second dose of BNT162b2. The subject was diagnosed with ALS on PPD and, based on early symptoms, the doctor believed the onset of ALS was in late PPD. The early symptoms, which were present in PPD, included speech and swallowing problems caused by partial paralysis of the throat muscles. The subject received supportive care and treatment for ALS (no specifics reported). The subject's bulbar ALS worsened in PPD, and PPD died of the event (disease progression) on PPD (Day 337). An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the worsening ALS was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (91)	PPD
VACCINATION 4	BNT162b2	PPD (113)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Death	PPD	PPD ()		PPD ()		
2	MUSC	Pain in extremity		PPD (113)	PPD	PPD (114)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal PPD	NOT RELATED/OTHER: unknown	4	324	Y
2	1	N	N	Resolved (PPD)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a 50-year-old PPD with no reported medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 91) and PPD (Day 113), respectively. The subject died on an unspecified date in PPD, approximately 323 days after receiving Dose 4 (the second dose of BNT162b2). The information about the subject's death was obtained from the subject's PPD when the site called regarding e-diary noncompliance. The reported cause of death was unknown. It was unknown if an autopsy was performed. On PPD, the site updated the subject's disposition status for the study follow-up phase as "withdrawn" because of the death. In the opinion of the investigator, there was no reasonable possibility that the death was related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (414)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain upper	PPD	PPD (415)	PPD	PPD (415)	PPD	1	1
2	GENRL	Asthenia		PPD (415)	PPD	PPD (415)	PPD	1	1
3	GENRL	Chills		PPD (415)	PPD	PPD (415)	PPD	1	1
4	NEOPL	Colon cancer stage III		PPD (518)		PPD (617)		100	3
5	NERV	Syncope		PPD (415)		PPD (415)		1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	Study Treatment	3	2	N
2	N	N	Resolved (PPD)	Study Treatment	3	2	N
3	N	N	Resolved (PPD)	Study Treatment	3	2	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Unknown cause	3	105	Y
5	N	N	Resolved (PPD)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD, Dose 2 on PPD (Day 22), and Dose 3 on PPD (Day 414).

Concomitant medications received within 2 weeks prior to the onset of the stage III colon cancer included PPD

The subject was diagnosed with stage III colon cancer on PPD, 104 days after receiving Dose 3, and died of the event on PPD, 203 days after receiving Dose 3.

On PPD (Day 318), the subject had a colonoscopy, which revealed a 4-cm polyp in the ascending colon and a 25-mm polyp in the cecum; PPD was diagnosed with stage III colon cancer. On PPD, a computed tomography (CT) scan of the chest, abdomen, and pelvis showed a cystic lesion in the proximal pancreatic body, which was suggestive of a complex pseudocyst or a cystic pancreatic neoplasm. An additional cystic area was also noted in the pancreatic tail. On PPD, a diagnostic aspiration showed benign epithelial cells with acellular mucin, suggestive of a mucinous neoplasm without high-grade dysplasia or malignancy. On the same day, an endoscopic ultrasound was performed, and the results were unknown. On PPD, the subject underwent a right hemicolectomy.

On PPD, the subject was treated with PPD for the colon cancer. On PPD, after PPD oncologist visit, PPD was immediately hospitalized for presumed dehydration after initiation of PPD. PPD was resuscitated with PPD During PPD hospitalization, PPD had continued complaints of abdominal pain. On PPD, a culture was positive for *Clostridioides difficile* colitis, and a CT scan of

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
the chest, abdomen, and pelvis showed toxic megacolon and microperforation. An abdominal x-ray showed severe interval development (ileus versus bowel obstruction). On PPD, PPD underwent a hemicolectomy procedure. After the procedure, the subject developed acute septic shock, which required intubation, PPD, and continuous renal replacement therapy. Due to PPD grave prognosis, PPD was transitioned to comfort care. On PPD (Day 617), the subject died of stage III colon cancer (disease progression). It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the stage III colon cancer was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (25)	PPD
VACCINATION 3	BNT162b2	PPD (146)	PPD
VACCINATION 4	BNT162b2	PPD (167)	PPD

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD, a 60-year-old PPD with a reported medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 29).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 146) and PPD (Day 167), respectively.

The subject died on an unspecified date. On PPD, the site updated the subject's disposition status for the study follow-up phase as "withdrawn" because of the death. This death event occurred outside the protocol-defined postvaccination safety reporting period and, as such, was reported only as an update to the subject's disposition status and not as an adverse event. No additional details will be provided for this event.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Death	PPD	PPD (8)		PPD (8)		1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: UNDETERMINED CAUSE OF DEATH	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	DEATH
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , a 40-year-old PPD with a reported medical history of PPD on unknown dates), PPD , received Dose 1 on PPD .

The subject died of an unknown cause on PPD , 7 days after receiving Dose 1.

The subject's PPD stated that the subject had no adverse events after receiving Dose 1. On PPD , PPD had a normal evening and went to bed. On PPD (Day 8), the subject's PPD found that the subject had died, and the cause of death was undetermined. On PPD , the subject's PPD reported that the medical examiner stated that the subject died from sudden cardiac failure brought on by 2 rounds of radiation for recurring PPD PPD , which weakened PPD heart. The subject had no changes in PPD health or medications. PPD was still in place at the time of death. The investigator felt that the cause of death was sudden cardiac failure from radiation therapy on 2 separate occasions for PPD . However, this could not be confirmed. In a follow-up report, it was reported that the medical examiner's office determined the cause of death as "undetermined." An autopsy was performed; however, the results were not available to the site.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Narrative Comment
In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention. The investigator further stated that although the full autopsy report was not available, the subject had possible risk factors for thromboembolic disease. PPD possibly had a thromboembolic event related to a history of PPD , or there was a potential toxicity related to the PPD The subject had an PPD since PPD for PPD PPD The investigator stated that PPD was a concomitant device that was a co-suspect in the subject's death. Pfizer concurred with the investigator's causality assessment and further stated that the death was not related to clinical trial procedures.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Shigella sepsis	PPD	PPD (20)		PPD (36)		17	4
2	NERV	Syncope		PPD (20)		PPD (20)		1	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Shigella infection	1	20	Y
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: sepsis related to shigella infection	1	20	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	DEATH
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD.
Concomitant medications received within 2 weeks prior to the onset of the *Shigella* sepsis included PPD
The subject was diagnosed with *Shigella* sepsis on PPD, 19 days after receiving Dose 1, and died of the event on PPD, 35 days after receiving Dose 1.
On PPD, it was reported that the subject was admitted to the hospital on PPD (Day 20) after PPD fainted in the middle of the night. On the same day (Day 20), the syncope resolved. Per medical records from the hospital admission, the subject complained of diarrhea for 2 days, with associated nausea, intermittent vomiting, and increasing lethargy. On arrival, PPD was febrile (body temperature was not reported) and hypotensive (blood pressure was not reported). The subject was awake, alert, and oriented × 3-4, but PPD had mild abdominal pain. The subject was transferred to the intensive care unit. The subject tested negative for COVID-19 at the hospital. Laboratory results showed lactic acidosis (lactic acid was 11.8 mmol/L [normal range: 0.7-2.1 mmol/L]), a stool test showed fecal leukocytosis, and a computed tomography scan of the chest/abdomen showed acute moderate colitis and abundant fluid in the small bowel. On PPD, a gastrointestinal pathogen panel test was positive for *Shigella* species. The subject was diagnosed with *Shigella* sepsis with an onset date of PPD (Day 20) and was treated with PPD PPD also received PPD to control hypotensive episodes. Per the investigator, the cause of the syncope was sepsis related to *Shigella* infection.
On PPD (Day 36), the subject died of *Shigella* sepsis. An autopsy was not performed.
In the opinion of the investigator, there was no reasonable possibility that the *Shigella* sepsis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (54)		PPD (54)		1
2	RESP	Respiratory arrest		PPD (54)		PPD (54)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	2	32	Y
2	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	2	32	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	DEATH
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (95)		PPD (95)		1

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: UNKNOWN	2	74	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 60-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 22). Concomitant medications received within 2 weeks prior to the PPD included PPD. The subject was involved in PPD on PPD, 73 days after receiving Dose 2, and died on the same day. On PPD, an emergency contact stated that the subject had PPD on PPD (Day 95) and was taken to the emergency room and died on the same day. The cause of death was PPD. The emergency contact declined to provide any additional information. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that PPD was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (21)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (363)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Sudden death	PPD	PPD (428)		PPD (428)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: UNKNOWN	3	66	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 60-year-old PPD with no reported medical history, received Dose 1 on PPD, Dose 2 on PPD (Day 21), and Dose 3 on PPD (Day 363). The subject died of an unknown cause on PPD, 65 days after receiving Dose 3. On PPD, the subject developed mild COVID-19 symptoms. On an unreported date, the study coordinator contacted the subject to confirm symptoms including chills, muscle pain, sore throat, and diarrhea. As a result, the subject had a potential COVID-19 illness visit on PPD; during this visit, a nasal swab for COVID-19 testing was collected, but the result was unknown. It was reported that the COVID-19 symptoms were resolving. On PPD (Day 428), the subject died in the middle of the night around PPD. The subject's PPD found PPD unresponsive and immediately called 911 and PPD. The subject was pronounced dead, and the event that caused the sudden death was unknown. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the sudden death was related to the study intervention. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the sudden death was also not related to the clinical trial procedures.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (23)	PPD

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	CARD	Cardio-respiratory arrest	PPD	PPD (234)		PPD (234)		1	4

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Possible cardiac causes	2	212	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, an ≥75-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 23). Concomitant medications received within 2 weeks prior to the onset of the cardiorespiratory arrest included PPD The subject suffered a cardiorespiratory arrest on PPD, 211 days after receiving Dose 2, and died on the same day. A relative found the subject dead at home on PPD (Day 234). The relative stated that they had seen the subject hours earlier in the day and that the subject had shown no signs of distress. According to the death certificate, the cause of death was cardiorespiratory arrest. The subject had preexisting comorbidities, but the relationship between the comorbidities and death was unknown. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the cardiorespiratory arrest was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to possible cardiac causes. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (23)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (475)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Hepatic cancer	PPD	PPD ()		PPD (580)			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Cancer(genetic/environmental factor)	2	210	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD, Dose 2 on PPD (Day 23), and Dose 3 on PPD (Day 475). Concomitant medications received within 2 weeks prior to the onset of the hepatic cancer included PPD (both since an unknown date) PPD (since an unknown date) PPD (since an unknown date) PPD (since an unknown date) PPD (since an unknown date) PPD (since an unknown date) PPD The subject was diagnosed with hepatic cancer in PPD, approximately 209 days after receiving Dose 2, and died of the event on PPD, 105 days after receiving Dose 3. During a 12-month follow-up visit on PPD, the subject reported to the site that PPD was diagnosed with hepatic cancer at another hospital. During a call, the subject's PPD informed the site about the subject's death due to the progression of hepatic cancer. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the hepatic cancer was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (177)	PPD
VACCINATION 4	BNT162b2	PPD (198)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (407)	PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	GENRL	Death	PPD	PPD (764)		PPD (764)		1	4	W

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Fatal (PPD)	NOT RELATED/OTHER: Cause of death has not yet been determined	5	358	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 70-year-old PPD with a reported medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 23). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 177), PPD (Day 198), and PPD (Day 407), respectively. Concomitant medications received within 2 weeks prior to the subject's death included PPD The subject died of an unknown cause on PPD, 357 days after receiving Dose 5 (the third dose of BNT162b2). On PPD, the subject presented to an emergency room (ER) with complaints of dizziness, diminished appetite, and a history of PPD. On arrival at the ER, the subject had irregular heartbeats and required hospitalization. Discharge was planned for PPD (Day 764) if PPD condition remained stable. On the morning of PPD (Day 764), the subject lost consciousness and had no pulse. Multiple attempts were made by the medical staff to save the subject's life, but they were unsuccessful. The cause of death was unknown. An autopsy was performed, but the results were unknown. In the opinion of the investigator, there was no reasonable possibility that the death was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Arteriosclerosis	PPD	PPD (4)		PPD (4)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: underlying disease	1	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH
Withdrawn	VACCINATION	PPD	DEATH

Narrative Comment

Subject PPD , a 60-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD .

Concomitant medications received within 2 weeks prior to the onset of the arteriosclerosis included PPD to an unspecified date) PPD to an unspecified date), PPD .

The subject was diagnosed with arteriosclerosis on PPD , 3 days after receiving Dose 1, and died on the same day.

On PPD (Day 4), the study site received PPD indicating that the PPD had visited the subject's home to perform PPD and found PPD dead. It was reported that the subject's body was cold and had visible lividity. According to the medical examiner, the probable cause of death was progression of atherosclerotic disease. It was unknown if an autopsy was performed (no autopsy results were available at the site).

In the opinion of the investigator, there was no reasonable possibility that the arteriosclerosis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (176)	PPD
VACCINATION 4	BNT162b2	PPD (197)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Cardiac arrest	PPD	PPD (256)		PPD (256)		1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown medical event	4	60	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 23). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 176) and PPD (Day 197), respectively. The subject suffered a cardiac arrest on PPD, 59 days after receiving Dose 4 (the second dose of BNT162b2), and died on the same day. The information about the subject's death was conveyed by PPD friend to the site. The reported cause of death was cardiac arrest. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Cardio-respiratory arrest	PPD	PPD (345)	PPD	PPD (350)	PPD	6

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Unknown	2	326	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 20).

Concomitant medications received within 2 weeks prior to the onset of the cardiorespiratory arrest included PPD

The subject experienced cardiorespiratory arrest on PPD, 325 days after receiving Dose 2, and died of the event on PPD, 330 days after receiving Dose 2.

The subject's PPD contacted the site on PPD to report the subject's death and the following information. On PPD (Day 345), the subject suffered intermittent chest pain. On PPD, the subject developed swollen neck glands and a sore throat, with multiple episodes of vomiting. PPD did not seek medical attention. On PPD, the subject was evaluated by PPD cardiologist, and PPD electrocardiogram showed normal results. On PPD (Day 350), the subject's PPD observed that PPD had labored breathing after PPD had gone to bed at night. The subject was unresponsive to cardiopulmonary resuscitation and emergency services were summoned at PPD; PPD remained unresponsive and resuscitation efforts were unsuccessful. PPD was pronounced dead on arrival at the emergency room. It was noted that PPD had acquired an infection, but the primary site was unknown. The cause of death was reported to be cardiorespiratory arrest. An autopsy was not performed.

In the opinion of the investigator, there was no reasonable possibility that the cardiorespiratory arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, an ≥75-year-old PPD with a reported medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22). The subject also received PPD, a nonstudy PPD, on PPD. The subject died on an unspecified date. On PPD the site updated the subject's disposition status for the study follow-up phase as "withdrawn" because of the death. This death event occurred outside the protocol-defined postvaccination safety reporting period and, as such, was reported only as an update to the subject's disposition status, but not reported as an adverse event. No additional details will be provided for this event.

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	VASC	Aortic dissection	PPD	PPD (86)		ONGOING			4	W	Y
2	CARD	Pericardial haemorrhage		PPD (86)		PPD (86)		1	4	W	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: Hemopericardium secondary to Acute Aortic Dissection	2	65	Y
2	Fatal (PPD)	NOT RELATED/OTHER: Acute Aortic Dissection	2	65	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22). Concomitant medications received within 2 weeks prior to the onset of the aortic dissection and pericardial hemorrhage included PPD The subject developed aortic dissection and pericardial hemorrhage on PPD, 64 days after receiving Dose 2, and died on the same day. On PPD, the subject had a "head cold" with symptoms of congestion and mild intermittent cough, and PPD took PPD and PPD. The symptoms improved on PPD. On PPD (Day 86), the subject was found PPD and was unresponsive at PPD. The paramedics arrived, and the subject was pronounced dead and taken to the medical examiner. An autopsy was performed. Per the death certificate and autopsy report, the cause of death was a pericardial hemorrhage secondary to acute aortic dissection. In the opinion of the investigator, there was no reasonable possibility that the aortic dissection and pericardial hemorrhage were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	COVID-19 pneumonia	PPD	PPD (144)		PPD (197)		54	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Post COVID SYNDROME	2	123	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22). Concomitant medications received within 2 weeks prior to the onset of the COVID-19 pneumonia included PPD The subject was diagnosed with COVID-19 pneumonia on PPD, 122 days after receiving Dose 2, and died of the event on PPD, 175 days after receiving Dose 2. On PPD, the subject showed COVID-19 symptoms. On PPD, a central laboratory test result was positive for COVID-19. PPD exhibited symptoms of shortness of breath for 3 days and presented to PPD primary care physician's office on PPD (Day 144). Due to the shortness of breath and an elevated heart rate of 160 beats/min, the subject was sent to the emergency room. On the same day (Day 144), PPD was admitted to the hospital with suspected viral pneumonia. A chest x-ray on Day 144 revealed patchy infiltrates in the right midlung and both lung bases, which were suggestive of pneumonia. On PPD, the subject was discharged from the hospital. On PPD, PPD was readmitted with the same symptoms as a continuation of the COVID-19 pneumonia. PPD second hospitalization lasted for 15 days. The subject died on PPD (Day 197). The causes of death were reported as hypoxic respiratory failure and COVID-19 pneumonia. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the COVID-19 pneumonia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (23)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Chills	PPD	PPD (24)		PPD (25)		2	1
2	GENRL	Injection site erythema		PPD (24)		PPD (25)		2	1
3	GENRL	Injection site pain		PPD (2)		PPD (4)		3	1
4	GENRL	Injection site pain		PPD (24)		PPD (25)		2	1
5	GENRL	Injection site swelling		PPD (24)		PPD (25)		2	1
6	GASTR	Large intestine perforation		PPD ()		PPD (296)			2
7	MUSC	Myalgia		PPD (24)		PPD (25)		2	1
8	RESP	Pulmonary embolism		PPD (306)		PPD (306)		1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	Study Treatment	2	2	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	N	N	Resolved (PPD)	Study Treatment	2	2	N
3	N	N	Resolved (PPD)	Study Treatment	2	2	N
4	N	N	Resolved (PPD)	Study Treatment	2	2	N
5	N	N	Resolved (PPD)	Study Treatment	2	2	N
6	N	Y	Resolved (PPD)	NOT RELATED/OTHER: Colitis	2	257	N
7	N	N	Resolved (PPD)	Study Treatment	2	2	N
8	W	Y	Fatal (PPD)	NOT RELATED/OTHER: surgery complication	2	284	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 23).

The subject experienced a pulmonary embolism on PPD, 283 days after receiving Dose 2, and died on the same day.

In PPD, the subject underwent an emergency colectomy due to a perforated colon. PPD recovered from the surgery and was discharged home. The perforated colon was considered resolved on PPD (Day 296).

On PPD (Day 306), the subject experienced a pulmonary embolism. PPD was pronounced dead on arrival at the emergency department. No further information or relevant tests were reported. The cause of death was reported as pulmonary embolism. An autopsy was not performed.

In the opinion of the investigator, there was no reasonable possibility that the pulmonary embolism was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per the investigator, the event was related to a surgical complication.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 50-year-old PPD with a reported medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22). The subject received an PPD (nonstudy vaccine) on PPD The subject died on an unspecified date. On PPD , the site updated the subject's disposition status for the study follow-up phase as "withdrawn" because of the death. This death event occurred outside the protocol-defined postvaccination safety reporting period and, as such, was reported only as an update to the subject's disposition status, but not reported as an adverse event. No additional details will be provided for this event.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (114)	PPD
VACCINATION 4	BNT162b2	PPD (135)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	VASC	Shock haemorrhagic	PPD	PPD (351)	PPD	PPD (351)	PPD	1	4	W

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Fatal (PPD)	NOT RELATED/OTHER: Aortic Aneurysm and Small Bowel Fistula	4	217	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , an ≥75-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 114) and PPD (Day 135), respectively.

Concomitant medications received within 2 weeks prior to the onset of the hemorrhagic shock included PPD

The subject suffered a hemorrhagic shock on PPD, 216 days after receiving Dose 4 (the second dose of BNT162b2), and died on the same day.

On PPD (Day 351), the subject died at PPD. The site learned about the death on PPD while checking local obituaries after the subject failed to complete the e-diary. The information about the subject's death was conveyed by PPD emergency contact when the site called on PPD to obtain the cause of death. An autopsy revealed a hemorrhagic shock as the cause of death.

In the opinion of the investigator, there was no reasonable possibility that the hemorrhagic shock was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Staphylococcal sepsis	PPD	PPD (371)		PPD (376)		6

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Microbes	2	352	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD, a 60-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 20).

Concomitant medications received within 2 weeks prior to the onset of the methicillin-resistant *Staphylococcus aureus* (MRSA) sepsis included PPD

The subject was diagnosed with MRSA sepsis on PPD, 351 days after receiving Dose 2, and died of the event on PPD, 356 days after receiving Dose 2.

On an unspecified date, the subject underwent a knee replacement procedure. On PPD, approximately 6 months after receiving Dose 2, the subject was first diagnosed with MRSA. On PPD (Day 371), the subject was hospitalized due to the recurrence of MRSA and progression to MRSA sepsis. On PPD (Day 376), the subject died of MRSA sepsis. It was unknown if an autopsy was performed.

In the opinion of the investigator, there was no reasonable possibility that the MRSA sepsis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Basilar artery aneurysm	PPD	PPD (173)		ONGOING			1
2	NERV	Ischaemic stroke		PPD (299)	PPD	PPD (301)	PPD	3	4

Adverse Events						
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: Possible incidental finding.	2	152	N
2	TCN/W	Y	Fatal (PPD)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	278	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD (since an unknown date), PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22). The subject suffered an ischemic stroke on PPD, 277 days after receiving Dose 2, and died of the event on PPD, 279 days after receiving Dose 2. On PPD (Day 173), the subject experienced a basilar artery aneurysm. On PPD (Day 299), the subject had dental work and was placed on PPD. Subsequently, the subject's PPD found PPD poorly responsive at home and called 911; PPD was transferred to the hospital. A computed tomography angiogram scan showed a basilar thrombus. PPD was put on mechanical ventilation. PPD also had hypertensive urgency with a blood pressure of 263/164 mm Hg. PPD was diagnosed with an ischemic stroke on

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Narrative Comment
Day 299 at PPD. After 48 hours of hospitalization, the subject remained poorly responsive, and PPD elected to terminally wean PPD from the ventilation. On PPD (Day 301), the subject died of an arterial ischemic stroke. The basilar artery aneurysm was considered a predisposing factor; no antipyretic medication was administered. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the ischemic stroke was related to the study intervention or clinical trial procedures, but rather it was related to hypertensive urgency due to PPD and PPD Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NEOPL	Adenocarcinoma pancreas	PPD	PPD (58)		PPD (459)		402	4	TC/TCN/W	Y
2	SKIN	Decubitus ulcer		PPD ()		PPD (169)			2	TCN	N
3	INFEC	Escherichia sepsis		PPD (85)		PPD (87)		3	2	TC	N
4	HEPAT	Hepatic cyst		PPD (83)		PPD (459)		377	1	N	N
5	GENRL	Impaired healing		PPD (120)		PPD (125)		6	2	N	Y
6	GENRL	Oedema peripheral		PPD ()		PPD (117)			1	TC	N
7	CARD	Tachycardia		PPD (99)		PPD (106)		8	1	TC	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	39	Y
2	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	91	N
3	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	66	N
4	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	64	N
5	Resolved (PPD)	NOT RELATED/OTHER: due to surgery pancreatic Adenocarcinoma	2	101	N
6	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	91	N
7	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	80	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
PPD		PPD	PPD	

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 20).

Concomitant medication received within 2 weeks prior to the onset of the adenocarcinoma of the pancreas included PPD

The subject was diagnosed with adenocarcinoma of the pancreas on PPD, 38 days after receiving Dose 2, and died of the event on PPD, 439 days after receiving Dose 2.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Narrative Comment
On PPD, the subject was hospitalized for further examination due to painless icterus. On PPD, an endoscopic retrograde cholangiopancreatography (ERCP) procedure showed suspicion of pancreatic head carcinoma, suspicion of stenosis of malignancy in the bile duct, and suspicion of tumor in the pancreatic duct. A stent was inserted. The pathology was unconfirmed by endosonography. On PPD, the subject was discharged from the hospital since PPD hospital roommate tested positive for COVID-19. On PPD, the subject was re-hospitalized for further examination, and PPD laboratory test results showed a gamma-glutamyl transferase (GGT) of 258 U/L (normal range: 10-71 U/L). On PPD, a SARS-CoV-2 test result was negative. On PPD, the subject was symptom-free and was discharged from the hospital. The subject was quarantined until PPD due to contact with PPD hospital roommate. Due to the COVID-19 regulations in the hospital, further examinations were postponed. On PPD, the subject's laboratory test result showed a GGT of 101 U/L. On PPD, the subject was hospitalized again, and a computed tomography scan of the thorax and abdomen showed a slightly distended pancreatic head with no signs of tumor expansion. On PPD (Day 83), an endosonography procedure showed no pancreatic malignancy, dislocation of the stent in the ductus hepatocholedochus (DHC) in the papilla area of the bile duct with thickened endothelium that was suspicious of a 1-cm tumor, fine needle aspiration in the same location, and an inconspicuous truncus coeliacus and adrenal gland; a small liver cyst was also found. The subject's GGT was 73 U/L, and an esophagogastroduodenoscopy showed no findings. The DHC stent was not visible. On PPD, an ERCP procedure showed the removal of the dislocated stent in the bile duct and filiform stenosis in the distal DHC. A histological biopsy and brush smear cytology were performed, and the removed stent and top of the used brush were also sent for cytology. A new 8 cm, non–self-expanding stent was inserted in the bile duct. The histology of the bile duct biopsy showed suspicion of high-grade intraepithelial neoplasm. The preliminary result of the cytopathology of the bile duct brush smear showed a Papanicolaou (PAP) class 3, atypical adenomatous hyperplasia. Cytopathology of the stent and brush showed a preliminary result PAP class 0 due to non-usable material, and further processing of brush and stent materials was needed. On PPD (Day 85), the subject had a fever (temperature not provided) due to *Escherichia coli* infection and was treated with PPD (from PPD to PPD). On PPD (Day 85) and PPD, the subject's laboratory test results showed a GGT of 272 U/L and 253 U/L, respectively. On PPD, a provisional cytology result showed PAP class 2 chronic erosive inflammation. On PPD, the subject was discharged from the hospital in good condition. The *E coli* sepsis was considered secondary to the suspected adenocarcinoma of the DHC.

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Narrative Comment
On PPD, the subject was hospitalized again. On PPD (Day 99), PPD underwent the following procedures: an exploratory laparotomy, a biopsy of the lobus caudatus, a biopsy of segment 3 of the left liver lobe, a proximal duodenopancreatectomy after a Whipple procedure, a local lymphadenectomy, and a cholecystectomy. On PPD, the subject's liver biopsy from segment 3 showed cholangiofibroma and 2 subcapsular liver exudates from segment 3 showed 2 inflammatory varied cholangiofibromas. The punch biopsy from the lobus caudatus showed fibrosis and edema. No malignancy was confirmed via rapid incision, and no parasites were noted. On PPD, a Whipple preparation histology revealed a tumor-free pancreatic resection margin, a tumor-free DHC resection margin, a Whipple preparation with low differentiate ductal pancreas adenocarcinoma (pancreas head 2, 3 cm), intratumoral and peritumoral lymphangitic carcinomatosis, intratumoral and peritumoral perineural spread of the tumor, tumor infiltration of peripancreatic fat tissue, immediately surrounding pancreatic tissue with high-grade intraepithelial neoplasia in the small pancreatic duct, the spread of the tumor circular in the distal DHC with plicate surrounding, 1 confirmed malignant lymph node (1/4) in the direct area of the tumor, secondary inflammatory changed papilla, tumor-free duodenum and excision margins of the DHC, and 16 tumor-free peripancreatic lymph nodes were noted. The subject developed tachycardia after surgery and was treated with PPD After stabilization, the subject was shifted to the ventilation ward on PPD (Day 106). On an unspecified date in PPD, the subject experienced peripheral edema and was treated with PPD During the course of admission, the subject developed a decubitus ulcer on PPD left heel, which was treated with ablation for superficial necrosis, but the subject refused further bandage. On PPD (Day 117), the peripheral edema resolved, and the subject was discharged from the hospital on the same day; however, PPD showed high inflammatory values (values not reported). On PPD (Day 120), the subject was re-hospitalized due to impaired healing (postoperative wound healing disturbance). The subject had subcutaneous bleeding at a drainage location on the right abdomen (from adenocarcinoma of the pancreas), where there was hemostasis with a Vicryl suture. On PPD (Day 125), the subject was discharged from the hospital at PPD request. The subject received prohibited PPD (from PPD to PPD; further specifics not reported) for the adenocarcinoma of the pancreas. The impaired healing resolved on PPD (Day 125), and the decubitus ulcer resolved on PPD (Day 169). On PPD (Day 459), the subject died at home due to pancreatic carcinoma. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the adenocarcinoma of the pancreas was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD
; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Pneumonia bacterial	PPD	PPD (93)		PPD (97)		5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: bacterial	2	72	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22). Concomitant medications received within 2 weeks prior to the onset of the bacterial pneumonia included PPD The subject was diagnosed with bacterial pneumonia on PPD, 71 days after receiving Dose 2, and died of the event on PPD, 75 days after receiving Dose 2. On PPD (Day 93), the subject presented to the emergency room with shortness of breath resulting in hospitalization with a pre-diagnosis of metabolic acidosis, pneumonia, subarachnoid hemorrhage, and liver cirrhosis. A computed tomography (CT) scan of the head and abdomen performed in the emergency room showed no pathological findings. A pulmonary CT angiography indicated that the pulmonary arteries were open. A CT scan of the thorax revealed parabronchial infiltration in the right lung and pleural effusion in both hemithoraces. A right internal jugular vein and hemodialysis catheters were inserted with an ultrasound. The subject was admitted to the intensive care unit and was sedated. A SARS-CoV-2 test result was negative.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD

Narrative Comment
Left radial artery cannulation was performed. The subject was intubated by using PPD (as reported)." A total of PPD was administered to the subject, who had a cardiac arrest after intubation. The subject's condition was rated as third degree. On PPD, the subject's general condition deteriorated, and a blood culture was positive for *Escherichia coli*; the subject's Acute Physiology and Chronic Health Evaluation (APACHE) II score was 31, PPD Glasgow coma score was 3, and PPD had a multiple organ failure score of 7 with an expected death rate of 79.6. During hospitalization, the subject received PPD (from PPD to PPD) and PPD PPD to PPD) for pneumonia. On PPD, the subject's general condition further deteriorated, and PPD continued receiving mechanical ventilator support. On PPD, the subject was found to have severe brainstem hypoxia while being intubated. On PPD (Day 97), the subject's general condition further deteriorated, and PPD became asystolic and hypotensive, despite receiving PPD Cardiopulmonary resuscitation (CPR) was performed, and PPD. However, the subject was unresponsive to the CPR, and PPD died of bacterial pneumonia that led to cardiac arrest. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the bacterial pneumonia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was a coincidental medical condition with the subject's predisposing factors like age and ongoing PPD.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (80)	PPD
VACCINATION 4	BNT162b2	PPD (99)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (447)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	RESP	Chronic obstructive pulmonary disease	PPD	PPD (337)		PPD (339)		3	2	TC/TCN	Y
2	GENRL	Death		PPD (498)	PPD	PPD (498)	PPD	1	4	W	Y
3	GASTR	Gastritis		PPD (327)	PPD	ONGOING			1	TC	N
4	GENRL	Injection site pain		PPD (80)		PPD (81)		2	1	N	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (PPD)	NOT RELATED/OTHER: the PPD	4	239	N
2	Fatal (PPD)	NOT RELATED/OTHER: Unknown	5	52	Y
3	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	4	229	N
4	Resolved (PPD)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , a 50-year-old PPD with a reported medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 22).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 80), PPD (Day 99), and PPD (Day 447), respectively.

Concomitant medications received within 2 weeks prior to the subject's death included PPD (all since unknown dates) for unknown indications.

The subject died of an unknown cause on PPD, 51 days after receiving Dose 5 (the third dose of BNT162b2).

The subject died at PPD AM while sleeping at home. An autopsy was performed, but the results were not provided.

In the opinion of the investigator, there was no reasonable possibility that the death was related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was also not related to concomitant medications.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (29)	PPD

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	PSYCH	PPD		PPD (258)		PPD (258)		1	4	W	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Fatal (PPD)	NOT RELATED/OTHER: PPD	2	230	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (-1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (354)	PPD

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: 13NOV2020; Date of Last Dose: 01NOV2021
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 40 year-old PPD with a reported medical history of PPD , received Dose 1 on PPD , Dose 2 on PPD (Day 20), and Dose 3 on PPD (Day 354). The subject died on an unspecified date. On PPD , the site updated the subject's disposition status for the study follow-up phase as "withdrawn" because of the death. This death event occurred outside the protocol-defined postvaccination safety reporting period and, as such, was reported only as an update to the subject's disposition status, but not reported as an adverse event. No additional details will be provided for this event.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PSYCH	PPD		PPD (114)		PPD (114)		1

Adverse Events							
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	2	93	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Past
			Past
			Present
			Present
			Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PSYCH	PPD		PPD (131)		PPD (131)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	2	112	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (194)	PPD
VACCINATION 4	BNT162b2	PPD (214)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	INFEC	PPD	PPD	PPD (235)		PPD (272)		38	1	TC
2	RESP	Acute respiratory failure		PPD (272)		PPD (272)		1	4	W
3	INFEC	PPD		PPD (255)		PPD (272)		18	4	N
4	GENRL	Injection site erythema		PPD (194)	PPD	PPD (196)		3	2	N
5	GENRL	Injection site pain		PPD (194)	PPD	PPD (196)		3	2	N
6	INFEC	Lower respiratory tract infection		PPD (272)		PPD (272)		1	4	N
7	INFEC	Pneumonia		PPD (235)		PPD (264)		30	2	TC
8	SKIN	Pruritus		PPD (95)		PPD (136)		42	1	N
9	CARD	Supraventricular tachycardia		PPD (246)		PPD (247)		2	3	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	4	22	Y
2	Y	Fatal (PPD)	NOT RELATED/OTHER: Acute Lower Respiratory Tract Infection	4	59	Y
3	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	4	42	Y
4	N	Resolved (PPD)	Study Treatment	3	1	N
5	N	Resolved (PPD)	Study Treatment	3	1	N
6	Y	Fatal (PPD)	NOT RELATED/OTHER: Unknown	4	59	Y
7	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown etiology	4	22	N
8	N	Resolved (PPD)	NOT RELATED/OTHER: allergy	2	74	N
9	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	33	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD
VACCINATION 3	BNT162b2	PPD (105)	PPD
VACCINATION 4	BNT162b2	PPD (127)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Injection site pain	PPD	PPD (359)		PPD (361)		3	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	NOT RELATED/OTHER: non-study pfizer vaccine	4	233	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a ≥75-year-old PPD with a reported medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 20). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 105) and PPD (Day 127), respectively. The subject died on an unspecified date. On PPD, the site updated the subject's disposition status for the study follow-up phase as "withdrawn" because of the death. This death event occurred outside the protocol-defined postvaccination safety reporting period and, as such, was reported only as an update to the subject's disposition status, but not reported as an adverse event. No additional details will be provided for this event.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	COVID-19 pneumonia	PPD	PPD (93)		PPD (97)	PPD	5
2	METAB	Diabetes mellitus		PPD (93)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Unknown	2	72	Y
2	4	N	Y	Yes	NOT RELATED/OTHER: unknown	2	72	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 60-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 22). Concomitant medications received within 2 weeks prior to the onset of the COVID-19 pneumonia included PPD for sinusitis.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
The subject was diagnosed with COVID-19 pneumonia on PPD, 71 days after receiving Dose 2, and died of the event on PPD, 75 days after receiving Dose 2. On PPD (Day 93), the subject presented to the emergency room with an elevated blood glucose level (values unavailable) and was subsequently hospitalized for type 2 diabetes mellitus (PPD had no previous history of the condition). PPD underwent further laboratory tests on PPD, including a SARS-CoV-2 polymerase chain reaction (PCR) test result, which was positive. Other relevant laboratory test reports were unavailable. A SARS-CoV-2 PCR test result was positive again on PPD, and the diagnosis of COVID-19 illness was confirmed. On PPD (Day 97), the subject died, and the cause of death was reported as COVID-19 pneumonia. An autopsy was not performed. A medical practitioner considered the primary cause of death to be COVID-19 pneumonia, with a secondary cause of type 2 diabetes mellitus. In the opinion of the investigator, there was no reasonable possibility that the COVID-19 pneumonia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	PPD	PPD	PPD (43)	PPD	ONGOING		
2	NEOPL			PPD (318)		PPD (319)	PPD	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	N	Yes	NOT RELATED/OTHER: NEOPLASIA	2	22	N
2	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Neoplasia	2	297	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (140)	PPD
VACCINATION 4	BNT162b2	PPD (161)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (445)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Death	PPD	PPD (783)		PPD (783)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: cause unknown	5	339	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 60-year-old PPD with a reported medical history of PPD (since PPD), received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 140), PPD (Day 161), and PPD (Day 445), respectively. The subject died in the hospital due to an unknown cause on PPD, 338 days after receiving Dose 5 (the third dose of BNT162b2). The information about the subject's death was reported to the site by PPD relative. The reason for the hospital visit, preceding symptoms if any, investigations, and treatment were all unknown. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the death was related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (209)	PPD
VACCINATION 4	BNT162b2	PPD (228)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (471)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RENAL	Acute kidney injury	PPD	PPD (639)	PPD	PPD (652)	PPD	14
2	NEOPL	Adenocarcinoma of colon		PPD (635)	PPD	PPD (718)	PPD	84
3	INFEC	Douglas' abscess		PPD (698)	PPD	PPD (718)	PPD	21
4	GASTR	Duodenal stenosis		PPD (668)	PPD	ONGOING		
5	GASTR	Intestinal obstruction		PPD (639)	PPD	PPD (652)	PPD	14
6	GASTR	Intestinal obstruction		PPD (693)	PPD	PPD (718)	PPD	26
7	GENRL	Multi-organ disorder		PPD (693)	PPD	PPD (718)	PPD	26
8	INFEC	Septic shock		PPD (693)	PPD	PPD (718)	PPD	26

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	5	169	N
2	3	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	5	165	Y
3	4	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	5	228	Y
4	2	N	N	Yes	NOT RELATED/OTHER: unknown	5	198	N
5	3	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	5	169	N
6	3	TC/TCN	Y	Fatal (PPD)	NOT RELATED/OTHER: vomiting	5	223	Y
7	4	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	5	223	Y
8	4	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	5	223	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD
		PPD

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD, a 50-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 209), PPD (Day 228), and PPD (Day 471), respectively.

The subject was diagnosed with adenocarcinoma of the colon on PPD, 164 days after receiving Dose 5 (the third dose of BNT162b2).

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
On an unspecified date in PPD, the subject developed PPD and lost 25 kgs of PPD weight (most recent weight: PPD kg; BMI: PPD). In PPD, the subject was assessed by PPD gastroenterologist, who requested abdominal and pelvic computed tomography (CT) scans, a video esophagogastroduodenoscopy, and a video colonoscopy. On PPD (Day 635), the abdominal and pelvic CT scans showed gastric and duodenal frame distension. The esophagogastroduodenoscopy showed multiple linear erosions larger than 5 mm in the middle and lower third of the esophagus, and Grade B esophagitis was confirmed. The colonoscopy showed a multilobulated, friable, and impassable lesion located 50 cm from the anal margin, and colon cancer was suspected. On PPD (Day 639), the subject was hospitalized for the suspected colon cancer and was in poor general condition. PPD COVID-19 test result was negative. PPD had no family history of cancer. In PPD, the subject's blood test showed hyponatremia and hypokalemia (values not provided); an abdominal CT scan showed intestinal occlusion at the Treitz angle. A laparoscopic extended left colectomy was performed, including partial resection of the stomach, partial resection of the duodenum, 40 cm of jejunum, gastroenteroanastomosis, colonic anastomosis due to splenic angle colon tumor with infiltration of the duodenojejunal loop causing intestinal occlusion, and infiltration of the posterior aspect of the gastric body with mesenteric lymphadenopathies. On PPD, abdominal surgery for excision of the tumor with end-to-end anastomosis was performed without any complications. The subject was stable in the intensive care unit (ICU) and treated with PPD (drug, dose, and frequency unknown) for pain management. The subject remained in the ICU for 5 days, after which PPD was transferred to the general department. A pathology report done on PPD showed moderately differentiated adenocarcinoma. A tumor size of 6 cm in diameter was seen. The lymph nodes were positive for metastasis, and the pathologic staging was pT4, pN2, and pMx. On PPD (Day 652), the subject showed positive clinical development and food tolerance; therefore, PPD was discharged from the hospital on PPD for pain PPD and was advised to clean the surgical wound with white soap and water regularly. PPD diet was controlled for 28 days and ambulation with a brace was advised. On PPD, the subject had PPD stitches removed. The subject remained asymptomatic with tolerance to solid food but experienced sporadic vomiting since surgery. On PPD (Day 668), a positron emission tomogram indicated hypermetabolic adenopathy and soft tissue nodular formations in multiple anatomical locations. On PPD, the subject's oncologist recommended to begin PPD (frequency and duration unknown for all), starting the following week.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
On PPD, the vomiting intensity gradually increased, with associated duodenal stenosis. The subject was diagnosed with an intestinal obstruction, multi-organ disorder, and septic shock on PPD, 222 days after receiving the third dose of BNT162b2. On PPD (Day 693), the subject was hospitalized with dehydration and in poor clinical condition. The subject underwent placement of a nasogastric tube and was treated with PPD (drug, dose, and frequency unknown). The same day (Day 693), the subject developed an intestinal obstruction, multi-organ disorder, and septic shock. On PPD, the nasogastric tube was removed as the vomiting subsided. However, PPD developed severe vomiting again; an upper gastric video endoscopy was performed which showed a 3 cm friable mamelonized area that was biopsied with no significant findings. The subject was diagnosed with a Douglas cul-de-sac abscess on PPD, 227 days after receiving the third dose of BNT162b2. A K108 catheter could not be placed endoscopically, thus decompressive gastrostomy, jejunostomy, and drainage of the Douglas abscess were performed. The subject's multi-organ dysfunction secondary to septic shock required PPD, and PPD condition deteriorated. The subject died in the hospital due to dehydration, septic shock, multi-organ disorder, and advanced colon cancer on PPD, 247 days after receiving the third dose of BNT162b2. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the adenocarcinoma of the colon, Douglas abscess, intestinal obstruction, multi-organ disorder, and septic shock were related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (187)	PPD
VACCINATION 4	BNT162b2	PPD (207)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Cardiac arrest	PPD	PPD (295)	PPD	PPD (295)	PPD	1	4
2	MUSC	Tendonitis		PPD (228)	PPD	PPD (232)	PPD	5	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	4	89	Y
2	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: When doing physical activity.	4	22	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 187) and PPD (Day 207), respectively. Concomitant medication received within 2 weeks prior to the onset of the cardiac arrest included PPD. The subject experienced a nontraumatic cardiac arrest on PPD, 88 days after receiving Dose 4 (second dose of BNT162b2), and died on the same day. The subject's PPD found PPD dead on PPD bed and notified the site. Per the death certificate, the causes of death were cardiac arrest, congestive heart failure, and chronic obstructive pulmonary disease (COPD). The site questioned the subject's medical history, but the PPD denied a previous history of congestive heart failure and COPD. No additional information was provided. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (24)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PSYCH	PPD		PPD (219)	PPD	PPD (219)	PPD	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Unknown	2	196	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (21)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Glioblastoma	PPD	PPD (219)	PPD	PPD (321)	PPD	103	4
2	VASC	Hypertensive emergency		PPD (229)	PPD	PPD (232)	PPD	4	3
3	INFEC	Pneumonia aspiration		PPD (222)	PPD	PPD (226)	PPD	5	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCNKW	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	199	Y
2	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: encephalopathy	2	209	N
3	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: encephalopathy	2	202	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, and a family history of PPD (PPD, date unknown), received Dose 1 on PPD and Dose 2 on PPD (Day 21). The subject experienced symptoms consistent with glioblastoma on PPD, 198 days after receiving Dose 2, and died of the event on PPD, 300 days after receiving Dose 2.

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Narrative Comment
On PPD (Day 219), the subject developed dysarthria, headache, mental confusion, and seizures. The subject was hospitalized due to a moderate-intensity right hemicranial headache secondary to dysarthria. Additionally, PPD showed a left brachiocrural paresis with worsening of the sensorium with gaze deviation to the right and tonic-clonic movements. PPD Glasgow coma score was 8/15, and PPD required orotracheal intubation with mechanical respiratory support. On the same day (Day 219), a COVID-19 test result was negative. The subject's vital signs included blood pressure of 110/70 mmHg, heart rate of 98 beats/min, respiratory rate of 16 breaths/min, temperature of 35.6°C, and oxygen saturation of 98%. A computed tomography (CT) scan of the brain was performed, and the result was unknown. Laboratory tests upon admission (date unknown) included creatinine of 1.26, urea of 0.52, potassium of 3.4, hematocrit of 32.7, hemoglobin of 10.4, pH of 7.44, partial carbon dioxide of 31, partial oxygen of 127, bicarbonate of 21.1, blood oxygen saturation of 99, and lactic acid of 10 (units and normal ranges not provided). On PPD, the subject required an PPD and was admitted to the intensive care unit (ICU). On PPD (Day 222), a chest CT scan showed parenchymal infiltrates with an air bronchogram located in both inferior lobe fields, indicating an infectious process, and was diagnosed with aspiration pneumonia. A brain CT scan showed lateral ventricles in normal position with reduced size and mucus thickening in the paranasal sinuses without signs of bleeding. The subject was treated with PPD (from PPD to PPD) and PPD (until PPD) for suspected viral meningitis. Cerebrospinal fluid from a lumbar puncture showed normal results, thus ruling out viral meningitis. The subject was successfully extubated on PPD. On PPD (Day 226), the aspiration pneumonia due to encephalopathy was considered resolved. On PPD (Day 232), the subject was transferred to the general department for close monitoring and treatment. A brain CT scan on PPD remained consistent with the previous report generated on PPD (Day 222). An electroencephalogram showed adequate organization without alterations. The subject was in good condition, globally oriented, responded to simple and complex orders without cranial nerve involvement, showed no motor focus, sensory focus, meningeal irritation, cerebellar or extrapyramidal alteration, and had a preserved gait. The subject was treated with PPD, hemo-glucose test with no corrections, PPD (dose, frequency, and route not specified), along with mechanical respiratory support. On PPD, the subject felt well and was discharged on PPD. The discharge diagnosis was encephalopathy under study. On PPD, an enhanced brain magnetic resonance imaging (MRI) showed 2 contiguous nodular images with intense restrictions in the diffusion series, peripheral contrast enhancement, and perilesional vasogenic edema in the left precentral gyrus. The sphenoidal sinusopathy was indicated by

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Narrative Comment
cephalic one (10 mm in diameter) and caudal one (12 mm in diameter). The subject was diagnosed with a primary or secondary brain lesion, with a differential diagnosis of early abscess. On PPD, the subject suffered a bradylalia and mild right brachiocrural paresis and was brought to the hospital. A brain CT scan was performed, and the result was unknown. However, the neurosurgeon confirmed that one of the lesions had increased in size and would need to be treated surgically. The subject was hospitalized and treated with PPD. On PPD, the subject suffered 2 episodes of involuntary facial movements lasting less than 5 minutes and worsening of right brachiocrural paresis, with difficulty in speech. On PPD, the subject was hospitalized after experiencing progressive sensorium deterioration over 24 hours associated with increased weakness in the right hemi-body and aphasia. PPD showed no response to simple commands and no motor response. The subject's neurological examination showed somnolence, disorientation in time, space, and person, and mixed aphasia with a predominance of expression. PPD obeyed simple commands with difficulty. Upon request, the subject could open PPD eyes and showed isochoric and reactive pupils. The subject had right faciobrachiocrural hemiparesis with brachiocrural predominance and right brachiocrural hemiparesthesia without any cerebellar or meningeal signs. On the same day, a new brain CT scan showed a voluminous left frontoparietal space-occupying lesion with abundant perilesional edema that produced a mass effect and deviated the midline by about 10 mm to the right, collapsing the left lateral ventricle and permeable basal cisterns without signs of intra or extra-axial bleeding. PPD condition improved, and PPD was transferred to the general department on PPD therapy. On PPD, during a neurosurgical evaluation, the subject responded to simple commands, could pronounce PPD age, and had fully recovered left hemi-body mobility with the persistence of moderate right brachiocrural paresis. The specialist recommended decreasing the frequency of PPD. On PPD, an MRI of the brain with spectroscopy showed a lesion compatible with glioblastoma; the left parietal level expansive formation had increased in size associated with significant perilesional vasogenic edema, causing the lateral ventricle to collapse partially, and areas of hemorrhagic petechiae were predominant with peripheral contrast enhancement and areas of central necrosis. The lesion measured 3.8×3.1 cm. The midline deviated to the right by 11 mm, and PPD was diagnosed with glioblastoma. On PPD, a left frontoparietal craniotomy with tumor excision was performed, and a biopsy confirmed the diagnosis of Grade IV glioblastoma. On PPD, a pathology report showed a 1.4 × 1 cm irregular friable fragment in the brain (when forceps came in contact, it crumbled), greyish hemorrhagic areas, and several 0.5 to 1 cm brownish fragments. The frozen sections showed poorly differentiated atypical neoproliferation fragments and foci of abscessation were observed; anisokaryosis cells with hyperchromatic nuclei indicated a malignancy.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
The PPD was gradually weaned off on PPD. On PPD, a brain biopsy showed positive immunolabeling with the following antibodies: clone V9, gliofibrilary acid protein (clone GA5); and P-53 (DO7) was 60% positive. KI-67 (clone MIB19: positive 15%, coctel) and cytocheratin (clone AE1/AE3) were both negative. PPD was diagnosed with an immunophenotypic profile corresponding to glioblastoma. On PPD, the subject developed 3 episodes of involuntary facial movements that lasted less than 5 minutes and suffered a headache. PPD was brought to the emergency room (ER), where PPD remained for 7 hours. A brain CT scan showed cerebral edema, and the subject was treated with PPD PPD. PPD was discharged from the hospital on PPD the same day. On PPD, the subject's neurological status deteriorated during an oncology visit. On PPD, the subject suffered a severe headache and was admitted to the ER for observation. On PPD, at PPD am, the subject suffered incoercible vomiting and underwent a 7-hour emergency brain surgery for a suspected herniated brain due to increased intracranial pressure. After surgery, the subject was returned to the ER on mechanical ventilation. On PPD, the subject was transferred to the ICU. The subject's blood and intracranial pressure were stable, and PPD continued to be on ventilatory support. On PPD (Day 321), the subject died at PPD. Per the death certificate, the reported causes of death were cardiac arrest, spontaneous intraparenchymal hematoma, and recurrent glioblastoma. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the glioblastoma was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PSYCH	PPD		PPD (415)	PPD	PPD (415)	PPD	1
2	INJ&P			PPD (415)	PPD	PPD (415)	PPD	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	1	415	Y
2	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	1	415	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_CSR_Safety_Narrative/profile. (Database Snapshot Date: 07MAR2023) Date of Generation: 13APR2023 (10:53)

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	WITHDRAWAL BY SUBJECT
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_CSR_Safety_Narrative/profile. (Database Snapshot Date: 07MAR2023) Date of Generation: 13APR2023 (10:53)

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (23)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (450)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Cardiac arrest	PPD	PPD (744)	PPD	PPD (744)	PPD	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	3	295	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD
		PPD
		PPD
		PPD
		PPD

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD, Dose 2 on PPD (Day 23), and Dose 3 on PPD (Day 450). Concomitant medication received within 2 weeks prior to the onset of the cardiac arrest included PPD. The subject suffered a cardiac arrest on PPD, 294 days after receiving Dose 3, and died on the same day. The subject's PPD found PPD dead at home. The information about the subject's death was reported to the site by PPD, who denied a history of PPD or a family history of cardiovascular disease. The reported cause of death was cardiac arrest. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Haemorrhagic stroke	PPD	PPD (34)	PPD	PPD (35)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	DEATH
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 20). Concomitant medication received within 2 weeks prior to the onset of the hemorrhagic stroke included PPD. The subject was diagnosed with a hemorrhagic stroke on PPD, 14 days after receiving Dose 2, and died of the event on PPD, 15 days after receiving Dose 2. On PPD (Day 34), the subject contacted the medical team complaining of a severe headache and incoercible vomiting, and PPD was advised to call the emergency system. On PPD (Day 35) at dawn, PPD arrived at the emergency room unconscious (unknown Glasgow coma score) with nonreactive intermediate pupils. The subject was admitted to the intensive care unit, requiring invasive mechanical ventilation and inotropic support (unknown drugs and doses). A computed tomography scan of the brain showed subarachnoid hemorrhage, intraventricular hemorrhage, and right cerebral hemisphere hematoma (Fisher Scale 4). A brain angiography showed cerebral circulatory arrest, and therefore the location of the aneurysm could

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Narrative Comment
not be established. A SARS-CoV-2 swab polymerase chain reaction test result was negative. The subject did not respond to life support measures and died of disease progression and hemorrhagic stroke on the same day (Day 35). It was not reported if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the hemorrhagic stroke was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was most likely related to the subject's underlying uncontrolled PPD .

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (165)	PPD
VACCINATION 4	BNT162b2	PPD (197)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Pulmonary embolism	PPD	PPD (412)	PPD	PPD (414)	PPD	3	4
2	NERV	Tension headache		PPD (52)	PPD	PPD (57)	PPD	6	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCTCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	4	216	Y
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: No treatment was given.	2	31	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD PPD), received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 165) and PPD (Day 197), respectively. Concomitant medications received within 2 weeks prior to the onset of the pulmonary thromboembolism included PPD . The subject was diagnosed with pulmonary thromboembolism on PPD, 215 days after receiving Dose 4 (second dose of BNT162b2), and died of the event on PPD, 217 days after receiving the second dose of BNT162b2. On PPD, the subject PPD. On PPD (Day 412), the subject experienced functional class III-IV dyspnea and pulmonary thromboembolism. On PPD (Day 414), the dyspnea worsened, and PPD requested medical assistance from PPD. At the time an ambulance arrived, PPD was in cardiac arrest. Cardiopulmonary resuscitation and orotracheal intubation were performed, and PPD was transferred to a hospital. The subject died on the same day (PPD). An autopsy was performed, and the cause of death was verbally reported as pulmonary thromboembolism (an autopsy report was not provided). It was unknown if a COVID-19 test was done. In the opinion of the investigator, there was no reasonable possibility that the pulmonary thromboembolism was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Cardio-respiratory arrest	PPD	PPD (383)	PPD	PPD (383)	PPD	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	364	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 20). Concomitant medications received within 2 weeks prior to the onset of the cardiorespiratory arrest included PPD. The subject experienced cardiorespiratory arrest on PPD, 363 days after receiving Dose 2, and died on the same day. On PPD (Day 383), the subject PPD. Subsequently, the subject's PPD was informed that PPD had suffered cardiorespiratory arrest. The subject received a pre-hospital cardiopulmonary resuscitation maneuver, which was unsuccessful. The subject was not transferred to the hospital and died from the cardiorespiratory arrest. An autopsy was not performed.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
In the opinion of the investigator, there was no reasonable possibility that the cardiorespiratory arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was related to the acute myocardial infarction associated with the subject's underlying contributory factors, including PPD .

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (446)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Aortic valve incompetence	PPD	PPD (582)	PPD	PPD (582)	PPD	1
2	HEPAT	Hepatic cyst		PPD (516)	PPD	PPD (516)	PPD	1
3	GASTR	Hiatus hernia		PPD (516)	PPD	PPD (516)	PPD	1
4	CARD	Mitral valve incompetence		PPD (582)	PPD	PPD (582)	PPD	1
5	NEOPL	Mucinous breast carcinoma		PPD (447)	PPD	ONGOING		
6	INFEC	Pneumonia		PPD (663)	PPD	PPD (674)	PPD	12
7	CARD	Tricuspid valve incompetence		PPD (582)	PPD	PPD (582)	PPD	1

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	3	137	N
2	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	3	71	N
3	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	3	71	N
4	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	3	137	N
5	3	TC	Y	Yes	NOT RELATED/OTHER: unknown	3	2	N
6	3	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	3	218	Y
7	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	3	137	N

Prohibited Concomitant Medications

Investigator Text	WHO Drug Preferred Term	Start Date	End Date	Route
PPD		PPD	ONGOING	PPD
		PPD	ONGOING	

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD
		PPD

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a ≥75-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD, Dose 2 on PPD (Day 22), and Dose 3 on PPD (Day 446). Concomitant medication received within 2 weeks prior to the onset of the pneumonia included PPD. The subject was diagnosed with pneumonia on PPD, 217 days after receiving Dose 3, and died of the event on PPD, 228 days after receiving Dose 3. On PPD (Day 447), the subject was diagnosed with mucinous carcinoma of the right breast, which was treated with protocol-prohibited medications PPD. PPD met with PPD oncologist on PPD and had PPD PPD scheduled for PPD. However, on PPD (Day 663), PPD complained of dyspnea (functional class unknown). On PPD, PPD went to the emergency room, and was subsequently admitted to the general ward due to a diagnosis of bilateral pneumonia. On PPD and PPD, during hospitalization, 2 COVID-19 tests were performed, and the results were negative. On PPD, PPD was transferred to an intensive care unit due to persisting dyspnea. Laboratory tests performed on PPD showed heart rate of 67 beats/min, respiratory rate of 14 breaths/min, blood pressure of 80/40 mmHg, and oxygen saturation of 95% on room air. On PPD (Day 674), the subject died. The cause of death was pneumonia. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the pneumonia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Gastric cancer	PPD	PPD (155)	PPD	PPD (461)	PPD	307	4
2	GASTR	Gastric ulcer		PPD (63)	PPD	PPD (208)	PPD	146	2
3	GASTR	Gastrooesophageal reflux disease		PPD (35)	PPD	PPD (63)	PPD	29	1
4	GASTR	Intestinal obstruction		PPD (416)	PPD	PPD (461)	PPD	46	4
5	RENAL	Oliguria		PPD (416)	PPD	PPD (461)	PPD	46	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	136	Y
2	TC	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	44	N
3	TC	N	Resolved (PPD)	NOT RELATED/OTHER: chronic antral ulcer	2	16	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Signet ring cell gastric carcinoma	2	397	Y
5	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	397	Y

Prohibited Concomitant Medications				
Investigator Text	WHO Drug Preferred Term	Start Date	End Date	Route
PPD		PPD	PPD	PPD
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications				
Investigator Text	WHO Drug Preferred Term	Start Date	End Date	Route
PPD		PPD	PPD	PPD
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	
		PPD	PPD	

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 60-year-old PPD with a pertinent medical history of PPD , and laparoscopic hernioplasty (PPD), received Dose 1 on PPD and Dose 2 on PPD (Day 20). Concomitant medications received within 2 weeks prior to the onset of the gastric cancer, intestinal obstruction, and oliguria included PPD . The subject was diagnosed with gastric cancer on PPD , 135 days after receiving Dose 2, and with intestinal obstruction and oliguria on PPD , 396 days after receiving Dose 2. The subject died of the gastric cancer, intestinal obstruction, and oliguria on PPD , 441 days after receiving Dose 2. On an unspecified date, the subject reported chronic symptoms of PPD , characterized by pyrosis and nausea. The symptoms worsened in PPD , and PPD was treated with PPD . On PPD (Day 35), PPD gastroenterologist changed the PPD . On PPD (Day 155), an upper digestive video endoscopy showed a polyp in the upper portion of the stomach (ectomized), a chronic ulcer in the anterior wall of gastric body, an elevated lesion in the antrum, and multiple biopsies were taken. On PPD , the pathology report described the following: macroscopy of the antrum: white irregular fragment measuring 0.3 cm; of the body: white irregular fragments measuring a total of 0.8×0.3 cm; and of the roof polyp: white irregular fragment measuring 0.3 cm. Microscopy of the antral gastric mucosa showed areas of ulceration, chorion with congestive capillaries, moderate inflammatory infiltrate of plasmocytes, and isolated signet ring cells; with presence of fibrinoleukocytic material in the specimen; microscopy of the antral and corpofundic gastric mucosa showed infiltration of signet ring cells in the chorion; and microscopy of the antral gastric mucosa showed congestive vessels. Based on the pathology results, PPD was diagnosed with Signet ring cell gastric carcinoma and was referred to an oncologist.

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Narrative Comment
On PPD, the subject's abdominal and pelvic magnetic resonance imaging scan showed an image suggestive of a small hiatal hernia; cortical cyst of 5 mm in the upper pole of the left kidney; cortical notches of sequelae appearance in the right kidney; diffuse thickening of the gastric folds; moderate amount of free abdominopelvic fluid, diverticulosis in the sigmoid colon with no signs of current complication; and multiple uterine myomas. In the left adnexal region, there was an ovoid image of 23×16 mm, with clear borders and hyperintense signal in T1, without post-contrast enhancement or restriction in diffusion sequence, suggestive of a cyst with high protein/hemorrhagic content. On PPD, a COVID-19 test result was negative. On PPD, the subject underwent laboratory tests, which showed an unremarkable hemogram, hepatogram, and urinalysis. The subject's hemogram showed the following results: urea of 37 mg/dL (normal range [NR]: 13-43 mg/dL), creatinine of 0.61 mg/dL (NR: 0.5-0.9 mg/dL), non–high-density lipoprotein cholesterol of 142 mg/dL (NR: <130 mg/dL), low-density lipoprotein cholesterol of 125 mg/dL (NR: <100 mg/dL), total protein of 6.3 g/dL (NR: 6.4-8.3 g/dL), carcinoembryonic antigen of 1.8 ng/mL (NR: <5 ng/dL), carbohydrate antigen (CA) 19-9 of 27.7 IU/mL (NR: <34 IU/mL), and CA 125 of 283 IU/mL (NR: <35 IU/mL). On PPD, computed tomography (CT) scans of the chest, abdomen, and pelvis showed the following results: mild bilateral pleural effusion with dense bibasal bands in the chest, and poorly delimited gastric lesion, with loss of parietal stratification of the gastric fundus and body. Additionally, impressed extramural extension towards the gastrohepatic ligament, some areas of cortical thinning in the right kidney, discretely irregular lipoma in the proximal region of the right thigh (64 mm), epiploic adipose rarefaction suggestive of peritoneal carcinomatosis in epigastrium and left hypochondrium, some areas of lamellar peritoneal thickening, more evident in the fundus of the pouch of Douglas, and abundant ascitic fluid were also noted. The subject's diagnosis was gastric lesion with signs of peritoneal carcinomatosis and abundant ascitic fluid associated with mild bilateral pleural effusion. On PPD (Day 208), an (18)F-fluorodeoxyglucose (FDG) positron emission tomography/computed tomography (PET/CT) whole body scan showed thickening of gastric folds, with discrete increase in metabolic activity and maximum standardized uptake value (SUV) 2.8 at the level of the antrum. Tomographic findings of the neck revealed the thyroid gland with heterogeneous density, and tomographic findings of the chest showed bilateral pleural effusion and pleuroparenchymal tracts in pulmonary vertices were noted. There was laminar atelectasis in the middle lobe, lingula, and inferior lobes. The tomographic findings of the abdomen and pelvis showed cortical notches in the right kidney, and a lipoma was noted in the proximal region of the right lower limb. Overall impression of thickening of gastric folds with discrete metabolic activity was seen. Additionally, ascites associated with focal peritoneal images of metastases were seen. There was no pathological accumulation of FDG in the left adnexal image; however, this did not exclude metastases. PPD gynecologist requested a follow-up with images without specific treatment regarding the uterine myoma and left ovarian cyst. PPD went to PPD oncologist appointment on PPD. On PPD, prior to PPD a COVID-19 test result was negative. On PPD, PPD was admitted for PPD first PPD cycle and on PPD received prohibited PPD On PPD, PPD also underwent ascitic fluid drainage of approximately 2.5 L for symptomatic relief; the liquid was not sent for analysis. PPD was discharged on PPD, and continued to exhibit nausea and pyrosis, exacerbated

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Narrative Comment
by PPD Between PPD and PPD, PPD underwent 5 more PPD cycles. Due to persistent nausea and pyrosis, PPD was discontinued. An FDG PET/CT whole body scan on PPD showed metabolic findings of persistent thickening of the gastric folds, without significant changes in their metabolic activity: maximum SUV 2.9 at the level of the antrum. The volume of free fluid in the abdominopelvic cavity had decreased. There was also a clear decrease in the extent of peritoneal focal images secondary aspect, as well as the lesion documented in the left adnexal region. Tomographic findings of neck were unremarkable. The volume of pleural effusion was noted to have slightly increased; bilateral breast prostheses were seen. In the abdomen, there was increased density of the thoracoabdominal subcutaneous cellular tissue and dorsolumbar spondylosis. A PET/CT scan showed a clear decrease in the extent of peritoneal focal images and no significant changes in the metabolic activity; the subject did not need another cycle of PPD PPD was asymptomatic as of PPD. On PPD, the subject underwent an abdominal ultrasound, which showed free fluid in the abdominal cavity. Transvaginal gynecological US showed the uterus with heterogeneous myometrial ultrastructure due to the presence of intramural myomas, ventral 12 mm, and dorsal 16.7 mm (with fatty degeneration), ascites with particulate fluid in the fundus of the pouch of Douglas. On PPD, a CT scan of the abdomen and pelvis showed persistent discrete thickening of gastric folds and increased free fluid in the abdominopelvic cavity, discrete diffuse thickening of the walls of the transverse and ascending colon, cortical cyst in the upper pole of the left kidney, and uterus with myomatous aspect. A new cycle of PPD PPD was asymptomatic. On PPD and PPD, PPD received the first cycles of PPD On PPD, after receiving PPD, therapeutic ascitic fluid drainage (approximately 1.5 L) was performed for symptomatic relief. On PPD and PPD, the subject received the third and fourth cycle of PPD and on PPD, PPD underwent further therapeutic ascitic fluid drainage of approximately 2.75 L to improve abdominal distention. On PPD, the subject was hospitalized for placement of a Tenckhoff catheter to facilitate drainage of ascitic fluid. The procedure was performed on PPD without complications. On PPD (Day 416), the subject presented with oliguria. The same day, PPD was diagnosed with intestinal subocclusion, possibly secondary to gastric carcinoma, in the context of vomiting and oliguria. A bladder catheter was placed, and PPD was prescribed PPD PPD (dose, frequency, and duration unknown) with the improvement of diuresis. Later, the subject presented again with deterioration of diuresis. The subject remained hospitalized in the general medicine department (reported verbally by the subject, details not provided). No COVID-19 test was performed during the hospitalization. The subject was discharged on PPD. The subject underwent placement of a nasogastric tube and received PPD. PPD was hemodynamically stable and afebrile, with a slightly distended abdomen and spontaneous diuresis while tolerating a soft diet. PPD received PPD. Home palliative care was decided due to no symptomatic improvement with medical treatment and recurrence of symptoms. PPD was discharged on PPD

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Narrative Comment
PPD . PPD reported 'feeling down' and remained in bed most of the day; PPD oliguria and intestinal subocclusion continued. On PPD, the subject was hospitalized again due to worsening of PPD general condition. The subject exhibited marked asthenia and significant weight loss. PPD was evaluated by the palliative care and oncology departments and was informed of the poor short-term prognosis; it was decided not to perform invasive procedures. PPD was placed in end-of-life care. The subject died in the hospital on PPD (Day 461). An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the gastric cancer, intestinal obstruction, and oliguria were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (50)	PPD
VACCINATION 3	BNT162b2	PPD (162)	PPD
VACCINATION 4	BNT162b2	PPD (183)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Bronchospasm	PPD	PPD (2)	PPD	PPD (19)	PPD	18	2
2	GASTR	Intestinal ischaemia		PPD (333)	PPD	PPD (336)	PPD	4	4
3	INFEC	Septic shock		PPD (334)	PPD	PPD (336)	PPD	3	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Unknown	1	2	N
2	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	4	151	Y
3	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Jejuno-ileal mesenteric ischemia	4	152	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 50). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 162) and PPD (Day 183), respectively. Concomitant medications received within 2 weeks prior to the onset of the intestinal ischemia and septic shock included PPD. The subject was diagnosed with intestinal ischemia on PPD, 150 days after receiving Dose 4 (the second dose of BNT162b2), and septic shock on PPD, 151 days after receiving the second dose of BNT162b2. The subject died of intestinal ischemia and septic shock on PPD, 153 days after receiving the second dose of BNT162b2. On PPD (Day 333), at PPD, the subject experienced abdominal pain, diarrhea, and vomiting (further details unknown). On PPD (Day 334), the subject presented bloody depositions and worsening abdominal pain. At PPD, PPD received home medical assistance and was prescribed PPD. At PPD, the subject was admitted to the intensive care unit (ICU) for abdominal pain associated with vomiting and hematochezia. Physical examination showed mean arterial pressure <40 mmHg, generalized lividity with poor peripheral perfusion, respiratory rate of 40 breaths/min, oxygen saturation on room air of 94%, and diffuse tenderness and rigidity of the abdomen. PPD was suspected to be in septic shock with an abdominal focus. PPD received an PPD. On the same day (Day 334), an abdominal computed tomography (CT) scan showed distension of small bowel loops, with hydro-aerial levels inside, diffuse fatty infiltration of the pancreas, and isolated diverticula in left colon with no signs of complication. Blood test results included pH of 7.17 (normal range [NR] not reported), pCO_2 of 22 mmHg (NR: 36.0-44.0 mmHg), PO_2 of 88.1 mmHg (NR: 60.0-80.0 mmHg), HCO_3 of 8.2 mEq/L (NR: 23.0-27.0 mEq/L), base excess of -20.3 mEq/L (NR: -2.0-2.0 mEq/L), urea of 67 mg/dL (NR: 21-43 mg/dL), creatinine of 2.44 mg/dL (NR: 0.55-1.02 mg/dL), hemoglobin of 17.8 g/dL (NR: 12-15 g/dL), hematocrit of 56 % (NR: 36-46 %), erythrocytes of 6.0×10^6/µL (NR: 3.8-4.8 $\times10^6$/µL), leukocyte formula was unremarkable, lactate dehydrogenase of 249 U/L (NR: 125-220 U/L), C-reactive protein of 7.4 mg/dL (NR low: not specified, NR upper: 0.8 mg/dL), prothrombin time of 66% (NR: 70-100%), international normalized ratio of 1.34 (NR: 0.95-1.05), potassium of 3.1 mEq/L (NR: 3.5-5.1 mEq/L), and blood glucose of 322 mg/dL (NR: 55-100 mg/dL). On PPD, laparotomy showed abundant dark-enteric hematic liquid. Mesenteric ischemia was visualized compromising a large part of the jejunum and the entire ileum. An exploratory laparotomy was performed with diagnosis of bowel ischemia of a large part of the jejunum and entire ileum. Drainage of an abscess located at the level of the pouch of Douglas was performed, and an extensive resection of 1.8 meters of jejuno-ileal intestine was also

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Narrative Comment
performed. The pathology report revealed jejuno-ileum resection measuring 123 cm in length, with flat serosa and hand sutures to one of the margins. At cut, it showed a flat mucosa and thinned wall with congestive-hemorrhagic foci. Microscopic examination showed hypoxic-ischemic type necrosis involving all histological layers of the organ and associated prominent acute inflammation, and vaso ectasia. Focal hypoxic-ischemic changes in the mucosa of the surgical margins of resection were also noted. Post-surgery, PPD was admitted to the ICU on mechanical ventilatory support. PPD developed marked hypotension requiring double vasoactive support with PPD . PPD underwent emergency hemodialysis due to metabolic acidosis secondary to septic shock with abdominal focus. On PPD (Day 336), the subject was discharged and subsequently died. The immediate cause of death was ascertained as cardiac arrest. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the intestinal ischemia and septic shock were related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was more likely associated with the subject's underlying predispositions, including PPD .

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Cardio-respiratory arrest	PPD	PPD (100)	PPD	PPD (101)	PPD	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	81	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 50-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 20). Concomitant medications received within 2 weeks prior to the onset of the cardiorespiratory arrest included PPD . The subject was diagnosed with a cardiorespiratory arrest on PPD , 80 days after receiving Dose 2, and died of the event on PPD , 81 days after receiving Dose 2. According to the subject's PPD , on PPD (Day 100), the subject experienced abdominal discomfort with an episode of vomiting, and had back pain. On PPD (Day 101), the subject was taken to a nearby hospital, but PPD had no vital signs on arrival at the hospital. That same day (Day 101), the subject died of cardiorespiratory arrest (also described as nontraumatic cardiac arrest). An autopsy was performed, but the results were not available.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
In the opinion of the investigator, there was no reasonable possibility that the cardiorespiratory arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the cardiorespiratory arrest was most likely related to the subject's underlying contributory factors, including PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	CARD	Atrial fibrillation	PPD	PPD (211)	PPD	PPD (284)	PPD	74	3	TC/TCN
2	CARD	Atrial flutter		PPD (211)	PPD	PPD (284)	PPD	74	3	TC/TCN
3	HEPAT	Bile duct stenosis		PPD (398)	PPD	PPD (407)	PPD	10	4	TC
4	MUSC	Bursitis		PPD (209)	PPD	PPD (243)	PPD	35	2	TC
5	NEOPL	Pancreatic neoplasm		PPD (398)	PPD	PPD (407)	PPD	10	4	TC/TCN/W
6	GASTR	Pancreatitis		PPD (401)	PPD	PPD (407)	PPD	7	4	TC/TCN/W
7	RESP	Pulmonary embolism		PPD (406)	PPD	PPD (407)	PPD	2	4	TC/W

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
8	RENAL	Renal infarct	PPD	PPD (404)	PPD	ONGOING			2	TC/TCN/W
9	INFEC	Sepsis		PPD (403)	PPD	PPD (407)	PPD	5	4	TC/TCN/W

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (PPD)	NOT RELATED/OTHER: Worsening of PPD	2	192	N
2	Y	Resolved (PPD)	NOT RELATED/OTHER: Worsening of PPD	2	192	N
3	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	379	Y
4	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	190	N
5	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	379	Y
6	Y	Fatal (PPD)	NOT RELATED/OTHER: performance of endoscopic retrograde cholangiopancretography	2	382	Y
7	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	387	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
8	N	Yes	NOT RELATED/OTHER: unknown	2	385	Y
9	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	384	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 20). Concomitant medications received within 2 weeks prior to the onset of the bile duct stenosis, pancreatic neoplasm, pancreatitis, pulmonary embolism, renal infarct, and sepsis included PPD for atrial fibrillation. The subject was diagnosed with bile duct stenosis and pancreatic neoplasm on PPD, 378 days after receiving Dose 2, pancreatitis on PPD, 381 days after receiving Dose 2, sepsis on PPD, 383 days after receiving Dose 2, renal infarct on PPD, 384 days after receiving Dose 2, and a pulmonary embolism on PPD, 386 days after receiving Dose 2. The subject died of the bile duct stenosis, pancreatic neoplasm, pancreatitis, pulmonary embolism, and sepsis on PPD, 387 days after receiving Dose 2. The subject had a history of PPD. On PPD (Day 398), the subject was hospitalized for pruritus, diarrhea, and coluria. Tests results on PPD (Day 398) included: an abdominal ultrasound showed dilated intrahepatic and extrahepatic biliary duct; choledochal duct of 15 mm, alanine aminotransferase (ALT) of 283 UI/L (normal range [NR] 2-55 UI/L), aspartate aminotransferase (AST) of 141 UI/L (NR: 5-34 UI/L), total bilirubin of 13 mg/dL (NR: 0.2-1.2 mg/dL), direct bilirubin of 10.6 mg/dL (NR upper: 0.5 mg/dL), alkaline phosphatase of 424 UI/L (NR not reported). An abdominal computed tomography (CT) scan showed findings leading to the diagnosis of choledochal syndrome secondary to a pancreatic head tumor. The subject was treated with PPD On PPD, an endoscopic retrograde cholangiopancreatography (ERCP) was performed, which revealed distal choledochal stenosis with dilatation of the biliary tract above the stenosis; sphincterotomy was performed with placement of a 10 FR × 7 cm stent. On PPD (Day 401), test results included

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Narrative Comment
serum amylase of 632 U/L (NR: 25-125 U/L), serum lipase of 907 U/L (NR: 8-78 U/L), ALT of 200 UI/L (NR: 2-55 UI/L), AST of 100 UI/L (NR: 5-34 UI/L), total bilirubin of 11.6 mg/dL (NR: 0.2-1.2 mg/dL), and alkaline phosphatase of 326 UI/L (NR not reported). Fasting and PPD were indicated. On PPD (Day 403), the subject developed a fever of 38°C without hemodynamic decompensation. PPD was diagnosed with post-ERCP pancreatitis without abdominal pain. On PPD (Day 403), laboratory examinations showed hematocrit of 37% (NR: 39-50%), hemoglobin of 12.7 g/dL (NR: 13-17.5 g/dL), ALT of 144 UI/L (NR: 2-55 UI/L), AST of 86 UI/L (NR: 5-34 UI/L), total bilirubin of 12.89 mg/dL (NR: 0.2-1.2 mg/dL), direct bilirubin of 9.9 mg/dL (NR upper: 0.5 mg/dL), carbohydrate antigen 19-9 of 226.4 U/mL (NR: ≤35 U/mL), carcinoembryonic antigen <1.73 ng/mL (NR: ≤3 ng/mL), and serum lipase of 117 U/L (NR: 8-78 U/L). PPD was diagnosed with sepsis and PPD was indicated. Blood work on PPD (Day 404) included a white blood cell count of 11.15×10^3/µL (NR: 3.5-10.5×10^3/µL), neutrophils of 80% (NR: 45-65%), total bilirubin of 17.3 mg/dL (NR: 0.2-1.2 mg/dL), ALT of 124 UI/L (NR: 2-55 UI/L), and glucose of 124 mg/dL (NR: 60-110 mg/dL). An abdominal and pelvic CT scan was performed on the same day, which showed an atrophic pancreas with a biliary stent, with the proximal end in the choledochal duct, with additional findings suggestive of bilateral kidney infarction. Due to these findings, PPD was seen by a hematologist, who prescribed an increasing dose of PPD On PPD (Day 406), at PPD PM, the subject experienced sudden dyspnea associated with right lumbar pain due to suspected pulmonary thromboembolism. PPD was transferred to the coronary care unit, where PPD received invasive mechanical ventilation, PPD. The subject died on PPD (Day 407), at PPD AM. An autopsy was not performed. Per medical records, the probable cause of death was pulmonary thromboembolism, with nontraumatic cardiac arrest as the immediate cause of death. PPD did not undergo a COVID-19 test. In the opinion of the investigator, there was no reasonable possibility that the renal infarct was related to the study intervention. In the opinion of the investigator, there was no reasonable possibility that the bile duct stenosis, pancreatic neoplasm, pancreatitis, pulmonary embolism, and sepsis were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the events were associated with the subject's underlying contributory factors of ongoing PPD.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (545)	PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Clear cell renal cell carcinoma	PPD	PPD (286)	PPD	PPD (677)		392	3
2	INJ&P	Fall		PPD (427)	PPD	PPD (427)	PPD	1	3
3	GENRL	Injection site pain		PPD (546)	PPD	PPD (546)	PPD	1	1
4	INJ&P	Joint dislocation		PPD (427)	PPD	PPD (509)	PPD	83	2
5	INFEC	Mastoiditis		PPD (540)	PPD	ONGOING			1
6	NEOPL	Meningioma		PPD (477)	PPD	ONGOING			1
7	MUSC	Pathological fracture		PPD (427)	PPD	PPD (614)	PPD	188	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	267	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	408	N
3	N	N	Resolved (PPD)	Study Treatment	3	2	N
4	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: fall from own height	2	408	N
5	N	N	Yes	NOT RELATED/OTHER: unknown	2	521	N
6	N	N	Yes	NOT RELATED/OTHER: unknown	2	458	N
7	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	408	N

Prohibited Concomitant Medications				
Investigator Text	WHO Drug Preferred Term	Start Date	End Date	Route
PPD		PPD	PPD	PPD
		PPD	PPD	
		PPD	ONGOING	
		PPD	ONGOING	

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , a 60-year-old PPD with a pertinent medical history of PPD and arterial hypertension PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 20).

Concomitant medications received within 2 weeks prior to the onset of the clear cell renal cell carcinoma included PPD for arterial hypertension.

The subject was diagnosed with clear cell renal cell carcinoma on PPD , 266 days after receiving Dose 2, and died of the event on PPD , 132 days after receiving Dose 3.

On PPD (Day 286), the subject experienced nonspecific slight abdominal pain. An abdominal and renal ultrasound was performed in PPD , where a solid tumor was noted in the left kidney. The subject was referred to a urologist, and the subject underwent ultrasound-guided cytologic biopsy of the solid tumor on PPD . A histopathological report showed neoplastic epithelial cells with large round nuclei, prominent nucleoli, and clear cytoplasm; the cells were found in small groups and in isolation, suggestive of neoplastic cells. A probable diagnosis of clear cell carcinoma was considered. The subject was referred to an oncologist and started treatment with the prohibited medication PPD . PPD did not have a COVID-19 test. A phone follow-up revealed that the subject was feeling well with mild medication-induced nausea, that improved with food intake. On PPD , an abdominal and pelvic computed tomography (CT) scan showed neoplasm in the upper pole of the left kidney, nodular images of

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Narrative Comment
secondary aspect in the lungs and adrenal glands, adenomegaly in the mediastinum, and both hilar and focal lesions on the hepatic surface (the complete report was not available). The blood test results of PPD showed an elevated thyrotropin 5.10 µUI/mL (normal range 0.4-4 µUI/mL). The subject recorded high blood pressure of 150/90 mmHg on the same day. On an unknown date, PPD was seen by PPD oncologist, who increased PPD . Subsequently, PPD cardiologist prescribed an increase of PPD for increased blood pressure, suspected to be due to PPD . On PPD (Day 427), the subject fell, resulting in a pathological fracture. On PPD , the subject was feeling well, with improvement of blood pressure to 130/80 mmHg. On PPD , the subject was admitted to the hospital for scheduled surgery with placement of endoprosthesis in the left humerus and was discharged on the same day. The subject was prescribed PPD . A histopathological report on PPD showed left humerus urothelial carcinoma metastasis. On PPD (Day 477), a brain CT scan showed hypodense punctate images in the right frontal subcortical white substance, enhanced after administration of PPD , nonspecific appearance, probably related to secondary lesions. In the posterior fossa, there was a slightly hyperdense image measuring 25×5 mm with calcifications in its interior, which remodeled and widened the left jugular foramen, showed intense enhancement after administration of PPD , and had an unspecific appearance possibly corresponding to a meningioma of the jugular sinus. Chest, abdominal, and pelvic CT scans taken on the same day (Day 477) showed an increase in the number and size of nodular and nodulillar images in both lung fields, linked to secondary lesions. There was an increase in the number and size of the secondary pulmonary, hepatic and adrenal lesions compared to the previous study. PPD was discontinued, and the subject was prescribed PPD . On PPD (Day 509), closed reduction of left shoulder dislocation under anesthesia was performed without complications, and the subject was discharged on PPD . On PPD , the subject was prescribed PPD . On PPD (Day 545), the subject received Dose 3 of the study intervention. On PPD , the subject exhibited generalized abdominal pain (intensity 4/10). On the same day, PPD was seen by PPD oncologist and a palliative care specialist, who prescribed PPD . PPD reported slight improvement in abdominal pain. On PPD (Day 677), the subject died due to disease progression. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the clear cell renal cell carcinoma and pathological fracture were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (175)	PPD
VACCINATION 4	BNT162b2	PPD (196)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Acute respiratory distress syndrome	PPD	PPD (260)	PPD	PPD (263)	PPD	4	4
2	INFEC	COVID-19 pneumonia		PPD (260)	PPD	PPD (263)	PPD	4	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Respiratory Distress Syndrome.	4	65	Y
2	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	4	65	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD (since an unknown date), received Dose 1 on PPD and Dose 2 on PPD (Day 20). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 175) and PPD (Day 196), respectively.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
The subject was diagnosed with acute respiratory distress syndrome and COVID-19 pneumonia on PPD, 64 days after receiving Dose 4 (the second dose of BNT162b2), and died of the acute respiratory distress and COVID-19 pneumonia on PPD, 67 days after receiving the second dose of BNT162b2. On PPD (Day 260), the subject experienced fever, dyspnea at rest, dry cough, and vomiting. The next day, the subject was taken to the hospital's emergency room, where a SARS-CoV-2 antigen detection test result was negative, and the subject was sent home. On PPD, the subject was admitted to the intensive care unit due to progression of dyspnea. The physician verbally reported that PPD chest x-ray showed bilateral cottony infiltrate and laboratory exams showed leukocytes of $18\times10^3/\mu L$ (normal range not reported). On PPD (Day 263) the subject died at the hospital at PPD due to acute respiratory distress syndrome and COVID-19 pneumonia. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the acute respiratory distress syndrome and COVID-19 pneumonia were related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	COVID-19	PPD	PPD (119)	PPD	PPD (156)	PPD	38	4
2	INFEC	Septic shock		PPD (119)	PPD	PPD (156)	PPD	38	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: COVID-19 infection	2	99	Y
2	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Severe Covid Disease	2	99	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD, a 60-year-old PPD with no reported medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 21).

The subject had severe COVID-19 illness and developed septic shock on PPD, 98 days after receiving Dose 2, and died of the events on PPD, 135 days after receiving Dose 2.

On PPD (Day 119), the subject was febrile (maximum temperature of 38.4°C), and complained of cough, chills, and fatigue. Two local COVID-19 tests were performed, on PPD and on PPD, with negative results. As part of the C4591001 study, a potential COVID-19 illness visit was also performed on PPD, and a nasal swab was collected at the site; the swab result was later reported as positive.

On PPD, the subject was hospitalized because of bilateral pneumonia. A chest computed tomography (CT) scan on the same day showed extensive bilateral patchy foci of ground-glass interstitial infiltrates, dense tracts, and bronchiectatic-like images in both lower lobes. On PPD, a chest CT scan showed mediastinum slightly retracted to the left without evidence of adenomegaly, and extensive, mixed (predominantly consolidated), bilateral parenchymal infiltrates were observed. On PPD, the subject was moved to the intensive care unit and required a mechanical ventilator from PPD because of respiratory failure. On PPD, a third local COVID-19 test result was positive. On PPD (Day 156), the subject died of septic shock in the context of the severe COVID-19 illness. The subject developed metabolic acidosis, acute renal failure with dialysis criteria, and marked cytopenias (anemia and thrombocytopenia).

Laboratory results on an unknown date showed hemoglobin of 8.4 g/dL, hematocrit of 25%, leukocytes of 6,000/mm^3, neutrophils of 79%, platelets of 16,000/mm^3, urea of 132 g/L, creatinine of 3.49 mg/dL, prothrombin time of 14.5 seconds, kaolin partial thromboplastin time of greater than 1 minute, prothrombin time of 66%, lactate dehydrogenase of 4367 IU/L, direct bilirubin of 2.9 mg/dL, total bilirubin of 3.8 mg/dL, aspartate aminotransferase of

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
329 IU/L, alanine aminotransferase of 222 IU/L, alkaline phosphatase of 545 IU/L, albumin of 2.8 g/dL, pH of 7.06, partial pressure of carbon dioxide of 72 mmHg, partial pressure of oxygen of 37 mmHg, and bicarbonates of 20 mmol/L (unknown normal ranges). The subject required vasopressor support with PPD (dose unknown) from PPD onward. On PPD (Day 156), the subject presented with severe bradycardia, followed by cardiac arrest. PPD received advanced resuscitation maneuvers (according to the American Heart Association protocol) for 30 minutes, without response. The causes of death reported on the death certificate were acute respiratory failure, multiorgan failure, and multilobar pneumonia. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the septic shock and severe COVID-19 illness were related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (142)	PPD
VACCINATION 4	BNT162b2	PPD (163)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Back pain	PPD	PPD (239)		PPD (248)		10
2	EYE	Optic ischaemic neuropathy		PPD (219)		PPD (244)		26
3	INFEC	Pneumonia		PPD (245)		PPD (248)		4

Adverse Events							
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC/W	N	Resolved (PPD)	NOT RELATED/OTHER: coughing	4	77	Y
2	2	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	4	57	N
3	3	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	4	83	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, and cholecystectomy PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 21). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 142), and PPD (Day 163), respectively. Concomitant medications received within 2 weeks prior to the onset of the back pain and pneumonia included PPD. The subject was diagnosed with back pain on PPD, 76 days after receiving Dose 4 (second dose of BNT162b2), and pneumonia on PPD ,82 days after receiving the second dose of BNT162b2. The subject died of pneumonia on PPD, 85 days after receiving the second dose of BNT162b2. On an unspecified date in PPD, the subject reported rib pain when coughing or sneezing, and was diagnosed with atypical pneumonia that was treated on an outpatient basis. The subject was treated with PPD. During the PPD, the subject experienced severe pain that began from under the ribcage, and gradually radiated to PPD back. PPD was treated with PPD from PPD. Due to persisting symptoms, PPD was stopped, and PPD was started on PPD on PPD (Day 239). The subject was treated with PPD, and all the PPD given for atypical pneumonia were stopped. On PPD (Day 244), the atypical pneumonia was considered resolved, and the subject continued to be treated for PPD persistent and worsening back pain/rib pain. On PPD (Day 245), the subject was unable to lay down or sit up without pain and went to the emergency room for cough congestion, shortness of breath, and back pain related to the previous event. A computed tomography (CT) scan showed pneumonia and a mass on the lung that was pressing against a nerve and causing pain. The pain was pleuritic in nature, and PPD reported that it 'hurts' when breathing. PPD was admitted for acute respiratory failure due to pneumonia or community-acquired pneumonia in the right, lower lobe of the lung. A SARS-CoV-2 test result on PPD was negative. Additional laboratory tests on the same day were as follows: high levels of D-dimer quantitative at >20.00, high white blood cell (WBC) count of 21.1; low arterial blood gas partial pressure of oxygen of 48.0, creatinine of 1.85, low estimated glomerular filtration rate of 36, and urine blood showed positive 2+ (normal ranges [NR] and units not reported). The subject was treated with PPD. The nature of PPD hypoxia and tachycardia was concerning for a pulmonary embolism (PE). A chest CT scan on PPD ruled out a PE but showed a mass on the right side; due to PPD history, it was thought to be possibly malignant. There were also possible spinal metastases. There appeared to be a postobstructive process in regard to the pneumonia, as well as a parapneumonic effusion. On the same day, the WBC count was

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
elevated at 17.2 (NR and unit not reported). PPD was awaiting pulmonary consultation. The subject died on PPD (Day 248) due to pneumonia. The subject's PPD reported that the day before passing, PPD showed troubled breathing and was utilizing oxygen. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the back pain was related to the study intervention. In the opinion of the investigator, there was no reasonable possibility that the pneumonia was related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the events were also not related to the concomitant medications.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Sepsis	PPD	PPD (282)		PPD (330)		49	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: multi-organ failure syndrome	2	263	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD (since unknown dates), received Dose 1 on PPD and Dose 2 on PPD (Day 20). Concomitant medications received within 2 weeks prior to the onset of the sepsis included PPD The subject was diagnosed with sepsis on PPD, 262 days after receiving Dose 2, and died of the event on PPD, 310 days after receiving Dose 2. The subject had an ongoing history of PPD and was suffering from PPD symptoms, including PPD since PPD. PPD had last used PPD on PPD.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
On PPD, the subject's anteroposterior and lateral side of the chest x-ray showed normal heart size and pulmonary vasculature; the right upper lobe had a new density of 1.1 cm and there were developing opacities in the left mid lung/lingula. On PPD (Day 282), the subject presented to the emergency room. PPD had worsened, as reported by PPD. PPD was noted to have nausea, vomiting, diarrhea, and weakness upon arrival. Examinations showed tachycardia of 131 (units and normal range [NR] not reported) and mild tachypnea. PPD appeared PPD during the neurological examination. A computed tomography (CT) scan of the abdomen and pelvis without contrast showed infiltrates in the lingula of the left upper lobe, and PPD was treated with PPD. On the same day (Day 282), a CT scan of the head with contrast showed no intracranial abnormality, and urinalysis showed amber colored urine with high glucose, protein levels, blood, and myoglobin detected. On PPD, the subject was hospitalized. PPD was treated for PPD and was admitted to the progressive care unit (PCU). PPD required intubation and mechanical ventilation. The subject's echocardiography showed cardiomyopathy with congestive heart failure (reduced ejection fraction of 20 to 25%); a CT scan of the abdomen and pelvis showed no acute findings. Laboratory test results showed blood creatine phosphokinase of greater than 14,000, low blood potassium (values and normal range not provided), and heart rate of 131 beats/min. The investigation revealed multi-organ failure, elevated troponin of 4.3, acute kidney injury, transaminitis, low potassium, metabolic acidosis, and rhabdomyolysis (blood creatine phosphokinase of >14,000 [NR not provided]). An abdominal ultrasound showed mild increased echogenicity of bilateral kidneys indicative of chronic renal disease. PPD and PPD were initiated per cardiology. On PPD, due to abnormal kidney function and acute kidney damage, PPD underwent successful insertion of 2 hemodialysis catheters via the right internal jugular vein. PPD was withdrawn when the subject's right internal jugular vein triple-lumen hemodialysis catheter started to bleed, and PPD received blood transfusions. On PPD, the subject was extubated. On PPD, the subject underwent right-sided thoracentesis, and 300 mL fluid was removed. On PPD, the subject was re-intubated. On PPD, the subject suffered a seizure and the electroencephalogram showed no findings, but the subject was treated with PPD. PPD continued to require blood transfusions and potassium replacement in dialysis. Additionally, due to the inability to control the thick secretions, a tracheostomy was suggested. However, the subject's family refused to consent to a tracheostomy despite prolonged intubation. Worsening infiltrates were noted on the x-ray. On PPD, the subject's right bronchoalveolar lavage showed heavy growth of *Acinetobacter baumannii*/*Acinetobacter nosocomialis* group. The subject was treated with PPD for the infection. PPD also received PPD.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
On PPD, the subject was PPD, and the PPD order for the subject: On PPD, a chest x-ray showed stable lines and tubes, right-sided pleural effusion, and no significant interval change in the bilateral patchy airspace opacity. On PPD (Day 330), at PPD, the subject died due to sepsis in the hospital. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the sepsis was related to the study intervention, concomitant medications, or clinical trial procedures but rather was related to multi-organ failure syndrome. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs – Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (141)	PPD
VACCINATION 4	BNT162b2	PPD (162)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (471)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Abdominal hernia obstructive	PPD	PPD (609)		PPD (610)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Unknown	5	139	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD a 60-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 21). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 141), PPD (Day 162), and PPD (Day 471), respectively. Concomitant medications received within 2 weeks prior to the onset of the obstructive abdominal hernia included PPD The subject was diagnosed with an obstructive abdominal hernia on PPD , 138 days after receiving Dose 5 (the third dose of BNT162b2), and died of the event on PPD , 139 days after receiving the third dose of BNT162b2. On PPD (Day 609), the subject developed intense abdominal pain and was hospitalized with an acute intestinal obstruction. A computed tomography scan of the abdomen showed an abdominal hernia. The subject's family member reported that the subject had lost at least 4 kg of weight since PPD and denied any other gastrointestinal symptoms. The subject underwent surgery. On PPD (Day 610), the subject died. The reported causes of death were disease progression of acute intestinal obstruction, sepsis, and obstructed abdominal hernia. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the obstructive abdominal hernia was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (135)	PPD
VACCINATION 4	BNT162b2	PPD (156)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Gastrointestinal haemorrhage	PPD	PPD (177)		PPD (181)		5	4
2	VASC	Hypovolaemic shock		PPD (181)		PPD (181)		1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: Unknown	4	22	Y
2	W	Y	Fatal (PPD)	NOT RELATED/OTHER: High digestive bleeding	4	26	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH
Withdrawn	OPEN LABEL TREATMENT	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 135) and PPD (Day 156), respectively. Concomitant medications received within 2 weeks prior to the onset of the gastrointestinal (GI) hemorrhage and hypovolemic shock included PPD. The subject experienced a GI hemorrhage on PPD, 21 days after receiving Dose 4 (second dose of BNT162b2). On PPD (Day 177), the subject was hospitalized for a GI hemorrhage of an unknown cause. The subject experienced hypovolemic shock due to the GI hemorrhage on PPD, 25 days after receiving the second dose of BNT162b2, and died in the hospital on the same day. The causes of death listed in the death certificate were hypovolemic shock and GI hemorrhage. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the GI hemorrhage and hypovolemic shock were related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (118)	PPD
VACCINATION 4	BNT162b2	PPD (139)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (433)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RENAL	Acute kidney injury	PPD	PPD (193)		PPD (198)		6	2
2	NEOPL	Adenocarcinoma of colon		PPD ()		PPD (547)			2
3	INFEC	Gastroenteritis		PPD (191)		PPD (198)		8	3
4	INFEC	Septic shock		PPD (552)		PPD (554)		3	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: Gastroenteritis	4	55	N
2	TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: Unknown	5	58	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: Unknown etiology	4	53	N
4	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Unknown	5	120	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD, an ≥75-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 118), PPD (Day 139), and PPD (Day 433), respectively.

Concomitant medications received within 2 weeks prior to the onset of the septic shock included PPD.

The subject suffered septic shock on PPD, 119 days after receiving Dose 5 (third dose of BNT162b2), and died of the event on PPD, 121 days after receiving the third dose of BNT162b2.

In PPD, the subject was diagnosed with an adenocarcinoma of the colon (sigmoid adenocarcinoma) via a routine colonoscopy. The subject was previously asymptomatic. On PPD (Day 547), the subject underwent segmental resection of the intestine via video laparoscopy. The routine pre-operative COVID-19 test result was negative. After surgery, the subject developed abdominal discomfort. A computed tomography (CT) scan of the abdomen was done in PPD, and the result showed anastomosis dehiscence. On PPD (Day 552), an additional surgery was performed. On the same day (Day 552), after surgery, the subject developed septic shock, requiring mechanical ventilation and unspecified vasoactive substances. Septic shock

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
was suspected due to abdominal discomfort, purulent discharge, hypotension, and abdominal CT scan findings; the event was considered associated with abdominal infection. There were no known reports of fever, chills, or respiratory symptoms. On PPD (Day 554), the subject was started on hemodialysis due to renal insufficiency (previous episode was from PPD to PPD [Days 193-198]), and the septic shock worsened, resulting in death on the same day (Day 554). Per death certificate, the primary cause of death was septic shock. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the septic shock was related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was a post-operative complication.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (143)	PPD
VACCINATION 4	BNT162b2	PPD (164)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	PPD		PPD (335)		PPD (335)		1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	4	172	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_CSR_Safety_Narrative/profile. (Database Snapshot Date: 07MAR2023) Date of Generation: 18APR2023 (17:51)

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (21)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (391)	PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	RESP	Chronic obstructive pulmonary disease	PPD	PPD (602)		PPD (602)		1	4	W

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Fatal (PPD)	NOT RELATED/OTHER: Subject has a history of PPD	3	212	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD, Dose 2 on PPD (Day 21), and Dose 3 on PPD (Day 391). The subject was diagnosed with chronic obstructive pulmonary disease (COPD) on PPD, 211 days after receiving Dose 3, and died on the same day. The subject's death information was provided by PPD, when the site sent a certified letter for the subject's noncompliance. An autopsy revealed the cause of death as COPD. In the opinion of the investigator, there was no reasonable possibility that the COPD was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per the investigator, the event was related to the subject's PPD history.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (23)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RENAL	Acute kidney injury	PPD	PPD (131)	PPD	PPD (132)	PPD	2
2	INFEC	COVID-19 pneumonia		PPD (131)	PPD	PPD (132)	PPD	2
3	INJ&P	Skin laceration		PPD (114)	PPD	PPD (114)	PPD	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Kidney damage	2	109	N
2	4	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Pneumonia	2	109	Y
3	1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Accident	2	92	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD , an ≥75-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 23). Concomitant medications received within 2 weeks prior to the onset of the COVID-19 pneumonia included PPD , and PPD for lower leg wound. The subject was diagnosed with COVID-19 pneumonia on PPD, 108 days after receiving Dose 2, and died of the event on PPD, 109 days after receiving Dose 2. On PPD (Day 131), the subject experienced garbled speech and increased confusion, and PPD was taken to the emergency room (ER). The subject's family reported that PPD was in rehabilitation care from PPD to PPD for a scalp laceration due to a PPD The subject had difficulty in ambulation and, hence, physical and occupational therapy was provided. PPD also had shortness of breath and chest congestion, but denied having fever, chills, nausea, vomiting, or diarrhea. A COVID-19 test done on PPD was negative. On arrival at the ER on PPD (Day 131), the subject's blood pressure was 124/68 mmHg, body temperature was 36.8°C, heart rate was 79 beats/min, respiratory rate was 20 breaths/min, and oxygen saturation was 98%. On the same day (Day 131), a SARS-CoV-2 test result was positive; laboratory test results showed elevated aspartate aminotransferase of 819 IU/L, estimated glomerular filtration rate of 13 mL/min, low hemoglobin of 9.2 g/dL (normal range [NR]: 14-18 g/dL), low hematocrit of 27.6% (NR: 40-52%), elevated international normalized ratio of 2.26, low lymphocytes of 8.8 (units not reported), and low platelets of $125\times10^3/\mu L$ (NR: 150-$450\times10^3/\mu L$); a chest x-ray showed bilateral airspace disease (cardiomegaly with congestive heart failure); and a computed tomography scan of the brain was normal. The subject was diagnosed with COVID-19 pneumonia, which was considered life-threatening by the investigator. On an unspecified date in PPD, the laboratory test results showed blood urea nitrogen (BUN) of 91, creatinine of 4.1, BUN/creatinine ratio of 21.9 (NR and units were not reported), and C-reactive protein of 24.7 mg/dL (NR not reported). The subject was not in any cardiopulmonary distress but had an acute kidney injury (on Day 131) secondary to acute tubular necrosis from the underlying COVID-19 infection. It was reported that there was no need for any dialysis at that time. Treatment with PPD was withheld because of the acute kidney injury and as the subject's baseline renal function results were unknown. On an unspecified date in PPD, the subject was kept in isolation, during which PPD oxygen saturation

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Narrative Comment
was 96% on room air. The subject was on telemetry and continued to do poorly. The family stated that the subject had a PPD order. Over the short stay in the telemetry unit, PPD oxygen saturation dropped to 83% and the subject was given 6 liters of oxygen via a nasal cannula. PPD continued to have dyspnea and became unresponsive. PPD was treated in the ER with PPD (on PPD) and PPD (from PPD to PPD) for COVID-19 pneumonia. On PPD (Day 132), the subject died of COVID-19 pneumonia. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the COVID-19 pneumonia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurrent with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History

Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (24)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (438)	PPD

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	BLOOD	Anaemia	PPD	PPD (143)	PPD	PPD (147)	PPD	5	1	N	N
2	RESP	Chronic obstructive pulmonary disease		PPD (143)	PPD	PPD (147)	PPD	5	3	TC	Y
3	RESP	Chronic obstructive pulmonary disease		PPD (631)		PPD (664)		34	4	W	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
4	METAB	Hyperkalaemia	PPD	PPD (143)	PPD	PPD (147)	PPD	5	1	N	N
5	INV	Lymphocyte count decreased		PPD (143)	PPD	PPD (147)	PPD	5	1	N	N
6	INV	Platelet count decreased		PPD (143)	PPD	PPD (147)	PPD	5	1	N	N
7	RESP	Respiratory failure		PPD (143)	PPD	PPD (147)	PPD	5	2	N	N
8	INFEC	Sepsis		PPD (143)	PPD	PPD (147)	PPD	5	2	TC	N
9	INV	Troponin increased		PPD (143)	PPD	PPD (147)	PPD	5	2	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (PPD)	NOT RELATED/OTHER: Probably due to anemia of chronic disease and without any symptoms of bleeding.	2	120	N
2	Resolved (PPD)	NOT RELATED/OTHER: Increased shortness of breath	2	120	N
3	Fatal (PPD)	NOT RELATED/OTHER: COPD	3	194	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	Resolved (PPD)	NOT RELATED/OTHER: Potassium level high in blood	2	120	N
5	Resolved (PPD)	NOT RELATED/OTHER: Infection	2	120	N
6	Resolved (PPD)	NOT RELATED/OTHER: Low number of platelets in blood	2	120	N
7	Resolved (PPD)	NOT RELATED/OTHER: Not enough of oxygen in the blood	2	120	N
8	Resolved (PPD)	NOT RELATED/OTHER: Probably due to Pneumonia	2	120	N
9	Resolved (PPD)	NOT RELATED/OTHER: Heart problem	2	120	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD, an ≥75-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD, Dose 2 on PPD (Day 24), and Dose 3 on PPD (Day 438). Concomitant medications included PPD. On PPD (Day 143), the subject experienced a COPD exacerbation manifested as shortness of breath and was hospitalized for the event. There was evidence of leukocytosis and possible pneumonia. A chest x-ray showed a right lower lobe or nodular density, right lower lobe pneumonia, and coarsened nodular right lower lung density. Diagnosis of sepsis was also documented on the discharge summary from the medical records; sepsis presented with leukocytosis, tachypnea and tachycardia, and normal lactic acid. The subject was tested for COVID-19 and the result was negative. PPD oxygen saturation was low at 47% on PPD (Day 143) and 33% on PPD. The subject received PPD. The increased troponin (0.035 ng/mL), hemoglobin: low at 12 g/dL (normal range [NR]: 14-18 g/dL), hematocrit: low at 36.2% (NR: 42-52%), hyperkalemia (potassium:

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Narrative Comment
5.4 mmol/L), decreased platelet count (214×10^3/µL; NR: 150-450×10^3/µL), and decreased lymphocyte count (7.0 µL) were positive laboratory results noted during hospital stay, resulting in a diagnosis of sepsis, pneumonia, chronic hypoxic respiratory failure, and anemia (all were considered as nonserious adverse events with onset of Day 143). On PPD (Day 147), all the events were considered resolved, and the subject was discharged on PPD . The subject experienced a severe COPD exacerbation on PPD, 193 days after receiving Dose 3, and died of the event on PPD, 226 days after receiving Dose 3. The subject died at home on hospice care. The reported cause of death was severe COPD exacerbation (disease progression). It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the severe COPD exacerbation was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (24)	PPD

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	INFEC	COVID-19 pneumonia	PPD	PPD (351)		PPD (355)	PPD	5	4
2	MUSC	Intervertebral disc disorder		PPD (186)		PPD (352)	PPD	167	2

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: community acquired pneumonia	2	328	Y
2	TC	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	163	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 24). Concomitant medications received within 2 weeks prior to the onset of the COVID-19 pneumonia included PPD for degeneration of lumbar intervertebral disease, and PPD. The subject was diagnosed with COVID-19 pneumonia on PPD, 327 days after receiving Dose 2, and died of the event on PPD, 331 days after receiving Dose 2. On PPD (Day 351), the subject was hospitalized with respiratory symptoms and malaise and was found to have COVID-19 bilateral pneumonia and hypoxia. Following admission, the subject's laboratory test results showed a positive COVID-19 rapid-test quantitative polymerase chain reaction, white blood cell count of 9.21×10^3/µL (high neutrophils of 80% [manual count]), low red blood cell count of 3.47×10^6/µL, low hemoglobin of 10.7 g/dL, low hematocrit of 32.3%, mean cell volume of 93 (units not reported), platelet count of 183×10^3/µL, creatinine clearance of 46.11 mL/min, sodium level of 140 mmol/L, critical potassium level of 2.8 mmol/L, chloride level of 108 mmol/L, low carbon dioxide level of 22 mmol/L, high aspartate aminotransferase of 54 U/L, high alanine transaminase of 44 U/L, critical protein total of 6.3 g/dL, low albumin level of 3.3 g/dL, high alkaline phosphatase of 259 U/L, high low-density lipoprotein of 284 U/L, high lactic acid level of 2.1 mmol/L, critical magnesium level of 2 mg/dL, and a high fibrinogen level of 897 mg/dL (normal ranges not provided). A chest x-ray showed multifocal pneumonia, and a computed tomography angiogram scan of the chest revealed diffuse ground glass infiltrates in the upper and lower lobes. The subject was diagnosed with COVID-19 bilateral pneumonia and hypoxia. PPD condition continued to deteriorate despite receiving treatment with PPD, oxygen support with respiratory therapy, nursing support, and incentive spirometry. On PPD, PPD was transferred to the intensive care unit because of intermittent tachycardia with a heart rate of 150 to 160 beats/min (atrial fibrillation on telemetry) and worsening of oxygen requirements coupled with decreased alertness. The subject's family decided to change PPD status to PPD because of PPD deteriorating condition, underlying PPD, and chronic illness. PPD treatments were withdrawn, and comfort care measures were taken. The subject was feeling comfortable after receiving PPD. On PPD (Day 355), the subject died in PPD sleep. The reported cause of death was COVID-19 pneumonia. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the COVID-19 pneumonia was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Death	PPD	PPD (382)		PPD (382)		1
2	GASTR	Diarrhoea		PPD (1)	PPD	PPD (3)	PPD	3
3	GASTR	Diarrhoea		PPD (22)	PPD	PPD (23)	PPD	2

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: natural causes	2	361	Y
2	1	N	N	Resolved (PPD)	Study Treatment	1	1	N
3	1	N	N	Resolved (PPD)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a 70-year-old PPD with a reported medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22). The subject died of an unknown cause on PPD , 360 days after receiving Dose 2. It was unknown if an autopsy was performed. In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (153)	PPD
VACCINATION 4	BNT162b2	PPD (174)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (406)	PPD

Adverse Events
No Adverse Events

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD a 50-year-old PPD with a reported medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 22).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 153), PPD (Day 174), and PPD (Day 406), respectively.

The subject died on an unspecified date. On PPD , the site updated the subject's disposition status for the study follow-up phase as "withdrawn" because of the death.

This death event occurred outside the protocol-defined postvaccination safety reporting period and as such was reported only as an update to the subject's disposition status but not reported as an adverse event. No additional details will be provided for this event.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (148)	PPD
VACCINATION 4	BNT162b2	PPD (169)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Angiosarcoma	PPD	PPD ()		PPD (348)			4
2	CARD	Cardio-respiratory arrest		PPD ()		PPD (348)			4
3	NEOPL	Vascular neoplasm		PPD ()		PPD (348)			4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/OTHER: epitheliod hemangioendothelioma - liver	4	140	Y
2	W	Y	Fatal (PPD)	NOT RELATED/OTHER: acute cardiopulmonary arrest	4	140	Y
3	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: Epithelioid hemangioendothelioma	4	140	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 148) and PPD (Day 169), respectively. The subject received nonstudy PPD on PPD. The subject developed angiosarcoma (epithelioid hemangioendothelioma - liver), malignant vascular neoplasm, and acute cardiorespiratory arrest on an unspecified date in PPD, at least 139 days after receiving Dose 4 (the second dose of BNT162b2), and died of the events on PPD, 179 days after receiving the second dose of BNT162b2. An autopsy was performed, and the reported causes of death were disease progression of angiosarcoma, vascular neoplasm, and cardiorespiratory arrest. In the opinion of the investigator, there was no reasonable possibility that the angiosarcoma, vascular neoplasm, and cardiorespiratory arrest were related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (140)	PPD
VACCINATION 4	BNT162b2	PPD (161)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD	PPD	PPD (215)		PPD (215)		1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Fatal (PPD)	NOT RELATED/CONCOMITANT DRUG TREATMENT	4	55	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (386)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Cardiac arrest	PPD	PPD (478)		PPD (478)		1	4
2	VASC	Hypertension		PPD (41)		PPD (83)		43	1
3	NERV	Hypoxic-ischaemic encephalopathy		PPD (481)		ONGOING			2
4	RESP	Pulmonary embolism		PPD (478)		PPD (484)	PPD	7	4

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: UNKNOWN	3	93	N
2	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Hypertension medication dose change	2	20	N
3	TC/TCN	N	Yes	NOT RELATED/OTHER: Unknown	3	96	N
4	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: UNKNOWN	3	93	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD , a 70-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD , Dose 2 on PPD (Day 22), and Dose 3 on PPD (Day 386).

Concomitant medications received within 2 weeks prior to the onset of the pulmonary embolism included PPD for hypertension, and PPD for hypertension.

The subject was diagnosed with a pulmonary embolism on PPD , 92 days after receiving Dose 3, and died of the event on PPD , 98 days after receiving Dose 3.

The subject experienced intermittent dizziness for approximately 1 month. Over the past week, PPD reported dyspnea on exertion and reduced exertional tolerance. On PPD (Day 478), the subject suffered cardiac arrest at home, and PPD was taken to the emergency room. A computed tomography scan revealed a pulmonary embolism. The subject was admitted to the intensive care unit and intubated. The subject was treated with PPD . On PPD (Day 481), the subject developed hypoxic-ischemic encephalopathy. On PPD (Day 484), the subject was transitioned to comfort care and was pronounced dead on the same day at PPD . The hypoxic-ischemic encephalopathy was ongoing at the time of death. The reported cause of death was pulmonary embolism. An autopsy was not performed.

In the opinion of the investigator, there was no reasonable possibility that the pulmonary embolism was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (165)	PPD
VACCINATION 4	BNT162b2	PPD (186)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Hypoaesthesia	PPD	PPD (435)	PPD	ONGOING		
2	MUSC	Muscular weakness		PPD (453)	PPD	ONGOING		
3	INJ&P	Wound dehiscence		PPD (418)	PPD	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Yes	NOT RELATED/OTHER: unknown	4	250	N
2	2	TCN	N	Yes	NOT RELATED/OTHER: Prolonged hospitalization	4	268	N
3	1	TCN	N	Yes	NOT RELATED/OTHER: unknown	4	233	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 60-year-old PPD with a reported medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 165) and PPD (Day 186). The subject died on an unspecified date. On PPD, the site updated the subject's disposition status for the study follow-up phase as "withdrawn" because of the death. This death event occurred outside the protocol-defined postvaccination safety reporting period and, as such, was reported only as an update to the subject's disposition status but not reported as an adverse event. No additional details will be provided for this event.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (168)	PPD
VACCINATION 4	BNT162b2	PPD (189)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (521)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RESP	Bronchopleural fistula	PPD	PPD (664)	PPD	PPD (695)	PPD	32
2	INFEC	Infectious pleural effusion		PPD (690)	PPD	PPD (695)	PPD	6
3	GENRL	Injection site pain		PPD (521)	PPD	PPD (523)	PPD	3
4	RESP	Pneumothorax spontaneous		PPD (661)	PPD	PPD (695)	PPD	35
5	RESP	Pulmonary embolism		PPD (677)	PPD	PPD (695)	PPD	19
6	SKIN	Subcutaneous emphysema		PPD (664)	PPD	PPD (695)	PPD	32

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	5	144	Y
2	4	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	5	170	Y
3	1	N	N	Resolved (PPD)	Study Treatment	5	1	N
4	4	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	5	141	Y
5	4	TC/TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	5	157	Y
6	3	TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	5	144	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment

Subject PPD a 60-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 23).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 168), PPD (Day 189), and PPD (Day 521), respectively.

Concomitant medication received within 2 weeks prior to the onset of the spontaneous pneumothorax, subcutaneous emphysema, bronchopleural fistula, pulmonary embolism, and infectious pleural effusion included PPD .

The subject suffered a spontaneous right pneumothorax on PPD , 140 days after receiving Dose 5 (third dose of BNT162b2).

On PPD (Day 661), the subject developed dyspnea (functional class IV) and severe right chest pain (intensity 9/10). On PPD (Day 664), the subject was brought to the emergency room because of PPD ongoing symptoms. On PPD , a chest x-ray revealed an image consistent with a right pneumothorax, and a right pleural drainage tube was placed. The subject was diagnosed with extensive subcutaneous emphysema and bronchopleural

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Narrative Comment
fistula on PPD, 143 days after receiving the third dose of BNT162b2. The subject was treated with PPD (dose, frequency, and duration unknown) and PPD symptoms improved. On an unknown date, the subject verbally stated that a chest computed tomography (CT) scan showed pulmonary bullae. The subject was hospitalized in the surgery department and was treated with PPD for pain management. On PPD (Day 677), 156 days after receiving the third dose of BNT162b2, the subject developed sudden dyspnea and desaturation, and a CT scan of the chest showed bilateral pulmonary thromboembolism. The subject was treated with an PPD, and on PPD, PPD required oxygen via high flow nasal cannula. On PPD, an inferior vena cava filter was placed. On the same day, a video-assisted thoracoscopic bullectomy was performed without any complications. The subject was transferred to the intensive care unit for postoperative follow-up. On PPD, analgesic was adjusted because of pain. The subject developed an infectious pleural effusion on PPD, 169 days after receiving the third dose of BNT162b2. The subject was treated with PPD following isolation of methicillin-sensitive *Staphylococcus aureus* in the pleural fluid. On PPD, the subject developed respiratory depression and desaturation, requiring mechanical ventilation for 24 hours. On PPD, the analgesic medication was readjusted for pain. On PPD, the pleural drainage tube was removed. On PPD (Day 695), a chest x-ray showed a bilateral alveolar interstitial infiltrate (4 quadrants). PPD developed severe psychomotor excitation, desaturation, poor ventilatory mechanics, tachycardia, and tendency to hypotension. On the same day (Day 695) at PPD, PPD experienced cardiorespiratory arrest and did not respond to cardiopulmonary resuscitation maneuvers. The subject died at PPD on PPD (Day 695). Per the death certificate, the reported cause of death was a pulmonary thromboembolism. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the spontaneous pneumothorax, subcutaneous emphysema, bronchopleural fistula, pulmonary thromboembolism, and infectious pleural effusion were related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past

PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_CSR_Safety_Narrative/profile. (Database Snapshot Date: 07MAR2023) Date of Generation: 18APR2023 (17:51)

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (23)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (431)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Acute myocardial infarction	PPD	PPD (665)	PPD	PPD (665)	PPD	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	3	235	Y

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD , a 60-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD , Dose 2 on PPD (Day 23), and Dose 3 on PPD (Day 431). Concomitant medications received within 2 weeks prior to the acute myocardial infarction included PPD The subject experienced an acute myocardial infarction on PPD , 234 days after receiving Dose 3, and died on the same day. The subject's PPD had last spoken to PPD on PPD . After unsuccessful attempts to contact PPD , a family member went to the subject's house and found PPD dead on the PPD . No additional details were provided. Per the death certificate, the subject died on PPD (Day 665), and the reported cause of death was acute myocardial infarction. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the acute myocardial infarction was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was more likely associated with the subject's underlying risk factors, including PPD .

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (429)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PSYCH	PPD	PPD	PPD (751)		PPD (751)		1
2	GENRL	Injection site pain		PPD (429)	PPD	PPD (430)	PPD	2
3	GENRL	Pyrexia		PPD (23)	PPD	PPD (23)	PPD	1

Adverse Events							
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	3	323	Y
2	1	TC	N	Resolved (PPD)	Study Treatment	3	1	N
3	2	TC	N	Resolved (PPD)	Study Treatment	2	2	N

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD
		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Narrative Comment
PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (419)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Cardiac arrest	PPD	PPD (755)	PPD	PPD (755)	PPD	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	3	337	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD, Dose 2 on PPD (Day 22), and Dose 3 on PPD (Day 419). Concomitant medications received within 2 weeks prior to the cardiac arrest included PPD. On PPD, the subject was involved in a PPD and suffered a right shoulder dislocation and right tibia and fibula fractures. The subject required a splint and was treated with unspecified PPD. On PPD, osteosynthesis of the fractures was performed without any complications. The subject suffered a cardiac arrest on PPD, 336 days after receiving Dose 3, and died on the same day. The subject's death information was reported by PPD when the site contacted PPD for follow-up. It was unknown if an autopsy was performed. Further details were not provided. In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was more likely related to the PPD and the subject's underlying diseases of PPD and history of PPD.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (150)	PPD
VACCINATION 4	BNT162b2	PPD (170)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Sudden death	PPD	PPD (257)	PPD	PPD (257)	PPD	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	TCN/W	Y	Fatal (PPD)	NOT RELATED/OTHER: PPD	4	88	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 150) and PPD (Day 170), respectively. Concomitant medications received within 2 weeks prior to the subject's sudden death included PPD. The subject died on PPD, 87 days after receiving Dose 4 (second dose of BNT162b2). On the morning of PPD (Day 257), the subject was feeling well and was asymptomatic. PPD went to bed at around PPD PM. Later, PPD heard a noise in the room and found the subject unconscious. PPD immediately called the emergency system, and the physician found the subject without any vital signs. Cardiopulmonary resuscitation was performed but was unsuccessful. The subject was pronounced dead the same day (Day 257). Per the death certificate, the primary cause of death was PPD, secondary cause of death was heart failure, and the final cause of death was cardiac arrest. An autopsy was not performed to determine the possible cause of death. In the opinion of the investigator, there was no reasonable possibility that the sudden death was related to BNT162b2, concomitant medications, or clinical trial procedures but rather was related to PPD. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the event was most likely coincidental and associated with the subject's underlying PPD conditions.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (21)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Benign gastrointestinal neoplasm	PPD	PPD (95)	PPD	PPD (95)	PPD	1	1
2	HEPAT	Cholangitis		PPD (343)	PPD	PPD (357)	PPD	15	3
3	HEPAT	Cholelithiasis		PPD (80)	PPD	PPD (105)	PPD	26	4
4	INJ&P	Craniocerebral injury		PPD (343)	PPD	PPD (357)	PPD	15	3
5	VASC	Deep vein thrombosis		PPD (315)	PPD	PPD (357)	PPD	43	3
6	INJ&P	Fall		PPD (343)	PPD	PPD (343)	PPD	1	2
7	NEOPL	Pancreatic carcinoma metastatic		PPD (137)	PPD	PPD (357)	PPD	221	3
8	GASTR	Pancreatitis acute		PPD (83)	PPD	PPD (105)	PPD	23	3
9	INFEC	Sepsis		PPD (343)	PPD	PPD (357)	PPD	15	3
10	INJ&P	Subdural haematoma		PPD (343)	PPD	PPD (357)	PPD	15	3

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	75	N
2	TC/TCN/W	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	323	Y
3	TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	60	N
4	TC/W	Y	Resolved (PPD)	NOT RELATED/OTHER: fall from your own height	2	323	Y
5	TC/W	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	295	Y
6	N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	323	N
7	TC/W	Y	Fatal (PPD)	NOT RELATED/OTHER: unknown	2	117	Y
8	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: gallstones	2	63	N
9	TC/W	Y	Resolved (PPD)	NOT RELATED/OTHER: cholangitis	2	323	Y
10	W	Y	Resolved (PPD)	NOT RELATED/OTHER: Head trauma	2	323	Y

Prohibited Concomitant Medications				
Investigator Text	WHO Drug Preferred Term	Start Date	End Date	Route
PPD		PPD	ONGOING	PPD
		PPD	ONGOING	

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a >65-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 21). Concomitant medications received within 2 weeks prior to the onset of the metastatic pancreatic adenocarcinoma, deep vein thrombosis (DVT), cholangitis, craniocerebral injury, sepsis, and subdural hematoma included PPD for bilateral lower limb DVT. The subject experienced abdominal pain and loss of appetite since PPD . The abdominal pain was resolved with PPD . During a gastroenterologist appointment, a blood test was performed (dates and results unknown) and the subject verbally stated that the blood work was unremarkable. The subject was diagnosed with metastatic pancreatic adenocarcinoma on PPD , 116 days after receiving Dose 2.

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Narrative Comment
On PPD, a renal and vesicoprostatic ultrasound showed 2 cortical cystic images of 34 mm and 13 mm and an abdominal ultrasound revealed a 12-mm long hypoechogenic nodular image in the right lobe; pancreas was normal in size, shape, and echogenicity; the right suprarenal gland showed a 15-mm nodule. On PPD, an enhanced abdominal and pelvic computed tomography (CT) scan revealed small slightly hypodense images with diffuse borders in the hepatic segments IVa and VII and the uncinate process of the pancreas. These images were not seen on a previous chest CT scan without contrast, which was done on PPD. Diffuse border hypodensity was noted in the hepatic segments V/VIII. Millimetric nodular hypodensity images in both adrenal glands were suggestive of adenomas, and the subject consulted PPD hepatologist. On PPD, a cholangioresonance and enhanced abdominal magnetic resonance imaging (MRI) showed solid focal liver lesions, the major one of which was on segment VII of approximately 32 mm of maximum diameter. On the inferior sector of the uncinate process, an area with regularly defined margins of approximately 38 mm suggestive of necrosis or cystic transformation was noted. The lesion was in intimate contact with the adjacent superior mesenteric artery with more than 25% compromise of its circumference. There was no ectasia of the main pancreatic duct. Cystic images of communication with the main pancreatic duct were found on the anterior face of the pancreatic body with a maximum diameter of approximately 6 mm and 5 mm. Another similar image was noted on the anterior face of the pancreatic head with a maximum diameter of approximately 7 mm. Evidence of prior cholecystectomy; the intra and extrahepatic biliary tract were nondilated. Nodules in both adrenal glands were compatible with adenomas (approximately 15 mm and 19 mm maximum diameter on the right and left, respectively). A possible diagnosis included pancreatic neoplastic lesion with secondary hepatic lesions and imaging criteria of unresectability. On PPD, the subject informed the site about the suspected pancreatic carcinoma with liver secondaries. On PPD, a CT scan and biopsy of the lesion were scheduled. PPD decreased appetite and abdominal pain persisted and worsened while lying down. The subject was treated with PPD available if required. PPD lost weight from PPD kg on PPD to PPD kg (current weight). On PPD, PPD underwent an enhanced chest, abdominal, and pelvic CT scan, and the results were unknown. According to a follow-up call on PPD, the subject's abdominal pain continued with analgesia required. On PPD, PPD presented to the emergency room (ER) because PPD abdominal pain worsened. PPD was admitted and received PPD. PPD verbally confirmed that PPD abdominal x-ray was unremarkable and abdominal ultrasound remained unchanged from previous studies. Results of blood tests were unremarkable. On PPD, PPD underwent a biopsy of the lesion without complications. After the procedure, PPD was taken back to the first hospital. PPD was discharged from the hospital on PPD on PPD and no discharge summary was provided. On PPD, PPD oncologist reported that the biopsy result was consistent with metastatic pancreatic carcinoma in both lesions (pancreas and liver). Owing to continued pain, on PPD, PPD met with a pain specialist, who prescribed PPD. The subject's abdominal pain improved

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Narrative Comment
slightly. On PPD, the subject started receiving PPD. It was planned to repeat the studies after 3 months for re-evaluation of treatment. The subject developed DVT on PPD, 294 days after receiving Dose 2. On PPD (Day 315), PPD was admitted to a local clinic and was treated with PPD for DVT. Upon admission, a physical examination revealed 4/6 edema in lower limbs with a positive Godet sign bilaterally; there was no alteration in color or temperature. The peripheral pulses were palpable. PPD blood test results showed hemoglobin of 9.6 g/dL, leukocytes of 11110/mm^3, platelets of 86000/mm^3, prothrombin time of 71%, activated partial thromboplastin time of 31, albumin of 2.8 g/dL (normal ranges and some units not reported). On the same day (Day 315), an abdominal ultrasound revealed multiple hypoechoic images of secondary aspect, most of 28 mm in segment VI of the liver. At the head of pancreas, a hypoechoic mass of poorly defined borders of 65×44×55 mm was seen consistent with previous reports. On PPD, a venous echo-doppler of lower limbs revealed thrombosis in both popliteal veins and both posterior tibial veins. On the same day, a transesophageal doppler echocardiogram revealed basal interventricular septum hypertrophy with left ventricular remodelling. Mild tricuspid insufficiency was also noted. PPD condition improved without complications. The subject remained hospitalized. PPD underwent PPD on PPD without complication; PPD therapy was continued. It was decided to discharge PPD from the hospital with outpatient care. On PPD, the subject revealed that PPD did not feel well so PPD last PPD regimen could not be completed. PPD did not specify the details. The subject developed cholangitis, craniocerebral injury, sepsis, and subdural hematoma on PPD, 322 days after receiving Dose 2. On PPD (Day 343), the subject was admitted to the hospital after falling and suffering head trauma. Upon admission, PPD was normotensive and had jaundiced skin and mucous membranes, edematous ascitic syndrome, PPD was eupneic with rales mostly in the right base, afebrile, and lucid. Owing to PPD advanced disease, it was decided not to continue with oncological treatment. PPD underwent biliary tract drainage with palliative intention. PPD received PPD and PPD coagulopathy improved. On an unreported date, a repeat brain CT scan showed parieto-occipital subdural collection consistent with the recent trauma. A Doppler ultrasound of the lower was consistent with deep vein thrombosis with distal extension, without suprapatellar involvement. The subject's PPD was restarted after discussion with the hematologist. On an unreported date, an abdominal ultrasound showed heterogeneous liver parenchyma with multiple focal lesions, most of which were 8 cm in segment VII. Dilated hepatocholedochal duct of 13 mm (maximum diameter) up to the intrapancreatic portion was partially visualized. Intrahepatic biliary tract was not dilated. Partially visualized pancreas, solid, hypoechoic, and ill-defined image at cephalic level. A CT scan of the abdomen revealed increased size of the mass and neoformative pancreatic nodules, increase in the number and size of retroperitoneal and locoregional adenomegalies, progression of pulmonary and hepatic secondaries, and bilateral pleural effusions and ascites.

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Narrative Comment
On PPD, home care was requested, and PPD was discharged on PPD. The symptoms and signs were attributed to cancer progression; the coagulopathy and cytopenia were stated to be known side effects of PPD and hypercoagulable state. On PPD, PPD was admitted to the hospital for palliative care. The subject remained hospitalized until PPD (Day 357) when PPD died. The subject's deep vein thrombosis was ongoing at the time of death. The cause of death was reported to be progression of metastatic pancreatic adenocarcinoma leading to multi-organ failure and cardiac arrest. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the metastatic pancreatic adenocarcinoma, deep vein thrombosis, cholangitis, craniocerebral injury, sepsis, and subdural hematoma were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per the investigator, the deep vein thrombosis was related to the hypercoagulable state secondary to cancer, whereas the craniocerebral injury and subdural hematoma were related to the fall.

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Reason(s) for Narrative: Death
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (19)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (417)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NEOPL	Adrenal adenoma	PPD	PPD (478)	PPD	ONGOING			1
2	BLOOD	Anaemia		PPD (495)	PPD	ONGOING			3
3	VASC	Aortic arteriosclerosis		PPD (478)	PPD	ONGOING			1
4	REPRO	Benign prostatic hyperplasia		PPD (478)	PPD	ONGOING			1
5	HEPAT	Bile duct stenosis		PPD (472)	PPD	ONGOING			2
6	HEPAT	Bile duct stone		PPD (472)	PPD	ONGOING			2
7	HEPAT	Cholangitis		PPD (513)	PPD	ONGOING			4
8	INV	Liver scan		PPD (478)	PPD	ONGOING			1
9	NEOPL	Pancreatic carcinoma		PPD (486)	PPD	ONGOING			3
10	INFEC	Septic shock		PPD (513)	PPD	ONGOING			4

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Reason(s) for Narrative: Death
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Yes	NOT RELATED/OTHER: unknown	3	62	N
2	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown	3	79	N
3	N	N	Yes	NOT RELATED/OTHER: unknown	3	62	N
4	N	N	Yes	NOT RELATED/OTHER: unknown	3	62	N
5	TC/TCN	Y	Yes	NOT RELATED/OTHER: Pancreatic head carcinoma	3	56	N
6	TC/TCN	Y	Yes	NOT RELATED/OTHER: unknown	3	56	N
7	W	Y	Fatal ()	NOT RELATED/OTHER: Carcinoma of the head of the pancreas	3	97	Y
8	N	N	Yes	NOT RELATED/OTHER: unknown	3	62	N
9	N	Y	Yes	NOT RELATED/OTHER: unknown	3	70	N
10	W	Y	Fatal ()	NOT RELATED/OTHER: Carcinoma of the head of the pancreas	3	97	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	DEATH

Narrative Comment
Subject PPD , a ≥75-year-old PPD with a pertinent medical history of PPD PPD), received Dose 1 on PPD , Dose 2 on PPD (Day 19), and Dose 3 on PPD (Day 417). On PPD (Day 472), the subject complained of non-specific abdominal pain, jaundice, skin pruritus, and choluria, for which PPD eventually went to PPD physician and was diagnosed with choledocholithiasis (bile duct stone) and choledochal stenosis. The physician requested an abdominal ultrasound that was performed on PPD , and it showed no abnormalities in the liver, gallbladder, kidney, spleen, or pancreas; however, the lower end of the biliary tract showed a 10-mm lithiasis image. On PPD (Day 478), a computed tomography scan of the abdomen and pelvis showed marked distension of the gallbladder, the topography of the left adrenal gland compatible with an adenoma, and an enlarged and heterogeneous prostate gland with small associated calcifications; dilatation of the intrahepatic and extrahepatic biliary tract with marked distension of the gallbladder without the presence of focal images in its interior were noted. The common bile duct reached approximately 15 mm in diameter without evidence of focal images. The uncinate process of the pancreas reached 3.5 cm in diameter, presenting an alteration of the adjacent fat density. The body and the caudal portion of the pancreas had preserved morphology and density. There were hypodense focal images at the level of both hepatic lobes, the largest of them towards segment IV of 2 cm in diameter. A focal hypodense image of approximately 2 cm in diameter was seen located in the topography of the left adrenal gland, compatible with

Narrative Comment
adenoma. Calcifications of the atheromatous aspect were noted at the level of the abdominal aorta and both iliac arteries. There were no retroperitoneal adenomegalies. Examination of the pelvis showed an enlarged and heterogeneous prostate gland with small associated calcifications imprinting the bladder floor. The urinary bladder presented a little distension. Laboratory results on PPD (Day 478) were abnormal with alanine aminotransferase (ALT) at 656 IU/L (normal range [NR]: ≤40 IU/L, aspartate aminotransferase (AST) at 281 IU/L (NR: ≤38 IU/L), alkaline phosphatase (ALP) at 1554 IU/L (NR: 90-300 IU/L), direct bilirubin at 16.31 mg/dL (NR: ≤0.2 mg/dL), indirect bilirubin at 3.63 mg/dL (NR: ≤0.8 mg/dL) and total bilirubin at 19.94 mg/dL (NR: ≤1 mg/dL); anti-hepatitis A antibody, hepatitis B surface antigen, and anti-hepatitis C antibody were within normal limits. Blood test results on the same day (Day 478) showed hemoglobin (Hgb) of 13.1 mg%, hematocrit (Hct) of 39.2%, leukocytes at 3200/mm^3, neutrophils at 73%, lymphocytes at 20%, platelets at 240,000/mm^3 and erythrocyte sedimentation rate of 77 mm (NR: ≤15 mm). PPD was also glycemic with glucose at 113 mg/dL (NR: 70-110 mg/dL) along with a cholesterol of 316 mg/dL (NR: ≤200 mg/dL), low-density lipoprotein of 198 mg/dL (NR:≤130 mg/dL), and triglyceride at 254 mg/dL (NR: ≤170 mg/dL). On the same day (Day 478), the subject was diagnosed with concurrent left adrenal adenoma, aortic arteriosclerosis, and benign prostatic hyperplasia. The subject was prescribed PPD from an unknown date. On PPD, a magnetic resonance cholangiopancreatography was performed, and the result confirmed dilatation of the intrahepatic and extrahepatic biliary tract. Small hypointense focal images in T1 and hyperintense in T2 at the level of both hepatic lobes, which was compatible with cysts, were noted. On PPD, the subject had the same symptoms, presented fever (temperature unknown), and was hospitalized for clinical control and treatment. During hospitalization, a COVID-19 test was performed with negative results. On PPD (Day 486), the subject was hospitalized to undergo an endoscopic retrograde cholangiopancreatography. The procedure was successful, and the subject remained clinically stable. As per the surgical report (on PPD), the subject presented a neoplastic ulcer in the upper supra-papillary knee with evidence of bleeding. Normal papilla, bile duct with terminal stenosis, and proximal dilatation were noted. Endoscopic papillotomy was performed and a stent of 10×12 cm was placed. PPD was eventually diagnosed with pancreatic carcinoma on the same day (Day 486). As per another surgical report on PPD, the first stent was in a good position, and another stent was placed in a shotgun tube with the previous one permeable. There was no great proximal dilatation of the biliary tract, which bled easily at the contact of the papilla and duodenal ulcer. The subject was discharged on PPD, since the abdominal pain resolved, and PPD was feeling well. Other symptoms like jaundice of the face and sclerae, face pruritus, and choluria persisted. The subject's PPD reported that the subject had another blood test on PPD (Day 495), which led to the diagnosis of anemia by the surgeon (no results available), who prescribed PPD. On PPD, a control blood test was performed, which revealed Hgb of 7.20 g/dL, Hct at 22.7%, leukocytes of 9,800/mm^3, neutrophils at 76%, lymphocytes at 20%, cholesterol of 298 mg/dL, AST at 180 IU/L, ALT at 251 IU/L, ALP at 2850 IU/L, and total bilirubin at 10.50 mg/dL. The next day (PPD), the subject experienced asthenia and PPD physician suggested a red blood cell transfusion based on the laboratory results; PPD received the transfusion and was discharged on the same day from the clinic. On PPD, the subject was febrile (temperature not reported) and took PPD. On PPD, the subject was taken to the emergency room with increased

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Narrative Comment
asthenia and muscle weakness and was admitted due to the anemia (reported on PPD [Day 495]). On PPD, the subject was discharged. However, on PPD, the subject was readmitted in the intensive care unit (ICU) as PPD asthenia worsened. The subject was diagnosed with cholangitis and septic shock on PPD, 96 days after receiving Dose 3. On PPD (Day 513), the subject was hospitalized because of choledochal stenosis due to pancreatic head carcinoma, wherein 2 polyvinyl chloride stents were placed. The total bilirubin decreased from 50 mg/dL to 6.4 mg/dL. On PPD (Day 513), an abdominal ultrasound scan revealed dilatated intrahepatic and extrahepatic biliary tract, choledochus of 19 mm with echogenic content and catheter inside, pancreas with a hypoechoic layer at the cephalic level, and heterogeneous nodular image of 61×37×46 mm compatible with pancreatic blastoma. No intra-abdominal fluid collections were observed. The laboratory test results on the same day (Day 513) included hematocrit of 27%, leukocytes of 18,700/mm^3, neutrophils of 80%, lymphocytes of 18%, platelets of 18,7000/mm^3, ALP of 1106 UI/L, AST of 28 UI/L, ALT of 53 UI/L, amylase of 117 U/L, direct bilirubin of 4 mg/dL, total bilirubin of 6.4 mg/dL (NR not provided). The subject remained in the ICU. PPD reported that the subject was in poor condition due to a locally advanced tumor. The subject died on PPD at PPD, and the cause of death was a pancreatic tumor which led to cholangitis and septic shock. All the events were ongoing at the time of the subject's death. An autopsy was not performed. In the opinion of the investigator, there was no reasonable possibility that the cholangitis and septic shock were related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (188)	PPD
VACCINATION 4	BNT162b2	PPD (208)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (443)	PPD

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	MUSC	Psoriatic arthropathy	PPD	PPD (59)	PPD	ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			2	TC	Y	Yes	Study Treatment	2	38	Y

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment

Subject PPD, a 30-year-old PPD, with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22)

Concomitant medication received within 2 weeks prior to the onset of the psoriatic arthropathy included PPD.

The subject was diagnosed with psoriatic arthropathy on PPD, 37 days after receiving Dose 2.

On an unspecified date, the subject was asymptomatic and came to the site for the 1-month post–Dose 2 visit and had PPD blood drawn for the immunogenicity assessment. After a few days, the subject developed swelling and pain in the left elbow that made it painful to externally rotate the elbow joint. About a week later, the subject experienced pain and swelling in PPD right foot, primarily the dorsum of the foot and the second and third toes. PPD also developed pain and swelling of the left index finger in the shaft area of the proximal interphalangeal (PIP) joints. The swelling was present in the morning and abated at night. The subject had no fever, chills, or night sweats, and no other joints were involved. PPD also had no prior history of arthritis or tenosynovitis and no recent history of urethral pain on urination, but PPD had a family history of PPD.

On physical examination (date not specified), the subject's left elbow was not warm or swollen, the index finger of the left hand was not swollen or tender to motion, the right foot was not warm but was swollen in the dorsal area, the second and third toes were diffusely swollen (sausage toes) without pain, and there was no joint pain. There was no sign of a tick bite or rash, and there was no adenopathy in the epitrochlear or axillary area. The site's clinical impression was tenosynovitis of the second and third right toes, resolving tenosynovitis of the left index finger, and possible tenosynovitis of the left elbow. Laboratory test results showed an erythrocyte sedimentation rate (ESR) of 2, C-reactive protein (CRP) of 0.168, white blood cell (WBC) count of 5.7, hemoglobin (Hgb) of 16.6, platelet count of 1.61, and lymphocyte count of 1.0 (units and normal ranges were not reported for all); and rheumatoid factor and Lyme serology tests were both negative.

The subject saw PPD primary care physician, who referred PPD to a rheumatologist for evaluation (date not specified). The subject was diagnosed with reactive arthritis. On PPD, laboratory investigations showed a CRP of 0.777 and ESR of 14 (normal range: 0-20); cyclic citrullinated peptide, rheumatoid factor, and human leukocyte antigen B27 assay tests were all negative; and urinalysis was normal. On the same day (Day 107), the subject was prescribed PPD. On PPD, following treatment with PPD, the subject reported improvement in the foot swelling but continued to have swelling in the second and third digits of PPD right foot, in PPD left index finger, and in PPD left elbow. The subject continued to have significant joint pain in the left elbow and in the index finger, resulting in limited sports activities, but PPD continued to work. On PPD, x-ray results of both hands and the right foot were normal. Since PPD last visit to the site, the subject had several appointments with a rheumatology/immunology consultant and had undergone several laboratory tests; the most notable was the slight rise in ESR to 14 from a prior value of 2, as well as an increase in CRP to 1.53 from 0.168, with unremarkable complete blood count and basic metabolic panels.

On PPD, the subject had an unscheduled visit to the site. At this visit, the swelling in PPD right foot and the second and third toes had resolved; PPD right index finger remained tender with movement of the PIP and distal interphalangeal joints; and PPD left elbow was more symptomatic with increased

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pain, swelling, and limited range of motion. On PPD, the WBC count was 5.50, platelet count was 233.000 and Hgb was 16.3 (units not reported for all); neutrophils were 70.6%, lymphocytes were 18.6%, and eosinophils were 2.2%; aspartate aminotransferase, alanine aminotransferase, blood electrolytes, blood urea nitrogen, and blood creatinine were all normal. A left elbow x-ray result was normal. The subject developed several new patchy, scaly cutaneous lesions above PPD right eyebrow, hairline, and scalp; and there were no cutaneous lesions on PPD trunk or extremities. The rheumatologist's tentative clinical diagnosis was psoriatic arthropathy. As the subject had limited ability to carry out prior activities, the investigator assessed the psoriatic arthropathy as a serious adverse event of special interest. The subject was treated with PPD

The psoriatic arthropathy was ongoing at the time of the last available report.

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether PPD was eligible for receipt of BNT162b2. It was confirmed that PPD had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 188), PPD (Day 208), and PPD (Day 443). respectively.

In the opinion of the investigator, there was a reasonable possibility that the psoriatic arthropathy was related to the study intervention and clinical trial procedure (blood draw) but was not related to the concomitant medication. Per Pfizer, the psoriatic arthropathy was not related to the study intervention, concomitant medications, or clinical trial procedures.

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (24)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	EYE	Corneal irritation	PPD	PPD (1)	PPD	PPD (4)		4
2	GENRL	Shoulder injury related to vaccine administration		PPD (24)	PPD	PPD (176)		153

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (PPD)	NOT RELATED/OTHER: Contact lens wear	1	1	N
2	3	N	Y	Resolved (PPD)	Study Treatment	2	1	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	PROTOCOL DEVIATION

Narrative Comment
Subject PPD, a 30-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 24). Concomitant medication received within 2 weeks prior to the onset of the shoulder injury related to vaccine administration (SIRVA) included PPD (since an unknown date) for allergies. The subject experienced SIRVA on PPD, the same day PPD received Dose 2.

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On PPD (Day 24), after Dose 2 administration and late in the evening, the subject experienced pain in the whole of PPD left arm. PPD noted that the adhesive bandage from Dose 2 was very high on PPD arm and experienced some soreness of PPD upper arm with very limited range of motion for the first few days and burning pain down PPD arm. Initially, PPD also had a tingling sensation down PPD arm; however, this resolved. On PPD, the subject had a sensation of numbness, which affected PPD arm and hand, with a loss of dexterity, notable when typing. The subject reported that PPD condition was improving gradually, especially in terms of pain, but PPD still had a significant limitation in range of motion and daily activities. On examination, PPD had no obvious swelling, color change, bruising, or tenderness over the left deltoid. PPD could raise PPD left arm slightly higher than 90 degrees and with assistance could lift higher, but this caused significant discomfort; PPD could not extend PPD left arm behind PPD back well. The strength was noted to be 5/5. When moving PPD arm against resistance, PPD experienced pain down PPD arm and increased sensation of numbness. The investigator reported a possible diagnosis of SIRVA. The subject was aware that the shoulder injury could be self-limited but could last for some time and was considering physical therapy as an option. The investigator suggested a neurology consultation and discussed arrangements for physical therapy. The subject was seen by a neurologist, who noted the following findings: motor function had normal muscle bulk and tone. No apparent fasciculation or scapular winging was noted. Shoulder abduction was limited to 70 degrees, shoulder internal rotation was limited as well, but PPD was able to extend PPD left hand behind PPD back. The neurologist considered 2 diagnoses: SIRVA and immune-mediated brachial plexus neuropathy (Parsonage-Turner syndrome), noting that the clinical picture demonstrated components of both. An electromyography (EMG) was recommended to determine if there was nerve involvement and, if so, to what degree. At the time of the neurological evaluation, the subject had started physical therapy.

On PPD, a needle EMG of the left upper extremity for all muscles was performed and was reported to be unremarkable. The deltoid sample was not collected because of the suspected prior injury to the area. It was reported that since onset, both the pain and limitation in range of motion had improved at this time; additionally, there was great improvement in the shoulder and upper arm, but less so in the hand or fingers. The EMG results did not reveal any neurophysiological evidence of a left brachial plexopathy, median dysfunction at the left wrist, ulnar dysfunction across the left elbow, or left cervical radiculopathy. On PPD, the neurologist considered SIRVA as the diagnosis, most likely based on the clinical improvement and the EMG result that did not reveal nerve involvement. The subject reported continued improvement, especially of the upper arm, with increased range of motion, but continued to experience decreased dexterity of the left hand. The subject was attending physical therapy twice weekly and reported satisfaction with the gradual and continued improvement. On PPD, the subject reported that 5 weeks of physical therapy had been completed and that the improvement was significant, but that PPD was not back to PPD usual state of health. Later, after completing physical therapy, PPD felt much better and had returned to baseline state of health, and the SIRVA was considered resolved on PPD (Day 176).

In the opinion of the investigator, there was a reasonable possibility that the SIRVA was related to the study intervention and to a clinical trial procedure (vaccine administration), but not related to concomitant medications. Pfizer concurred with the investigator's causality assessment. Per Pfizer, from the location of the band-aid, it appeared that the vaccine was erroneously administered into or near the shoulder joint capsule. As postulated in the medical literature, unintentional injection of vaccines into the shoulder joint synovial tissues may result in an immune-mediated inflammatory reaction causing SIRVA.

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Reason(s) for Narrative: Related Serious Adverse Event, Myocarditis/Pericarditis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Related Serious Adverse Event, Myocarditis/Pericarditis
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD
VACCINATION 3	BNT162b2	PPD (71)	PPD
VACCINATION 4	BNT162b2	PPD (94)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (351)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	PPD	PPD (351)	PPD	PPD (353)	
2	GENRL	Fatigue		PPD (351)	PPD	PPD (353)	
3	NERV	Headache		PPD (351)	PPD	PPD (353)	
4	CARD	Myocarditis		PPD (354)	PPD	PPD (454)	
5	GENRL	Pain		PPD (351)	PPD	PPD (353)	
6	GENRL	Pyrexia		PPD (351)	PPD	PPD (353)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	1	TC	N	Resolved (PPD)	Study Treatment	5	1	N

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Reason(s) for Narrative: Related Serious Adverse Event, Myocarditis/Pericarditis
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	3	1	N	N	Resolved (PPD)	Study Treatment	5	1	N
3	3	1	TC	N	Resolved (PPD)	Study Treatment	5	1	N
4	101	3	TC	Y	Resolved (PPD)	Study Treatment	5	4	Y
5	3	1	TC	N	Resolved (PPD)	Study Treatment	5	1	N
6	3	1	TC	N	Resolved (PPD)	Study Treatment	5	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

Narrative Comment

Subject PPD, a ≤24-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 20).

In accordance with the protocol allowance, the subject's PPD agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 71), PPD (Day 94), and PPD (Day 351), respectively.

Concomitant medications received within 2 weeks prior to the onset of the myocarditis included PPD, and PPD (since an unknown date) PPD.

The subject was diagnosed with myocarditis on PPD, 3 days after receiving Dose 5 (third dose of BNT162b2).

On PPD (Day 351), the subject received the third dose of BNT162b2 and experienced reactogenicity symptoms, including body aches, fatigue, low grade temperature, chills, and headache. On PPD (Day 353), the reactogenicity symptoms subsided and PPD felt better. PPD On PPD (Day 354), the subject complained of joint pain and muscle pain (upper arms, neck, and upper middle back). PPD felt better after taking PPD and went to work. PPD. On PPD at PPD, PPD suffered intense pain and took more PPD. PPD felt better but the pain was bothersome and persisted throughout the day. PPD was able to go PPD. Around PPD PM,

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Reason(s) for Narrative: Related Serious Adverse Event, Myocarditis/Pericarditis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
PPD complained of indigestion (later described as left-sided chest pain). At PPD PM, the subject was hospitalized due to intense pain. During the hospitalization, an electrocardiogram (ECG) showed ST elevation suggestive of pericarditis. The subject's laboratory test results included elevated creatine kinase of 720 IU/L (normal range (NR): 30-200 IU/L), troponin I of 6.160 ng/mL (NR: 0.000-0034 ng/mL), blood pressure of 133/88 mmHg, heart rate of 67 beats/min, respirations of 15 breaths/min, oxygen saturation of 98%, B-type natriuretic peptide of 69.4 pg/mL (NR: 0-85 pg/mL). PPD chest x-ray was normal. The subject was transferred to the PPD hospital. PPD was treated with PPD for pain management and PPD symptoms were monitored. On PPD, PPD troponin level was 14.865 ng/mL (AM level), 12.508 ng/mL (PM level), and 12.194 ng/mL (time not reported) and was diagnosed with myocarditis by the cardiologist. PPD remained hospitalized to monitor troponin levels every 8 hours until they peaked. Before discharge, PPD was monitored until 2 troponin test results showed a decline. PPD cardiac magnetic resonance imaging (MRI) was consistent with myocarditis. Left ventricular volume and function remained normal. An echocardiogram showed normal ejection fraction and mild mitral regurgitation. The cardiologist felt that the mitral regurgitation was not related to myocarditis and was likely present for a while. PPD COVID-19 immunoglobulin (Ig) G spike protein antibody was positive, COVID-19 IgM antibody was negative, and C-reactive protein (CRP) was 1.3 mg/dL (NR: less than 0.5 mg/dL). Laboratory results on PPD were a CRP of 0.9 mg/dL (NR: less than 0.5 mg/dL) and troponin I of 19.178 ng/mL, 20.242 ng/mL (at PPD AM per PPD report), 21.619 ng/mL, and 18.244 ng/mL, respectively (NR: 0.034-0.000 ng/mL). On PPD, PPD ECG was abnormal with low right atrial bradycardia and ST elevation indicating pericarditis. PPD symptoms began to improve, and PPD laboratory results were CRP of 0.4 mg/dL, troponin I of 14.310 ng/mL (at PPD AM) and 9.662 ng/mL (at PPD AM). The subject was discharged from the hospital at PPD AM. The subject had an intermittent increase in chest and back pain throughout the hospital stay and was treated with PPD. On PPD, the subject's PPD reported that the subject was feeling better but still felt tired. During the follow-up visit on PPD, an echocardiogram was normal, and the ECG showed T wave inversion, normal ST segments, and normal PR and QT intervals. The cardiologist examination revealed normal left ventricular systolic function. On PPD (Day 454), the stress test showed mild exercise impairment, which was consistent with the subject's forced sedentary behavior. There were no ST segment changes or indications of arrhythmia noted. The subject recovered from myocarditis with sequelae on the same day (Day 454). A follow-up MRI 2 months after the illness was planned. Depending on the MRI result, an exercise stress test would be scheduled 3 months after the illness. On PPD, the MRI showed persistent, but moderately improved patchy enhancement of the left ventricle myocardium in similar distribution to previous and normal size and function of the left ventricle. No hypokinesis of the left ventricle was identified. There was an improvement in the late gadolinium enhancement. In the opinion of the investigator, there was a reasonable possibility that the myocarditis was related to BNT162b2 but was not related to the concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Paraesthesia	PPD	PPD (68)		PPD (288)	

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	221	2	TC	Y	Resolved (PPD)	Study Treatment	2	47	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA

Narrative Comment

Subject PPD , a 50-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 22).

Concomitant medications received within 2 weeks prior to the onset of the paresthesia included PPD .

The subject experienced right leg paresthesia on PPD , 46 days after receiving Dose 2. On PPD (Day 68), the subject began experiencing right leg paresthesia. On PPD , PPD had a nasal/sinus operation and received PPD . On PPD , PPD had lower back pain and bilateral lower extremity pain that was described as shooting pain, worse on the right side. PPD legs and parietal area of the scalp were sensitive to touch, with an associated burning pain. PPD also reported tenderness in the bilateral inguinal area. The symptoms gradually developed over approximately the past 3 weeks. The subject's spine magnetic resonance imaging (MRI) was unremarkable; and the subject did not consult PPD primary care physician or a neurologist at that time. The subject denied any neurological or lower back problems. PPD stated that when PPD began experiencing the symptoms, PPD pain score was assessed as 8-9 on a scale of 10 for a couple of weeks and PPD used PPD PPD also reported that there had been a significant decrease in PPD level of activity. On PPD , during a follow-up visit with the investigator, the subject reported that the paresthesia and skin sensitivity over the parietal area had improved. The subject reported that PPD used PPD initially, and later received PPD . After treatment with PPD , PPD pain score at its worst was 6-7 on a scale of 10. PPD continued to use PPD and was able to function adequately despite persistence of mild (1-2/10 in severity) constant pain in PPD lower back and legs. The subject also reported that PPD had not noticed any exacerbating factors and denied any recent injury, travel, infection, or change in diet. On PPD , the subject reported that PPD walked approximately 1 mile without any problem. Despite still not having an official diagnosis, the investigator opted to report this as an important medical event

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Narrative Comment
since symptoms had persisted and the subject believed the symptoms started closer to 5 weeks after vaccination, which was close to the 4-week postvaccination observation period. The site obtained the medical records from the neurologist and the subject was seen on PPD. As per the neurologist's note, an MRI of the cervical spine performed several years before showed mild degenerative changes and spondylosis. The MRI of the lumbar spine performed recently showed "degenerative discopathy with small left central disc protrusion at T5-T6 with minimal indentation thecal sac. No spinal cord compression, spinal canal stenosis, or neural foramina narrowing was observed. Multilevel hypertrophic changes of the facets within the lumbar spine with no neural foramina stenosis was noted. An incidental finding revealed multilevel small hemangiomas in the cervical and thoracic vertebral bodies." A neurological examination on the same day was normal, including gait and tandem walk. Tenderness was noted throughout the lower extremity musculature bilaterally and large mobile inguinal lymph nodes were palpable bilaterally. The laboratory tests ordered by the neurologist were normal, including erythrocyte sedimentation rate of 15 mm/hour (NR: 0-20 mm/hour), C-reactive protein of 0.3 mg/dL (NR: <0.5 mg/dL), Lyme antibody of 0.25 (negative less than 0.9; units not reported); antinuclear antibody was negative, serum protein electrophoresis was normal, and no monoclonal protein was seen. Imaging study reports were not available; the neurologist's impression included possible post-viral syndrome or an autoimmune process. There was no mention of concern for myelitis or any plan for further workup. The neurologist's recommendation was to continue PPD, and follow up with the primary care physician if laboratory results were unrevealing. It was planned to have the subject return to the clinic to obtain a more in-depth history and possibly some laboratory tests as well as request reports of MRIs. The right leg paresthesia resolved on PPD (Day 288). In the opinion of the investigator, there was a reasonable possibility that the right leg paresthesia was related to the study intervention, but not related to concomitant medications or clinical trial procedures. Pfizer did not assess the right leg paresthesia as related to the study intervention and considered that there is not enough evidence to establish a causal relationship with the study intervention apart from a chronological association at the time of the report. Based on the information currently available, it was more likely that the right leg paresthesia was associated with the subject's underlying known PPD conditions.

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (159)	PPD
VACCINATION 4	BNT162b2	PPD (179)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (414)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	SKIN	Angioedema	PPD	PPD (414)		PPD (415)		2
2	EYE	Conjunctival haemorrhage		PPD (416)		ONGOING		
3	INFEC	Conjunctivitis		PPD (274)		PPD (288)		15
4	EAR	Ear pain		PPD (272)		PPD (275)		4
5	VASC	Hypertension		PPD (309)		ONGOING		

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	TC	Y	Resolved (PPD)	Study Treatment	5		Y
2	1	TC	N	Yes	Study Treatment	5	3	N
3	2	N	N	Resolved (PPD)	NOT RELATED/OTHER: unk	4	96	N
4	2	TC	N	Resolved (PPD)	NOT RELATED/OTHER: unk	4	94	N
5	1	TC	N	Yes	NOT RELATED/OTHER: unk	4	131	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

Narrative Comment
Subject PPD a 50-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 21). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 159), PPD (Day 179), and PPD (Day 414), respectively. The subject experienced angioedema on PPD, the same day PPD received Dose 5 (the third dose of BNT162b2). On PPD (Day 414), 30 minutes after taking PPD last meal of the day, the subject experienced itching/tingling sensation of face/eyes. The subject had pronounced angioedema of both eyes at PPD, followed by itching/tingling sensation in PPD throat, along with tongue heaviness/swelling. PPD was brought to the emergency room by PPD at PPD for an allergic reaction. PPD was diagnosed with angioedema and treated with PPD,

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
PPD as a standard care for allergic reaction. The event angioedema resolved on PPD (Day 415). There were no lifestyle habit (product/food) changes for the subject, nor did PPD report a previous allergic history. In the opinion of the investigator, there was a reasonable possibility that the angioedema was related to BNT162b2 but was not related to clinical trial procedures. Pfizer did not concur with the investigator's causality assessment. Per Pfizer, a reaction to the food ingested during the last meal was a reasonable alternative explanation.

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (59)	PPD
VACCINATION 4	BNT162b2	PPD (79)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Injection site pain	PPD	PPD (79)	PPD	PPD (81)	PPD	3	2
2	MUSC	Osteoporosis		PPD (83)	PPD	ONGOING			2
3	NERV	Transient ischaemic attack		PPD (83)	PPD	PPD (83)		1	3

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (PPD)	Study Treatment	4	1	N
2	TC	N	Yes	NOT RELATED/OTHER: new onset of disease	4	5	N
3	TC	Y	Resolved (PPD)	Study Treatment	4	5	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA

Narrative Comment

Subject PPD , a 70-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 23).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 59) and PPD (Day 79), respectively.

Concomitant medications received within 2 weeks prior to the onset of the transient ischemic attack (TIA) included PPD

The subject suffered a TIA on PPD , 4 days after receiving Dose 4 (the second dose of BNT162b2).

On the evening of PPD (Day 83), the subject experienced slurred speech and dizziness followed by unsteady gait. All symptoms had resolved by the time the subject arrived at the emergency room. The subject had no history of similar symptoms, and PPD denied having any other symptoms, including headache, blurred vision, chest pain, shortness of breath, nausea, vomiting, diarrhea, weakness, or numbness in the extremities. The subject had no similar symptoms since the event. There was no known other cardiovascular risk factor, and it was unknown if the subject had a Holter monitor at any point. On

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Narrative Comment
the same day (Day 83), a computed tomography (CT) scan without contrast showed no significant abnormality. A TIA or cerebrovascular accident (CVA) was suspected, and the subject was hospitalized for further workup. The subject was treated with PPD for possible CVA. The subject's echocardiogram showed no patent foramen ovale or shunt of thrombus. PPD blood pressure was 148/70 mmHg, and PPD heart rate was 57 beats/min. The subject's laboratory test results showed a white blood cell (WBC) count of 3.5 K/mm^3 (normal range [NR]: 4.5-11.0 K/mm^3), a red blood cell (RBC) count of 3.82 K/mm^3 (NR: 3.65-5.03 K/mm^3), international normalized ratio (INR) of 0.95 (NR: 0.87-1.13), glucose of 86 mg/dL (NR: 65-100 mg/dL), troponin T of <0.010 ng/mL (NR: 0.00-0.029 ng/mL), and blood urea nitrogen (BUN) of 24 mg/dL (NR: 7-17 mg/dL). The TIA was considered resolved on the same day (Day 83). On PPD, magnetic resonance imaging showed no focal parenchymal lesion or acute ischemia. A non-contrast CT angiogram scan of the neck showed no abnormality. The subject's repeat laboratory test results showed a WBC count of 2.8 K/mm^3, an RBC count of 3.68 K/mm^3, INR of 1.01, glucose of 96 mg/dL, cholesterol of 165 mg/dL (NR: 50-199 mg/dL), triglycerides of 72 mg/dL (NR: 2-149 mg/dL), and BUN of 24 mg/dL. Following PPD hospital discharge on PPD, the subject started treatment with PPD. A neurology follow-up was scheduled on PPD, and no further details were reported. In the opinion of the investigator, there was a reasonable possibility that the TIA was related to BNT162b2 but was unrelated to concomitant medications or clinical trial procedures. Per Pfizer, there was no reasonable possibility that the TIA was related to BNT162b2.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Related Serious Adverse Event, Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (26)	PPD
VACCINATION 3	BNT162b2	PPD (67)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	IMMUN	Anaphylactoid reaction	PPD	PPD (69)	PPD	PPD (69)	PPD

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Reason(s) for Narrative: Related Serious Adverse Event, Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	4	TC/P	Y	Resolved (PPD)	Study Treatment	3	3	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	

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Reason(s) for Narrative: Related Serious Adverse Event, Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	OPEN LABEL TREATMENT	PPD	ADVERSE EVENT
Completed	FOLLOW-UP	PPD	

Narrative Comment

Subject PPD , a ≤24-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 26).

In accordance with the protocol allowance, the subject's PPD agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first dose of BNT162b2 on PPD (Day 67).

Concomitant medications received within 2 weeks prior to the onset of the anaphylactoid reaction included PPD

The subject experienced an anaphylactoid reaction on PPD , 2 days after receiving Dose 3 (the first dose of BNT162b2).

On PPD (Day 69), at PPD , the subject developed hives on the left arm and self-administered PPD at PPD . Shortly after that, at PPD , PPD developed shortness of breath. PPD denied any other symptoms and confirmed no exposure to allergens prior to these events. PPD did not seek medical attention. The investigator considered the anaphylactoid reaction as life-threatening given the history of PPD . On the same day (Day 69), the hives resolved at PPD and the shortness of breath resolved around PPD , and the anaphylactoid reaction was considered resolved.

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Reason(s) for Narrative: Related Serious Adverse Event, Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
The subject was discontinued from the study intervention on PPD (Day 69) because of the anaphylactoid reaction. PPD completed the study follow-up phase on PPD. In the opinion of the investigator, there was a reasonable possibility that the anaphylactoid reaction was related to BNT162b2 but not related to Doses 1 and 2 of the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (24)	PPD
VACCINATION 3	BNT162b2	PPD (177)	PPD
VACCINATION 4	BNT162b2	PPD (196)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	PPD	PPD (25)		PPD (27)	
2	MUSC	Myalgia		PPD (254)		PPD (304)	

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	1	N	N	Resolved (PPD)	Study Treatment	2	2	N
2	51	1	TC	Y	Resolved (PPD)	Study Treatment	4	59	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

Narrative Comment

Subject PPD, a 40-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 24).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 177) and PPD (Day 196), respectively. The subject received a nonstudy PPD on PPD.

The subject experienced myalgia on PPD, 58 days after receiving Dose 4 (the second dose of BNT162b2).

On PPD (Day 254), the subject developed mild generalized muscle pain, which gradually increased in severity over the following week to a maximum pain scale score of 10/10. PPD was severely debilitated and unable to perform normal daily activities due to the pain. PPD denied other symptoms from the COVID-19 symptoms list. On PPD, PPD, diagnosed PPD with possible polymyalgia rheumatica and treated PPD with PPD (PPD to an unknown date). On PPD, the subject added PPD symptoms to an e-diary for potential COVID-19 illness. On PPD (Day 304), the pain scale score had reduced to 1/10, and the myalgia was considered resolved on the same day (Day 304).

In the opinion of the investigator, there was a reasonable possibility that the myalgia was related to BNT162b2 but was not related to clinical trial procedures. Per Pfizer, there was no reasonable possibility that the myalgia was related to BNT162b2.

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_CSR_Safety_Narrative/profile. (Database Snapshot Date: 07MAR2023) Date of Generation: 18APR2023 (17:51)

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (24)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	CARD	Ventricular arrhythmia	PPD	PPD (24)		PPD (31)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	8	3	TC	Y	Resolved (PPD)	Study Treatment	2	1	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject PPD , a 70-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 24). Concomitant medications received within 2 weeks prior to the onset of the ventricular arrhythmia included PPD . The subject experienced ventricular arrhythmia on PPD , the day of receiving Dose 2.

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Narrative Comment
On PPD (Day 24) at PPD, the subject's pacemaker recorded non-sustained ventricular tachycardia (NSVT) with an average heart rate of 134 beats/min, lasting 8 seconds. On PPD at PPD, the pacemaker recorded NSVT with an average heart rate of 199 beats/min, lasting 15 seconds. On PPD at PPD, the pacemaker recorded NSVT with an average heart rate of 164 beats/min, lasting 9 seconds. On PPD at PPD and PPD, the subject had 2 episodes of NSVT with average heart rates of 185 beats/min and 194 beats/min, lasting 9 seconds and 8 seconds, respectively. On PPD at PPD, the subject had an episode of NSVT with an average heart rate of 174 beats/min, lasting 9 seconds. The subject reported fatigue and general malaise during the NSVT episodes. On PPD, the subject reported to the site that PPD experienced subsequent episodes of ventricular tachycardia, as noted above, and that PPD cardiologist recommended placement of a defibrillator. Relevant laboratory test results on PPD (Day 31) included troponin I, creatine kinase (CK), CK-MB, CK-MB index, sodium, potassium, carbon dioxide, and anion gap. According to PPD cardiologist, the CK-MB index result was within acceptable limits and the other test results were also normal. The ventricular arrhythmia was considered resolved on PPD (Day 31). On PPD, COVID-19 polymerase chain reaction molecular test and SARS-CoV-2 immunoglobulin antibody test results were negative. An electrophysiology study on PPD showed no evidence of sustained VT/pmVT/VF (ventricular tachycardia/polymorphic ventricular tachycardia/ventricular fibrillation); however, brief paroxysms of pmVT were seen. No indication for an implantable cardioverter-defibrillator was observed. On PPD, the subject received PPD, a nonstudy Pfizer vaccine. The subject requested withdrawal from the study follow-up phase on PPD. In the opinion of the investigator, there was a reasonable possibility that the ventricular arrhythmia was related to the study intervention based on the temporal relationship since the arrhythmias began within 24 hours of Dose 2 but was not related to concomitant medications or clinical trial procedures. Per Pfizer, there was no reasonable possibility that the ventricular arrhythmia was related to the study intervention. Additionally, Pfizer commented that there was not enough evidence to establish a causal relationship with the study intervention apart from a chronological association at the time of this report. In the absence of evidence for an inflammatory response to the study intervention, it was more likely that the ventricular arrhythmia was associated with the subject's underlying known PPD conditions.

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (131)	PPD
VACCINATION 4	BNT162b2	PPD (152)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (366)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INFEC	Appendicitis	PPD	PPD (155)		PPD (155)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	2	TC	Y	Resolved (PPD)	Study Treatment	4	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Narrative Comment
Subject PPD, a ≤24-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 21). In accordance with the protocol allowance, the subject's PPD agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 131), PPD (Day 152), and PPD (Day 366), respectively. The subject developed appendicitis on PPD, 3 days after receiving Dose 4 (the second dose of BNT162b2). On PPD (Day 155), the subject presented to the hospital with complaints of abdominal pain (periumbilical; right flank) and vomiting. The subject described PPD pain as moderate, achy, and crampy. The pain worsened upon movement and was relieved upon rest. An abdominal ultrasound scan showed findings consistent with acute appendicitis. PPD underwent an outpatient appendectomy procedure on the same day (Day 155). The histology report revealed the appendix of 7.5 cm in length and up to 0.8 cm in diameter. The subject was treated with PPD On the same day (Day 155), the subject was discharged with a prescription for PPD . In the opinion of the investigator, there was a reasonable possibility that the appendicitis was related to BNT162b2 but was not related to clinical trial procedures. Per the investigator, regional lymphadenopathy might cause blockages to the outflow of the appendix, which traps fluids and causes inflammation that leads to appendicitis. Per Pfizer, there was no reasonable possibility that the event was related to BNT162b2.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Related Serious Adverse Event, Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	PPD	PPD (2)	PPD	PPD (2)	PPD
2	GENRL	Injection site erythema		PPD (1)	PPD	PPD (2)	PPD
3	GENRL	Injection site pain		PPD (1)	PPD	PPD (3)	
4	GENRL	Injection site warmth		PPD (1)	PPD	PPD (2)	PPD
5	BLOOD	Lymphadenopathy		PPD (13)		PPD (78)	

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Reason(s) for Narrative: Related Serious Adverse Event, Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	TC	N	Resolved (PPD)	Study Treatment	1	2	N
2	2	1	N	N	Resolved (PPD)	Study Treatment	1	1	N
3	3	2	N	N	Resolved (PPD)	Study Treatment	1	1	N
4	2	1	N	N	Resolved (PPD)	Study Treatment	1	1	N
5	66	2	TC/P	Y	Resolved (PPD)	Study Treatment	1	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	FOLLOW-UP	PPD	

Narrative Comment

Subject PPD, a 50-year-old PPD with no pertinent medical history, received Dose 1 on PPD in PPD left deltoid.

Concomitant medications received within 2 weeks prior to the onset of the lymphadenopathy included PPD

The subject was diagnosed with lymphadenopathy on PPD, 12 days after receiving Dose 1.

On PPD (Day 1), approximately 6 hours after Dose 1 administration, the subject reported mild injection site erythema, warmth, and moderate injection site pain. On PPD (Day 2), PPD reported mild chills. That same day (Day 2), the injection site erythema, warmth, and chills were considered resolved, and on PPD (Day 3), the injection site pain resolved. On PPD (Day 13), the subject reported discomfort in PPD right arm, shoulder, and chest region, which PPD described as feeling like a pulled muscle, even at rest. Additionally, the subject reported that PPD physician referred PPD to the regional hospital emergency room (ER) for further evaluation. On PPD, the subject visited the ER, at which time PPD right axilla was examined, and an ultrasound examination of the right axilla on the same day revealed at least 4 enlarged lymph nodes; the largest was 2.5×1.1×2.4 cm. The laboratory results on the same day showed a white blood cell count of 7.0 K/µL (normal range [NR]: 4.0-10.0 K/µL) with 35.2% lymphocytes (NR: 20%-40%), and an absolute lymphocyte count of 2.4 K/µL (NR: 1.0-4.0 K/µL). The subject denied any injuries, cuts, or puncture wounds to the right arm or having had a similar problem previously. It was reported that no other areas other than the right axilla were assessed for lymphadenopathy. The subject received PPD (on PPD) while in the ER for lymphadenopathy. A biopsy was completed on PPD without issue. On PPD, the subject communicated via telephone the results of PPD workup, and the biopsy showed no markers for lymphoma or other cancer. Per the subject report, the oncologist considered the vaccine as the most likely etiology for PPD lymphadenopathy. The lymphadenopathy was considered resolved on PPD (Day 78). A follow-up oncological visit was planned in 3 months with a possible repeat of the axillary ultrasonography. The subject was scheduled to have a follow-up visit and ultrasound examination on PPD.

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Reason(s) for Narrative: Related Serious Adverse Event, Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
The subject was discontinued from the study intervention on PPD because of the lymphadenopathy. PPD completed the study follow-up phase on PPD. In the opinion of the investigator, there was a reasonable possibility that the lymphadenopathy was related to the study intervention but was not related to concomitant medications or clinical trial procedures. Per Pfizer, there was no reasonable possibility that the lymphadenopathy was related to the study intervention. Pfizer considered that there was not enough evidence to establish a causal relationship with the study intervention apart from a chronological association at the time of this report. It was also noted that the subject received the study intervention in the left deltoid and the lymphadenopathy was in the right axillary area.

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (393)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Myalgia	PPD	PPD (73)	PPD	PPD (77)	PPD	5
2	CARD	Myocardial infarction		PPD (92)	PPD	PPD (92)	PPD	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: workout	2	52	N
2	4	TC/TCN	Y	Resolved (PPD)	Study Treatment	2	71	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Narrative Comment
Subject PPD, a 40-year-old PPD with no reported medical history, received Dose 1 on PPD, Dose 2 on PPD (Day 22), and Dose 3 on PPD (Day 393). The subject was diagnosed with a myocardial infarction on PPD, 70 days after receiving Dose 2. On PPD, the subject presented to the emergency room with chest pain, numbness in the left arm, and PPD. The laboratory test results showed normal values of high-sensitivity troponin of 10.01 ng/L (normal range [NR]: 0-34.2 ng/L) and creatine phosphokinase-MB of 14 IU/L (NR: 0-24 IU/L) at that time. An electrocardiogram was normal; however, the high-sensitivity troponin values approximately after 4 and 6 hours were elevated at 139 ng/L and 282.2 ng/L, respectively. On PPD (Day 92), the subject was hospitalized because of a non-ST-elevation myocardial infarction, diagnosed by a cardiologist. A coronary angiography scan showed slow flow, and a plaque was detected in the left descending artery. On the same day (Day 92), the subject was started on treatment with PPD. On PPD (Day 92), the myocardial infarction was considered resolved. Discharge information was not reported. In the opinion of the investigator, there was a reasonable possibility that the myocardial infarction was related to the study intervention but was not related to clinical trial procedures. The investigator additionally stated that it was difficult to state if the myocardial infarction was related or unrelated to the study intervention, as the subject described PPD as healthy with no cardiac disease, cardiac complaint, or coronary obstruction before the study intervention and no family history of heart disease. Pfizer did not concur with the investigator's causality assessment and considered the event was not related to the study intervention, concomitant medications, or clinical trial procedures based on the finding of slow flow and plaque in the left descending coronary artery and the temporal latency of 2 months 8 days.

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Reason(s) for Narrative: Related Serious Adverse Event, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: Related Serious Adverse Event, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (117)	PPD
VACCINATION 4	BNT162b2	PPD (139)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (428)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PPD	PPD	PPD	PPD (532)		PPD (533)		2
2				PPD (440)		PPD (440)		1
3	INJ&P			PPD (428)	PPD	PPD (440)		13
4	GENRL	Fatigue		PPD (117)	PPD	PPD (119)		3
5	GENRL	Fatigue		PPD (140)		PPD (143)		4
6	GENRL	Fatigue		PPD (429)		PPD (429)		1
7	GENRL	Injection site erythema		PPD (23)	PPD	PPD (24)		2
8	GENRL	Pain		PPD (429)		PPD (429)		1
9	GENRL	Pyrexia		PPD (140)		PPD (143)		4

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Reason(s) for Narrative: Related Serious Adverse Event, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: Unknown	5	105	N
2	1	N	Y	Resolved (PPD)	Study Treatment	5	13	Y
3		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	1	Y
4	1	N	N	Resolved (PPD)	Study Treatment	3	1	N
5	1	N	N	Resolved (PPD)	Study Treatment	4	2	N
6	1	N	N	Resolved (PPD)	Study Treatment	5	2	N
7	1	N	N	Resolved (PPD)	Study Treatment	2	1	N
8	2	N	N	Resolved (PPD)	Study Treatment	5	2	N
9	1	TC	N	Resolved (PPD)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

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Reason(s) for Narrative: Related Serious Adverse Event, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD
		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	PROTOCOL DEVIATION

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Reason(s) for Narrative: Related Serious Adverse Event, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Narrative Comment
PPD

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (140)	PPD
VACCINATION 4	BNT162b2	PPD (161)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Malaise	PPD	PPD (141)		PPD (144)	
2	GENRL	Pain		PPD (141)		PPD (144)	
3	HEPAT	Portal vein thrombosis		PPD (221)		PPD (228)	
4	GENRL	Pyrexia		PPD (141)		PPD (144)	

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	2	N	N	Resolved (PPD)	Study Treatment	3	2	N
2	4	2	TC	N	Resolved (PPD)	Study Treatment	3	2	N
3	8	3	TC	Y	Resolved (PPD)	Study Treatment	4	61	Y
4	4	2	TC	N	Resolved (PPD)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	

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Reason(s) for Narrative: Related Serious Adverse Event
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

Narrative Comment

Subject PPD, a 40-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 21).

The subject developed COVID-19 illness symptoms on PPD, and PPD tested positive for COVID-19 on PPD. The subject was diagnosed with COVID-19 infection on PPD and was treated with PPD. Additional medications included PPD. The subject was neither hospitalized nor used any oxygen therapy. The COVID-19 infection resolved on PPD.

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 140) and PPD (Day 161), respectively.

Concomitant medications received within 2 weeks prior to the onset of the portal vein thrombosis included PPD.

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Narrative Comment
On PPD, the subject again experienced COVID-19 illness symptoms, which included sore throat, fatigue, sneezing, and nasal congestion. On PPD, a nasopharynx swab was done with a negative COVID-19 test result, and the subject was diagnosed with pharyngitis. The subject was treated with PPD.
On PPD, the subject presented to the investigator with complaints of abdominal discomfort and pain. Allergy test results revealed a few (unspecified) food allergies.
The subject was diagnosed with portal vein thrombosis on PPD, 60 days after receiving Dose 4 (the second dose of BNT162b2).
On PPD (Day 221), a computed tomography scan of the abdomen showed portal vein thrombosis extending into the left and right portal veins and portal radicles causing complete obstruction. The subject was hospitalized for portal vein thrombosis. On the same day (Day 221), PPD SARS-CoV-2 test result was negative.
On the same day (Day 221), laboratory test results showed C-reactive protein (CRP) of 28 mg/dL (normal range [NR]: 0-5 mg/dL), hemoglobin (Hgb) of 10.6 g/dL (NR: 12-16 g/dL), mean cell hemoglobin (MCH) of 23 pg (NR: 26-34 pg), mean cell volume (MCV) of 76 fL (NR: 80-100 fL), red cell distribution width (RDW) of 18% (NR: 11-16%), alanine aminotransferase (ALT) of 88 IU/L (NR: 7-35 IU/L), aspartate aminotransferase (AST) of 30 IU/L (NR: 13-35 IU/L), albumin of 34 g/L (NR: 35-52 g/L), bilirubin of 6.4 µmol/L (NR: <21 µmol/L), gamma glutamyltransferase (GGT) of 84 IU/L (NR: <36 IU/L), globulin of 41 g/L (NR: 20-35 g/L), hematocrit (Hct)of 34.6% (NR: 36-46%), platelet count of 258×10^9/L (NR: $150\text{-}450\times10^9$/L), and protein C of 102.4% (NR: 70-140%); antiphospholipid antibodies were not detected. The subject was treated with PPD.
On PPD, laboratory test results included ALT of 64 IU/L, AST of 22 IU/L, albumin of 32 g/L, bilirubin of 9 µmol/L, GGT of 67 IU/L, globulin of 41 g/L, Hct of 33.6%, Hgb of 10.7 g/dL, MCH of 24 pg, MCV of 75 fL, and RDW of 18%.
On PPD, laboratory test results showed ALT of 53 IU/L, AST of 19 IU/L, albumin of 28 g/L, bilirubin of 7 µmol/L, GGT of 58 IU/L, globulin of 38 g/L, CRP of 231 mg/dL, Hgb of 10.0 g/dL, Hct of 30.8%, MCH of 24 pg, MCV of 74 fL, and RDW of 18%. An ultrasound doppler showed thrombus in the same location with no evidence of recanalization or resorption; an abdominal ultrasound showed dense non-homogenous liver parenchyma, cirrhosis, portal vein was dilated from 14 to 17 mm and totally occluded, and thrombus was observed in medial splenic vein.
On PPD, laboratory test results showed ALT of 42 IU/L, AST of 14 IU/L, albumin of 26 g/L, bilirubin of 5.4 µmol/L, GGT of 57 IU/L, globulin of 37 g/L, Hgb of 9.5 g/dL, HCT of 30.1%, MCH of 24 pg, MCV of 75 fL, RDW of 18%, and normal thromboelastogram.
On PPD, laboratory test results showed CRP of 224 mg/dL, MCH of 24 pg, Hgb of 9.8 g/dL, HCT of 31.0%, MCV of 74 fL, and RDW of 18%.

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Narrative Comment
On PPD, the treatment was changed from PPD. On PPD (Day 228), the portal vein thrombosis resolved (as reported by the investigator), and the subject was discharged from the hospital on PPD for pain control. On PPD, laboratory test results showed Hgb of 11.9 g/dL and CRP of 9 mg/dL; an abdominal ultrasound showed liver of normal size, portal vein 12-13 mm still totally occluded with thrombus, thrombus was still noted in the medial part of splenic vein although smaller; in portal area, small tortuous blood vessel noted cavernous malformation. The subject was treated with PPD. In the opinion of the investigator, there was a reasonable possibility that the portal vein thrombosis was related to BNT162b2 and concomitant medication PPD but was not related to other concomitant medications or clinical trial procedures. Per the investigator, the event was also possibly related to COVID-19. Pfizer did not concur with the investigator's causality assessment. Per Pfizer, there was no reasonable possibility that event was related to BNT162b2, but it could be related to PPD, which have a well-known venous thromboembolic risk.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered):
Date of First Dose: N/A; Date of Last Dose: N/A
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline
No Vital Signs - Baseline

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered):
Date of First Dose: N/A; Date of Last Dose: N/A
==========

Study Vaccination(s)
No Study Vaccination(s)

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	NERV	Syncope	PPD	PPD (1)		PPD (1)		1	2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	W	N	Resolved (PPD)	NOT RELATED/OTHER: subject faints on occasion	.	.	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT
Completed	SCREENING	PPD	

Narrative Comment
Subject PPD , a 30-year-old PPD with no pertinent medical history, experienced syncope on PPD , before PPD was to receive Dose 1. The subject was withdrawn from the study before administration of study vaccination on PPD (Day 1) because of the syncope, which resolved on the same day. The investigator reported that the subject faints on occasion. In the opinion of the investigator, there was no reasonable possibility that the syncope was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GENRL	Facial pain	PPD	PPD (4)		PPD (14)		11	2	TC/P	N
2	GENRL	Injection site pain		PPD (2)		PPD (5)		4	2	N	N
3	GENRL	Swelling face		PPD (4)		PPD (14)		11	2	TC/P	N
4	INFEC	Upper respiratory tract infection		PPD (4)		PPD (14)		11	2	TC	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (PPD)	NOT RELATED/OTHER: ALLERGIC REACTION TO UNKNOWN AGENT	1	4	Y
2	Resolved (PPD)	Study Treatment	1	2	N
3	Resolved (PPD)	NOT RELATED/OTHER: ALLERGIC REACTION TO UNKNOWN AGENT	1	4	Y
4	Resolved (PPD)	NOT RELATED/OTHER: CONCURRENT ILLNESS	1	4	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	FOLLOW-UP	PPD	

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD. On PPD (Day 2), the subject experienced moderate injection site pain that resolved on PPD (Day 5). The subject experienced facial pain and facial swelling that began on PPD, 3 days after receiving Dose 1. On PPD (Day 4), the subject also experienced upper respiratory infection. The subject was discontinued from the study intervention on PPD because of the facial pain and facial swelling. On PPD (Day 14), the facial pain, facial swelling, and upper respiratory infection resolved. On PPD, the subject completed the study follow-up phase. In the opinion of the investigator, there was no reasonable possibility that the facial pain and facial swelling were related to the study intervention, but rather they were related to an allergic reaction to an unknown agent.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Acute myocardial infarction	PPD	PPD (14)		PPD (16)		3	3	TC/TCN
2	CARD	Angina pectoris		PPD (10)		PPD (16)		7	2	TCN
3	CARD	Coronary artery occlusion		PPD (14)		PPD (16)		3	4	TC/TCN/P/W
4	RESP	Dyspnoea exertional		PPD (14)		PPD (16)		3	2	TCN
5	CARD	Mitral valve incompetence		PPD (14)		PPD (16)		3	3	TCN

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	14	N
2	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	10	N
3	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	14	Y
4	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	14	N
5	N	Resolved (PPD)	NOT RELATED/OTHER: PROGRESSION OF MYXOMATOUS MITRAL VALVE	1	14	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment

Subject PPD , a ≥75-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD .

Concomitant medications received within 2 weeks prior to the onset of the coronary artery occlusion included PPD .

The subject was diagnosed with a coronary artery occlusion on PPD , 13 days after receiving Dose 1.

On PPD (Day 10), the subject reported angina pectoris. On PPD (Day 14), the subject presented to the emergency room (ER) reporting shortness of breath, for which PPD was admitted to the hospital with chief complaints of exertional dyspnea and angina with little exertion that did not abate as usual. In the ER, the subject received PPD . A chest x-ray showed no evidence of acute cardiopulmonary disease. An electrocardiogram showed a previously diagnosed right bundle branch block with ST depression in lead II and T-wave inversion in leads I and Vl/ arteriovenous fistula and inferior infarct of undetermined age with no ST-elevation; the subject had an elevated troponin level of 0.84 ng/mL (normal range [NR]: 0-0.15 ng/mL). PPD was diagnosed with an acute non–ST-elevation myocardial infarction. Additional

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Narrative Comment
laboratory test values included an elevated glucose level (value not reported) and a prothrombin time of 20.6 seconds (NR: 12.2-15.5 seconds). Other laboratory test results included brain natriuretic peptide, fibrin D-dimer, complete blood count, and lipase, which were within normal limits (values not provided). No COVID-19 testing was performed. That same day (Day 14), the subject was also diagnosed with mitral valve incompetence. On PPD, an angiogram was performed, which showed worsening coronary artery disease and severe multivessel coronary artery disease with significant multivessel coronary artery occlusion. The subject was given PPD, and on PPD (Day 16), PPD underwent 2-vessel coronary artery bypass graft surgery, during which it was recognized that the mitral regurgitation was severe, and the mitral valve was repaired. The subject was treated with PPD, but was quickly weaned off. On PPD (Day 16), the exertional dyspnea, angina pectoris, coronary artery occlusion, acute myocardial infarction, and mitral valve incompetence were considered resolved. The subject was withdrawn from the study on PPD because of the coronary artery occlusion. In the opinion of the investigator, there was no reasonable possibility that the coronary artery occlusion was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to coronary atherosclerosis. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 3	BNT162b2	PPD (110)	PPD
VACCINATION 4	BNT162b2	PPD (132)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (411)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	CARD	Atrial fibrillation	PPD	PPD (11)	PPD	PPD (12)		2	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/P	Y	Resolved (PPD)	NOT RELATED/OTHER: history of PPD	1	11	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD
		PPD

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	PROTOCOL DEVIATION

Narrative Comment
Subject PPD , a 70-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD .
Concomitant medications received within 2 weeks prior to the onset of the atrial fibrillation included PPD .
The subject was diagnosed with atrial fibrillation on PPD , 10 days after receiving Dose 1.
On PPD (Day 11), the subject experienced palpitations and presented to the emergency room. PPD denied having palpitations previously and had no history of atrial fibrillation. PPD also denied recent illness, dizziness, shortness of breath, chest pain, syncope, nausea, vomiting, or diarrhea. PPD was

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Narrative Comment
hospitalized, and an electrocardiogram (ECG) showed atrial fibrillation. On the same day (Day 11), a SARS-CoV-2 RNA nasopharyngeal swab test result was negative, and a chest x-ray was normal. The subject was treated with PPD . The PPD and PPD were discontinued on PPD (Day 12), after the subject achieved cardiac sinus rhythm, and PPD was placed on PPD with cardiology follow-up scheduled for PPD . The subject's troponin I was <0.015 ng/mL (normal range [NR]: 0-0.045 ng/mL) on PPD (Day 11) and PPD (Day 12). On PPD (Day 12), thyroid stimulating hormone was 1.280 µIU/mL (NR: 0.358-3.74 µIU/mL); an echocardiogram was normal; and an ECG showed incomplete right bundle branch block, old inferior infarct, and sinus rhythm (abnormalities consistent with previous history). The atrial fibrillation resolved on the same day (Day 12), and the subject was discharged from the hospital on PPD . The subject was discontinued from the study intervention on PPD because of the atrial fibrillation. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that PPD had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 110), PPD (Day 132), and PPD (Day 441), respectively. The subject was withdrawn from the study on PPD because of the receipt of a nonstudy PPD (PPD) on the same day (protocol deviation). In the opinion of the investigator, there was no reasonable possibility that the atrial fibrillation was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a history of PPD . Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Paraesthesia	PPD	PPD (1)	PPD	PPD (1)	PPD	1
2	GASTR	Paraesthesia oral		PPD (1)	PPD	PPD (1)	PPD	1
3	GASTR	Toothache		PPD (23)	PPD	PPD (41)	PPD	19

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (PPD)	Study Treatment	1	1	N
2	1	P	N	Resolved (PPD)	Study Treatment	1	1	Y
3	1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: tooth ache	1	23	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	SCREENING	PPD	
Withdrawn	FOLLOW-UP	PPD	OTHER

Narrative Comment
Subject PPD, a 60-year-old PPD with no reported medical history, received Dose 1 on PPD. The subject experienced oral paresthesia at PPD on PPD, the day of receiving Dose 1. On PPD (Day 1), the subject also experienced paresthesia (tingling) of fingertips starting at PPD. The oral paresthesia and paresthesia of fingertips resolved on the same day (Day 1) at PPD and PPD, respectively. The subject was discontinued from the study intervention on PPD because of the oral paresthesia and was withdrawn from the study on PPD because PPD was enrolled in Study BNT162-17. In the opinion of the investigator, there was a reasonable possibility that the oral paresthesia was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site dermatitis	PPD	PPD (3)		ONGOING	
2	PSYCH	PPD		PPD (4)		ONGOING	
3	INV	Weight decreased		PPD (6)		PPD (26)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	P/W	N	Yes	Study Treatment	1	3	Y
2		2	TC	N	Yes	Study Treatment	1	4	N
3	21	3	N	N	Resolved (PPD)	Study Treatment	1	6	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment
Subject PPD a 40-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD . The subject experienced injection site dermatitis (left upper arm) on PPD , 2 days after receiving Dose 1. The subject was discontinued from the study intervention on PPD and was withdrawn from the study on PPD because of the injection site dermatitis, which was ongoing at the time of withdrawal. In the opinion of the investigator, there was a reasonable possibility that the injection site dermatitis was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 3	BNT162b2	PPD (117)	PPD
VACCINATION 4	BNT162b2	PPD (140)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (404)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	PPD	PPD (140)	PPD	PPD (142)	
2	GASTR	Diarrhoea		PPD (2)		PPD (2)	
3	NERV	Headache		PPD (2)		PPD (6)	
4	NERV	Headache		PPD (141)	PPD	PPD (142)	
5	GENRL	Injection site pain		PPD (117)		PPD (118)	
6	GENRL	Injection site pain		PPD (140)	PPD	PPD (142)	
7	GASTR	Nausea		PPD (2)		PPD (6)	
8	EAR	Vertigo		PPD (2)		PPD (117)	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	1	N	N	Resolved (PPD)	Study Treatment	4	1	N
2	1	1	N	N	Resolved (PPD)	Study Treatment	1	2	N
3	5	1	N	N	Resolved (PPD)	Study Treatment	1	2	N
4	2	2	TC	N	Resolved (PPD)	Study Treatment	4	2	N
5	2	1	N	N	Resolved (PPD)	Study Treatment	3	1	N
6	3	1	N	N	Resolved (PPD)	Study Treatment	4	1	N
7	5	1	N	N	Resolved (PPD)	Study Treatment	1	2	N
8	116	2	P	N	Resolved (PPD)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD
		PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	OTHER

Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD. The subject experienced a worsening and continuing episode of vertigo on PPD, 1 day after receiving Dose 1. On PPD (Day 2), the subject also experienced diarrhea, headache, and nausea. The diarrhea resolved on the same day (Day 2), and the headache and nausea resolved on PPD (Day 6). The subject received the PPD on PPD. The subject was discontinued from the study intervention on PPD because of the worsening and continuing episode of vertigo. On PPD (Day 117), the worsening and continuing episode of vertigo resolved.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 117), PPD (Day 140), and PPD (Day 404), respectively. The subject was withdrawn from the study follow-up phase on PPD because PPD was enrolled in Study C4591031.. In the opinion of the investigator, there was a reasonable possibility that the worsening and continuing episode of vertigo was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site swelling	PPD	PPD (1)		PPD (10)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	10	3	TC/P	N	Resolved (PPD)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	FOLLOW-UP	PPD	

Narrative Comment
Subject PPD , a 40-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD . The subject reported severe injection site swelling on PPD , the day of receiving Dose 1. The injection site swelling resolved on PPD (Day 10). The subject was discontinued from the study intervention on PPD because of the injection site swelling and completed the study follow-up phase on PPD . In the opinion of the investigator, there was a reasonable possibility that the injection site swelling was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Cardiac arrest	PPD	PPD (59)		PPD (59)		1	4	TCN	Y

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
2	CARD	Cardiac arrest	PPD	PPD (61)		PPD (61)		1	4	TCN	Y
3	GASTR	Gastrointestinal mucosa hyperaemia		PPD (42)		PPD (43)		2	4	N	Y
4	RESP	Pneumothorax		PPD (42)		PPD (72)		31	4	N	Y
5	RESP	Pulmonary embolism		PPD (42)		PPD (72)		31	3	N	Y
6	INJ&P	Rib fracture		PPD (42)		PPD (279)		238	3	N	Y
7	INJ&P	PPD		PPD (42)		PPD (279)		238	4	W	Y
8	INJ&P	Spinal column injury		PPD (42)		PPD (279)		238	3	N	Y
9	NERV	Spinal cord compression		PPD (42)		PPD (279)		238	4	N	Y
10	INJ&P	Subdural haematoma		PPD (42)		PPD (71)		30	3	N	Y
11	VASC	Superficial vein thrombosis		PPD (42)		PPD (72)		31	3	N	Y
12	INJ&P	Traumatic haemothorax		PPD (42)		PPD (72)		31	4	N	Y
13	GASTR	Volvulus		PPD (42)		PPD (43)		2	4	N	Y

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (PPD)	NOT RELATED/OTHER: Injury secondary to PPD	2	38	N
2	Resolved (PPD)	NOT RELATED/OTHER: Injury secondary to PPD	2	40	N
3	Resolved (PPD)	NOT RELATED/OTHER: Injury Secondary to PPD	2	21	N
4	Resolved (PPD)	NOT RELATED/OTHER: Injury Secondary to PPD	2	21	N
5	Resolved (PPD)	NOT RELATED/OTHER: injury Secondary to PPD	2	21	N
6	Resolved (PPD)	NOT RELATED/OTHER: Injury Secondary to PPD	2	21	N
7	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	21	Y
8	Resolved (PPD)	NOT RELATED/OTHER: Injury Secondary to PPD	2	21	N
9	Resolved (PPD)	NOT RELATED/OTHER: T2 distraction injury	2	21	N
10	Resolved (PPD)	NOT RELATED/OTHER: Injury Secondary to PPD .	2	21	N
11	Resolved (PPD)	NOT RELATED/OTHER: Injury Secondary to PPD	2	21	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
12	Resolved (PPD)	NOT RELATED/OTHER: Injury Secondary to PPD	2	21	N
13	Resolved (PPD)	NOT RELATED/OTHER: Hyperemic Bowel	2	21	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment

Subject PPD, a 60-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 22).

The subject was involved in PPD on PPD, 20 days after receiving Dose 2.

On PPD (Day 42), the subject was PPD and sustained an injury. The subject was hospitalized and was stabilized in the trauma unit. A computed tomography scan showed a small parafalcine subdural hematoma, severe T2 distraction injury with spinal cord compression, right hemopneumothorax, left pneumothorax, bilateral rib fractures, left pulmonary emboli, left superficial deep vein thrombosis, and sigmoid volvulus with hyperemic bowel. The subject was on a ventilator until PPD. The subject coded on PPD (Day 59) and again on PPD (Day 61). On PPD, a pacemaker was implanted. The subject was treated with PPD

The subject was discontinued from the study intervention on PPD and was withdrawn from the study on PPD (Day 279) because of the PPD PPD.

In the opinion of the investigator, there was no reasonable possibility that the PPD was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (162)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	PPD	PPD (162)	PPD	PPD (164)	PPD
2	GASTR	Diarrhoea		PPD (165)	PPD	PPD (168)	PPD
3	NERV	Headache		PPD (162)	PPD	PPD (164)	PPD
4	GENRL	Injection site pain		PPD (162)	PPD	PPD (165)	PPD
5	MUSC	Myalgia		PPD (162)	PPD	PPD (164)	PPD

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	2	P	N	Resolved (PPD)	Study Treatment	3	1	Y
2	4	2	P	N	Resolved (PPD)	Study Treatment	3	4	Y
3	3	2	P	N	Resolved (PPD)	Study Treatment	3	1	Y

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	4	3	P	N	Resolved (PPD)	Study Treatment	3	1	Y
5	3	2	P	N	Resolved (PPD)	Study Treatment	3	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	OPEN LABEL TREATMENT	PPD	ADVERSE EVENT
Completed	FOLLOW-UP	PPD	

Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first dose of BNT162b2 on PPD (Day 162). The subject experienced moderate chills, moderate headache, moderate myalgia, and severe injection site pain on PPD, approximately 7.5 hours after receiving Dose 3 (the first dose of BNT162b2). The subject experienced diarrhea on PPD, 3 days after receiving the first dose of BNT162b2. On PPD (Day 164), the chills, headache, and myalgia resolved. On PPD (Day 165), the injection site pain resolved. On PPD (Day 168), the diarrhea resolved. The subject was discontinued from the study intervention on PPD because of the chills, headache, myalgia, injection site pain, and diarrhea and completed the study follow-up phase on PPD. In the opinion of the investigator, there was a reasonable possibility that the chills, headache, myalgia, injection site pain, and diarrhea were related to BNT162b2.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Back pain	PPD	PPD (12)		PPD (15)		4
2	MUSC	Back pain		PPD (15)		PPD (18)		4
3	GENRL	Chest pain		PPD (12)		PPD (12)		1
4	IMMUN	Drug hypersensitivity		PPD (2)		PPD (15)		14
5	GASTR	Gastrooesophageal reflux disease		PPD (12)		ONGOING		
6	NERV	Hypoaesthesia		PPD (15)		PPD (15)		1
7	MUSC	Muscular weakness		PPD (14)		PPD (14)		1
8	RESP	Pharyngeal swelling		PPD (2)		PPD (12)		11

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: GERD	1	12	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: GERD	1	15	N
3	1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Gerd	1	12	N
4	2	TC/P	N	Resolved (PPD)	Study Treatment	1	2	Y
5	1	TC	N	Yes	NOT RELATED/OTHER: acid reflux	1	12	N
6	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: Unknown	1	15	N
7	2	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: Unknown	1	14	N
8	2	TC	N	Resolved (PPD)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP

Narrative Comment

Subject PPD, a 50-year-old PPD with a pertinent medical history of PPD PPD), received Dose 1 on PPD.

The subject developed pharyngeal swelling considered to be an allergic reaction to the investigational product on PPD, 1 day after receiving Dose 1.

The subject experienced throat swelling and difficulty swallowing, and PPD was treated with PPD. PPD symptoms persisted and PPD was seen by a gastroenterologist. An endoscopy was normal. The event was intermittent, and the subject was not hospitalized for the event.

The pharyngeal swelling resolved on PPD (Day 12), and the allergic reaction to the investigational product resolved on PPD (Day 15).

The subject was discontinued from the study intervention on PPD (Day 15) because of the allergic reaction to the investigational product and was lost to follow-up on PPD. In the opinion of the investigator, there was a reasonable possibility that the allergic reaction to the investigational product was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD	Not reported	PPD

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	INJ&P	PPD		PPD (108)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1				W	N	Yes	Study Treatment	2	87	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Narrative Comment
PPD

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD	Not reported	PPD

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (36)	PPD
VACCINATION 3	BNT162b2	PPD (159)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	PPD		PPD (150)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N	Yes	NOT RELATED/OTHER: PPD	2	115	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Withdrawn	OPEN LABEL TREATMENT	PPD	PPD
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Narrative Comment
PPD

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (147)	PPD
VACCINATION 4	BNT162b2	PPD (169)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	HEPAT	Cholecystitis chronic	PPD	PPD (497)		PPD (497)		1	2
2	HEPAT	Cholelithiasis		PPD (497)		PPD (497)		1	2
3	NERV	Dementia		PPD ()		ONGOING			2
4	METAB	Hypokalaemia		PPD (190)		PPD (197)		8	3
5	MUSC	Osteoarthritis		PPD (279)		ONGOING			3
6	METAB	Type 2 diabetes mellitus		PPD (279)		ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: GALLBLADDER DISEASE	4	329	N
2	N	Y	Resolved (PPD)	NOT RELATED/OTHER: GALLBLADDER DISEASE	4	329	N
3	W	N	Yes	NOT RELATED/OTHER: memory loss	4	311	Y

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	22	N
5	TC	Y	Yes	NOT RELATED/OTHER: Worsening of Medical History	4	111	N
6	TC	Y	Yes	NOT RELATED/OTHER: Worsening Medical History	4	111	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment

Subject PPD , a ≥75-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 20).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 147) and PPD (Day 169), respectively.

Concomitant medications received within 2 weeks prior to the onset of the dementia included PPD .

The subject was diagnosed with dementia on an unspecified date in PPD , at least 310 days after receiving Dose 4 (the second dose of BNT162b2).

The subject was withdrawn from the study on PPD because of the dementia, which was ongoing at the time of withdrawal.

In the opinion of the investigator, there was no reasonable possibility that the dementia was related to BNT162b2.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 3	BNT162b2	PPD (202)	PPD
VACCINATION 4	BNT162b2	PPD (223)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Dizziness	PPD	PPD (1)	PPD	PPD (1)	PPD
2	GASTR	Nausea		PPD (1)	PPD	PPD (1)	PPD

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	P	N	Resolved (PPD)	Study Treatment	1	1	Y
2	1	1	P	N	Resolved (PPD)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	SCREENING	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

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Narrative Comment
Subject PPD, a 70-year-old PPD with no pertinent medical history, received Dose 1 at PPD on PPD. The subject experienced dizziness and nausea at PPD on PPD, 8 minutes after receiving Dose 1, and the events resolved at PPD on the same day. The subject was discontinued from the study intervention on PPD (Day 1) because of the dizziness and nausea. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 202) and PPD (Day 223), respectively. The subject requested withdrawal from the study follow-up phase on PPD. In the opinion of the investigator, there was a reasonable possibility that the dizziness and nausea were related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Cerebral capillary telangiectasia	PPD	PPD (30)		ONGOING			1
2	GENRL	Chronic fatigue syndrome		PPD (131)		ONGOING			2
3	GASTR	Dysphagia		PPD ()		ONGOING			1
4	CONG	Ehlers-Danlos syndrome		PPD (369)		ONGOING			2
5	MUSC	Fibromyalgia		PPD (131)		ONGOING			2
6	MUSC	Pain in extremity		PPD (44)		ONGOING			1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Yes	NOT RELATED/OTHER: anatomical abnormality	1	30	N
2	N	N	Yes	NOT RELATED/OTHER: Unknown etiology	1	131	N
3	P	N	Yes	NOT RELATED/OTHER: unknown, GI or neurological abnormality	1	1	Y
4	N	N	Yes	NOT RELATED/OTHER: Unknown	1	369	N
5	TC	N	Yes	NOT RELATED/OTHER: Unknown etiology	1	131	N
6	TC	N	Yes	NOT RELATED/OTHER: Cause is being evaluated	1	44	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD
		PPD
		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 40-year-old PPD with no reported medical history, received Dose 1 on PPD. The subject experienced dysphagia in late PPD. The subject was discontinued from the study intervention on PPD because of the dysphagia and was withdrawn from the study follow-up phase on PPD because PPD no longer met the eligibility criteria. The dysphagia was ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the dysphagia was related to the study intervention, but rather it was related to an unknown gastrointestinal or neurological abnormality.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	CARD	Coronary artery disease	PPD	PPD (12)		ONGOING			2	TCN/P/W	Y

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: PPD	1	12	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

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Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD (since an unspecified date), received Dose 1 on PPD. Concomitant medications received within 2 weeks prior to the worsening coronary artery disease included PPD. The subject was diagnosed with worsening coronary artery disease on PPD, 11 days after receiving Dose 1. On PPD, the subject underwent a coronary angiogram, and PPD doctor called PPD back that week and stated that PPD needed surgery. On PPD (Day 12), the subject was hospitalized, and PPD underwent quadruple coronary artery bypass graft surgery on PPD. According to the medical records, PPD postoperative course was unremarkable, and PPD had recovered well and was deemed stable for discharge (discharge date not reported). The subject was discontinued from the study intervention on PPD (Day 12) and was withdrawn from the study on PPD because of the worsening coronary artery disease, which was ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the worsening coronary artery disease was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to PPD. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD	PPD	PPD (18)		PPD (31)		14	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	P/W	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	18	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (182)	PPD
VACCINATION 4	BNT162b2	PPD (203)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Leukaemia	PPD	PPD (427)	PPD	ONGOING	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	W	Y	Yes	NOT RELATED/OTHER: Unknown	4	225	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment
Subject PPD, a 70-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 23). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 182) and PPD (Day 203), respectively. The subject was diagnosed with low-grade leukemia on PPD, 224 days after receiving Dose 4 (the second dose of BNT162b2). The subject was withdrawn from the study on PPD because of the leukemia, which was ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the leukemia was related to BNT162b2 or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Adenocarcinoma gastric	PPD	PPD (23)	PPD	ONGOING	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		3	P/W	Y	Yes	NOT RELATED/OTHER: n/a	1	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

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Narrative Comment

Subject PPD , a 50-year-old PPD with a pertinent medical history of PPD), received Dose 1 on PPD .

The subject was diagnosed with poorly differentiated gastric adenocarcinoma on PPD , 22 days after receiving Dose 1.

On PPD (Day 23), the subject visited PPD physician's office, and an upper gastrointestinal endoscopic biopsy revealed infiltrating poorly differentiated adenocarcinoma. No information was available about gastrointestinal symptoms beyond ongoing reflux disease; staging and PPD were planned, but no further details were available.

The subject was discontinued from the study intervention on PPD (Day 23) and was withdrawn from the study on PPD because of the poorly differentiated gastric adenocarcinoma, which was ongoing at the time of withdrawal.

In the opinion of the investigator, there was no reasonable possibility that the poorly differentiated gastric adenocarcinoma was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Malignant melanoma	PPD	PPD (83)		ONGOING		
2	MUSC	Neck pain		PPD (19)		ONGOING		

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	W	Y	Yes	NOT RELATED/OTHER: etiology unknown	2	63	Y
2	1	TC	N	Yes	NOT RELATED/OTHER: previous PPD	1	19	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

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Narrative Comment
Subject PPD, a 50-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 21). Concomitant medications received within 2 weeks prior to the onset of the malignant melanoma included PPD for neck pain. The subject was diagnosed with malignant melanoma on PPD, 62 days after receiving Dose 2. The subject contacted the site and reported the new diagnosis of malignant melanoma. The subject was withdrawn from the study on PPD (Day 83) because the malignant melanoma required surgical procedures. The malignant melanoma was ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the malignant melanoma was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Atrial fibrillation	PPD	PPD (20)		PPD (36)	PPD	17	3
2	CARD	Atrial flutter		PPD (30)	PPD	PPD (36)	PPD	7	3
3	EAR	Ear pain		PPD (123)	PPD	ONGOING			1
4	VASC	Hypertension		PPD (21)	PPD	ONGOING			1
5	CARD	Left atrial enlargement		PPD (37)	PPD	ONGOING			1

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
6	CARD	Left ventricular hypertrophy	PPD	PPD (21)	PPD	ONGOING			1
7	CARD	Mitral valve incompetence		PPD (37)	PPD	ONGOING			1
8	CARD	Mitral valve prolapse		PPD (37)	PPD	ONGOING			1
9	CARD	Myocardial infarction		PPD (36)	PPD	PPD (36)	PPD	1	1
10	INJ&P	Skin laceration		PPD (29)	PPD	PPD (43)	PPD	15	2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN/P	Y	Resolved (PPD)	NOT RELATED/OTHER: Heart Disease	1	20	Y
2	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: Cardiac Disease	1	30	N
3	TC	N	Yes	NOT RELATED/OTHER: Strep Prevention	1	123	N
4	TC	N	Yes	NOT RELATED/OTHER: Medical Illness	1	21	N
5	N	N	Yes	NOT RELATED/OTHER: Heart Disease	1	37	N
6	TC	N	Yes	NOT RELATED/OTHER: Medical Illness	1	21	N
7	N	N	Yes	NOT RELATED/OTHER: Heart Disease	1	37	N
8	N	N	Yes	NOT RELATED/OTHER: Heart Disease	1	37	N
9	N	N	Resolved (PPD)	NOT RELATED/OTHER: Heart Disease	1	36	N
10	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: Hobby Injury	1	29	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	FOLLOW-UP	PPD	

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Narrative Comment
Subject PPD, a 50-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD. Concomitant medications received within 2 weeks prior to the onset of the atrial fibrillation included PPD The subject was diagnosed with paroxysmal atrial fibrillation with a rapid ventricular response on PPD, 19 days after receiving Dose 1. On PPD (Day 20), an electrocardiogram (ECG) showed atrial fibrillation with a rapid ventricular response of 141 beats/min, normal QRS, and normal-appearing ST and T waves. The ventricular rate was controlled by treatment with PPD. Cardiac telemetry showed a heart rate ranging from 80 to 90s (beats/min). The subject's echocardiogram revealed mild left ventricular hypertrophy. The estimated ejection fraction was 55% to 60%. Additional laboratory results on PPD (Day 20) showed an elevated nonfasting blood glucose level of 195 mg/dL (normal range [NR]: 70-110 mg/dL) (and it was reported that the subject had eaten high-sugar food prior to the ER visit), high blood urea nitrogen of 25 mg/dL (NR: 7-18 mg/dL), and low blood potassium of 3.4 mmol/L (NR: 3.5-5.1 mmol/L). On PPD (Day 21), the subject went to the emergency room with palpitations and a "funny sensation in PPD head" and was hospitalized for the atrial fibrillation. On the same day (Day 21), the subject's blood pressure was 136/89 (units not reported), and a diagnosis of hypertension was made. Additionally, the subject was treated with PPD for atrial fibrillation, PPD for hypertension, and PPD for atrial fibrillation. The subject was monitored for PPD response to the PPD. On PPD, the subject was discharged from the hospital and was scheduled for outpatient cardioversion with a transesophageal echocardiogram. On PPD (Day 30), the subject followed up with PPD cardiologist, who performed a stress test and cardiac catheterization (results unknown). On the same day (Day 30), cardiac evaluation showed paroxysmal atrial fibrillation (symptomatic without adequate rate control). An ECG performed on the same day was abnormal and showed atrial fibrillation with a nonspecific T-wave abnormality, and the subject was diagnosed with atrial flutter with an onset date of PPD (Day 30). On PPD (Day 36), the transesophageal electrocardiogram results revealed findings suggestive of an old septal myocardial infarction, mitral valve incompetence, bileaflet mitral valve prolapse, and left atrial enlargement. On the same day (Day 36), the atrial fibrillation and atrial flutter were considered resolved. On PPD (Day 36), a transesophageal echocardiography with cardioversion was performed with no complications. The cardiac rhythm

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Narrative Comment
was successfully converted from atrial fibrillation to normal sinus rhythm with a ventricular rate of 69 beats/min. The subject was treated with PPD since PPD) as prophylaxis. The subject was discontinued from the study intervention on PPD (Day 20) because of the atrial fibrillation and completed the study follow-up phase on PPD . The hypertension, mitral valve incompetence, left atrial enlargement, left ventricular hypertrophy, and mitral valve prolapse were ongoing at the time of the study completion. In the opinion of the investigator, there was no reasonable possibility that the paroxysmal atrial fibrillation with rapid ventricular response was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 3	BNT162b2	PPD (213)	PPD
VACCINATION 4	BNT162b2	PPD (232)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (426)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain	PPD	PPD (9)	PPD	PPD (19)	PPD	11	4
2	INFEC	Cellulitis		PPD (15)	PPD	PPD (15)	PPD	1	3
3	GASTR	Diverticular perforation		PPD (9)	PPD	PPD (19)	PPD	11	4
4	INFEC	Diverticulitis		PPD (15)	PPD	PPD (20)		6	4
5	INFEC	Diverticulitis		PPD (21)		ONGOING			3
6	GENRL	Fatigue		PPD (214)	PPD	PPD (215)	PPD	2	1
7	NERV	Headache		PPD (214)	PPD	PPD (215)	PPD	2	1
8	GENRL	Injection site pain		PPD (214)	PPD	PPD (215)	PPD	2	1
9	MUSC	Myalgia		PPD (214)	PPD	PPD (215)	PPD	2	1

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
10	INJ&P	Postoperative ileus	PPD	PPD (13)	PPD	PPD (18)	PPD	6	2
11	GASTR	Small intestinal obstruction		PPD (15)	PPD	PPD (15)	PPD	1	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Ruptured Diverticulum	1	9	N
2	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: Diverticulitis	1	15	N
3	TC/TCN/P	Y	Resolved (PPD)	NOT RELATED/OTHER: Infection	1	9	Y
4	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: Infection	1	15	N
5	TC	N	Yes	NOT RELATED/OTHER: Medical event	1	21	N
6	N	N	Resolved (PPD)	Study Treatment	3	2	N
7	N	N	Resolved (PPD)	Study Treatment	3	2	N
8	N	N	Resolved (PPD)	Study Treatment	3	2	N
9	N	N	Resolved (PPD)	Study Treatment	3	2	N
10	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Surgical Side Effect	1	13	N
11	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: Ruptured Diverticulum	1	15	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD
		PPD
		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Narrative Comment
Subject PPD, a 50-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD. Concomitant medications received within 2 weeks prior to the onset of the diverticular perforation included PPD (since PPD) for stomach cramps, and PPD (since PPD) for fever. The subject was diagnosed with a diverticular perforation on PPD, 8 days after receiving Dose 1. On PPD (Day 1), the subject did not report any symptoms related to the diverticular perforation. On PPD, the subject had a fever, and on PPD, PPD experienced abdominal pain and reported both to the site. The subject was prescribed PPD for possible gastritis by PPD, who was a PPD; additionally, the subject was also taking PPD before the onset of the abdominal pain for fever. The subject stated that PPD had abdominal cramps since PPD; however, PPD did not report this to the clinical research coordinator at the time of screening. On PPD (Day 9), the subject presented to the emergency department with worsening right-sided abdominal pain and was hospitalized for a small-bowel obstruction. PPD was diagnosed with a heterogeneous cecal mass via a computed tomography scan of the abdomen/pelvis with contrast performed on the same day (Day 9). On PPD, a SARS-CoV-2 test result was negative. On PPD, 4 benign lymph nodes, ruptured diverticulum, sessile serrated polyps/adenoma, focal serosal colon adhesions, and benign liver cyst were observed via an exploratory laparotomy. The subject underwent bowel resection with a right hemicolectomy and allograft tissue reinforcement of anastomosis and abdominal wall excision; the right colon and appendix were removed. The pathology test result was negative for malignancy. On PPD, a magnetic resonance imaging scan with and without contrast showed a benign liver cyst. On PPD (Day 13), the subject experienced postoperative ileus. On PPD (Day 15), PPD was diagnosed with cellulitis (phlegmon formation), small-intestinal obstruction, and diverticulitis. Per the investigator, the underlying cause for the worsening of abdominal pain was the ruptured diverticulum with phlegmon formation secondary to small-intestinal obstruction. The small-intestinal obstruction and cellulitis resolved on the same day (Day 15), and the subject was able to tolerate an oral diet without difficulties. On PPD (Day 18), the postoperative ileus was considered resolved. On PPD (Day 19), the subject's laboratory tests showed an elevated alanine aminotransferase of 114 IU/L (normal range [NR]: 16-61 IU/L) and elevated aspartate aminotransferase of 82 IU/L (NR: 15-37 IU/L). The subject recovered from the diverticular perforation and worsening abdominal pain on PPD (Day 19). PPD was discharged from the hospital on the same day (Day 19) with the following medications: PPD. On PPD, the subject reported that PPD was not stable enough to travel or attend the safety visit. The subject was discontinued from the study intervention on PPD (Day 9) because of the diverticular perforation but remained in the study to be evaluated for safety, immunogenicity, and efficacy. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on

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Narrative Comment
PPD (Day 213), PPD (Day 232), and PPD (Day 426), respectively, and completed the study follow-up phase on PPD. The diverticulitis was ongoing at the time of the study completion. In the opinion of the investigator, there was no reasonable possibility that the diverticular perforation was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to infection. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs – Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (24)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	INJ&P	PPD	PPD	PPD (138)		ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1			W	N	Yes	NOT RELATED/OTHER: Unknown	2	115	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	BLOOD	Blood loss anaemia	PPD	PPD (20)		PPD (22)		3	3
2	HEPAT	PPD		PPD (20)		ONGOING			3
3	GASTR	Gastrointestinal haemorrhage		PPD (20)		PPD (22)		3	3
4	GASTR	Haematochezia		PPD (20)		PPD (22)		3	3
5	METAB	Hypernatraemia		PPD (20)		PPD (22)		3	2
6	GASTR	Oesophageal ulcer		PPD (20)		PPD (22)		3	3
7	BLOOD	Thrombocytopenia		PPD (20)		ONGOING			3
8	GASTR	Varices oesophageal		PPD (20)		PPD (22)		3	3

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (PPD)	NOT RELATED/OTHER: due to varices	1	20	N
2	N	N	Yes	NOT RELATED/OTHER: Worsening of previous condition	1	20	N
3	TC/TCN/P/W	Y	Resolved (PPD)	NOT RELATED/OTHER: Due to Ulcers	1	20	Y
4	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Due to ulcers	1	20	N
5	N	N	Resolved (PPD)	NOT RELATED/OTHER: Spontaneous event	1	20	N
6	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: Worsening of previous condition	1	20	N
7	N	N	Yes	NOT RELATED/OTHER: Due to cirrhosis	1	20	N
8	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: Worsening of previous condition	1	20	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment

Subject PPD , a 70-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD .

Concomitant medication received within 2 weeks prior to the onset of the gastrointestinal hemorrhage included PPD .

The subject was diagnosed with a gastrointestinal hemorrhage on PPD , 19 days after receiving Dose 1.

On PPD (Day 20), the subject was hospitalized for a gastrointestinal hemorrhage. The clinical chemistry laboratory test results on the same day (Day 20) showed sodium of 147, potassium of 3.7, chloride of 116, carbon dioxide (CO_2) of 16.6, blood urea nitrogen (BUN) of 22, creatinine of 1.07, international normalized ratio of 1.18, albumin of 3.0, total protein of 6.5, direct bilirubin of 0.61, alanine aminotransferase (ALT) of 24, aspartate aminotransferase (AST) of 28, and alkaline phosphatase (ALP) of 96 (normal ranges and units were not reported). On PPD (Day 20), the subject was diagnosed with acute blood-loss anemia, PPD , hematochezia, esophageal ulcer, thrombocytopenia, esophageal varices, and hypernatremia. An esophagogastroduodenoscopy performed on PPD revealed postbanding ulcers and residual esophageal varices. The esophageal varices were rebanded, and the subject was observed overnight. The subject failed to report a history of PPD . Laboratory results on PPD revealed a hematocrit (Hct) of 22.9, hemoglobin (Hgb) of 7.1, sodium of 147, potassium of 3.7, chloride of 119, CO_2 of 19.8, BUN of 18, creatinine of 0.86, white blood cell count of 2.9, platelet count of 70, albumin of 2.7, total protein of 5.3, ALT of 15, AST of 31, and ALP of 82 (normal ranges and units were not reported). On PPD (Day 22), the laboratory results showed Hct of 21.4, Hgb of 7.0, sodium of 143, potassium of 3.6, chloride of 115, CO_2 of 21.0, BUN of 14, and creatinine of 0.73 (normal ranges and units were not reported). A COVID-19 test was not performed during the hospitalization. The blood-loss anemia, gastrointestinal hemorrhage, hematochezia, hypernatremia, esophageal ulcer, and esophageal varices were considered resolved on PPD (Day 22). It was noted that the bleeding did not reoccur, and the subject was discharged on the same day (Day 22). The subject notified the site that PPD was feeling well and had recovered from the event.

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Narrative Comment
The subject was withdrawn from the study on PPD (Day 22) because of the gastrointestinal hemorrhage. The PPD and thrombocytopenia were ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the gastrointestinal hemorrhage was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to ulcers. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present

Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	VASC	Accelerated hypertension	PPD	PPD (9)		PPD (12)		4	3	N	N
2	RENAL	Acute kidney injury		PPD (9)		PPD (13)		5	2	N	N
3	RESP	Acute respiratory failure		PPD (9)		PPD (10)		2	3	TC	N
4	CARD	Atrial fibrillation		PPD (9)		PPD (14)		6	2	N	N
5	CARD	Cardiac failure congestive		PPD (9)		PPD (14)		6	3	TC/P/W	Y
6	METAB	Dehydration		PPD (9)		PPD (10)		2	2	TCN	N
7	NERV	Dizziness		PPD (11)		PPD (14)		4	2	TCN	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
8	RESP	Dyspnoea	PPD	PPD (9)		PPD (10)		2	3	N	N
9	METAB	Hypokalaemia		PPD (10)		PPD (12)		3	2	TC	N
10	VASC	Hypotension		PPD (11)		PPD (13)		3	2	N	N
11	MUSC	Pain in extremity		PPD (11)		PPD (12)		2	2	TC	N
12	RESP	Pulmonary oedema		PPD (9)		PPD (11)		3	2	N	N
13	GENRL	Pyrexia		PPD (11)		PPD (12)		2	2	N	N
14	INFEC	Urinary tract infection		PPD (9)		PPD (14)	PPD	6	2	TC	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (PPD)	NOT RELATED/OTHER: worsening of pre-existing condition	1	9	N
2	Resolved (PPD)	NOT RELATED/OTHER: Dehydration	1	9	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	Resolved (PPD)	NOT RELATED/OTHER: due to congestive heart failure	1	9	N
4	Resolved (PPD)	NOT RELATED/OTHER: URINARY TRACT INFECTION	1	9	N
5	Resolved (PPD)	NOT RELATED/OTHER: worsening of pre-existing condition	1	9	Y
6	Resolved (PPD)	NOT RELATED/OTHER: DUE TO DIURETICS	1	9	N
7	Resolved (PPD)	NOT RELATED/OTHER: due to UTI	1	11	N
8	Resolved (PPD)	NOT RELATED/OTHER: CONGESTIVE HEART FAILURE	1	9	N
9	Resolved (PPD)	NOT RELATED/OTHER: DUE TO DIURESIS	1	10	N
10	Resolved (PPD)	NOT RELATED/OTHER: due to diuresis	1	11	N
11	Resolved (PPD)	NOT RELATED/OTHER: WORSENING OF PRE-EXISTING CONDITION	1	11	N
12	Resolved (PPD)	NOT RELATED/OTHER: CONGESTIVE HEART FAILURE	1	9	N
13	Resolved (PPD)	NOT RELATED/OTHER: URINARY TRACT INFECTION	1	11	N
14	Resolved (PPD)	NOT RELATED/OTHER: spontaneous	1	9	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

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Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD. Concomitant medications received within 2 weeks prior to the worsening of chronic congestive heart failure included PPD. The subject experienced worsening of chronic congestive heart failure on PPD, 8 days after receiving Dose 1. On PPD (Day 9), the subject went to an emergency room with dyspnea (shortness of breath), accelerated hypertension, and an acute kidney injury and was subsequently admitted to the hospital with an exacerbation of chronic congestive heart failure resulting in acute respiratory failure. On the same day (Day 9), the subject's blood pressure (BP) was 217/113 (units not reported) and laboratory test results showed cardiac troponin I of 0.095 (units not reported), carbon dioxide of 21.8 mmol/L, blood urea nitrogen (BUN) of 35 mg/dL, creatinine of 2.61 mg/dL, N-terminal prohormone brain natriuretic peptide (NT-proBNP) of 19,381 pg/mL, and hemoglobin A_{1C} of 5.40 mg/dL (normal ranges not reported for all). A chest x-ray showed previous cardiac surgery with sternotomy wires in place and mild to moderate pulmonary opacities that were suspicious for inflammation/infection or edema; no significant pleural effusions were noted. A second chest x-ray performed on the same day (Day 9) revealed bilateral pulmonary edema, for which the subject was treated with PPD, then transitioned to PPD administration. A urinalysis was positive for nitrites and leukocytes, and a urine culture showed *Citrobacter freundii* complex. On PPD (Day 9), the subject was also diagnosed with a urinary tract infection, paroxysmal atrial fibrillation, and dehydration. PPD was treated with PPD for the urinary tract infection. While PPD was in the hospital, PPD SARS-CoV-2 (COVID-19) test result was negative. On PPD (Day 10), laboratory test results showed a hemoglobin (Hgb) of 96 g/dL, sodium (Na) of 140 mmol/L, potassium (K) of 3.3 mmol/L, chloride (Cl) of 110 mmol/L, creatinine of 2.55 mg/dL, and NT-proBNP of 20,860 pg/mL. On the same day (Day 10), the dyspnea, acute respiratory failure, and dehydration were considered resolved, and the subject was noted to have hypokalemia. On PPD (Day 11), the subject experienced dizziness, hypotension, worsening of bilateral foot pain, and pyrexia (low-grade fever). PPD BP was 118/69 (units not reported; lower than PPD typical BP) because of treatment with PPD. Laboratory test results showed Na of 140 mmol/L, K of 3.3 mmol/L, Cl of 110 mmol/L, and creatinine of 2.61 mg/dL. On the same day (Day 11), the pulmonary edema resolved. On PPD (Day 12), laboratory test results showed Na of 136 mmol/L, K of 3.7 mmol/L, Cl of 104 mmol/L, creatinine of 2.45 mg/dL, and NT-proBNP of 3,465 pg/mL. On the same day (Day 12), the accelerated hypertension, hypokalemia, worsening of bilateral foot pain, and pyrexia resolved. On PPD (Day 13), laboratory test results showed Hgb of 10.6 g/dL, Na of 137 mmol/L, K of 3.9 mmol/L, Cl of 107 mmol/L, and creatinine of 2.49 mg/dL. On the same day (Day 13), the acute kidney injury and hypotension resolved. On PPD (Day 14), the atrial fibrillation, worsening of chronic congestive heart failure, dizziness, and urinary tract infection resolved, and the subject was discharged from the hospital on PPD.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
The subject was withdrawn from the study on PPD because of the worsening of chronic congestive heart failure. In the opinion of the investigator, there was no reasonable possibility that the worsening of chronic congestive heart failure was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events						
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)
1	GENRL	Fatigue	PPD	PPD (4)		ONGOING
2	MUSC	Myalgia		PPD (4)		ONGOING
3	GENRL	Vaccination site pain		PPD (1)		ONGOING

Adverse Events										
AE Number	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1			1	N	N	Yes	Study Treatment	1	4	N
2			1	P/W	N	Yes	Study Treatment	1	4	Y
3			1	N	N	Yes	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment
Subject PPD, a <24-year-old PPD with no reported medical history, received Dose 1 on PPD.
The subject experienced myalgia on PPD, 3 days after receiving Dose 1.
The subject experienced vaccination site pain on PPD (Day 1) and developed fatigue and myalgia on PPD (Day 4).
The subject was withdrawn from the study on PPD because of the myalgia. The fatigue, myalgia, and vaccination site pain were all ongoing at the time of withdrawal.
In the opinion of the investigator, there was a reasonable possibility that the myalgia was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, [≤24]
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD	PPD	PPD (11)		PPD (227)		217	
2	HEPAT	Hyperbilirubinaemia		PPD (227)		PPD (243)		17	2
3	RESP	PPD		PPD (227)		PPD (243)		17	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	R	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	11	Y
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	227	N
3	TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	227	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	PPD
Withdrawn	FOLLOW-UP	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	HEPAT	Acute hepatic failure	PPD	PPD (100)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		4	W	Y	Yes	NOT RELATED/OTHER: unknown	2	79	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment
Subject PPD, a 50-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 22). The subject was diagnosed with acute hepatic failure on PPD, 78 days after receiving Dose 2. On PPD (Day 100), the subject visited the emergency room because of the acute hepatic failure, which required hospitalization. The subject was withdrawn from the study on PPD (Day 100) because of the acute hepatic failure, which was ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the acute hepatic failure was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 3	BNT162b2	PPD (127)	PPD
VACCINATION 4	BNT162b2	PPD (147)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	VASC	Hypertension	PPD	PPD (23)		ONGOING		
2	INFEC	Sinusitis		PPD (14)		PPD (56)		43

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC/P	N	Yes	NOT RELATED/OTHER: unknown	1	23	Y
2	2	TC	N	Resolved (PPD)	NOT RELATED/OTHER: unk	1	14	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD
		PPD
		PPD
		PPD
		PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

Narrative Comment

Subject PPD , a 70-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD .

The subject was diagnosed with hypertension on PPD , 22 days after receiving Dose 1.

The subject was withdrawn from the study intervention on PPD because of the hypertension, which was ongoing at the time of withdrawal.

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 127) and PPD (Day 147), respectively, and completed the study follow-up phase on PPD .

In the opinion of the investigator, there was no reasonable possibility that the hypertension was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 3	BNT162b2	PPD (147)	PPD
VACCINATION 4	BNT162b2	PPD (167)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (393)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Injection site pain	PPD	PPD (148)		PPD (149)	
2	GENRL	Injection site swelling		PPD (394)		PPD (398)	
3	BLOOD	Lymphadenopathy		PPD (168)		PPD (170)	
4	BLOOD	Lymphadenopathy		PPD (150)		PPD (152)	
5	BLOOD	Lymphadenopathy		PPD (394)		PPD (398)	
6	SKIN	Urticaria		PPD (4)		PPD (7)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	2	N	N	Resolved (PPD)	Study Treatment	3	2	N
2	5	2	N	N	Resolved (PPD)	Study Treatment	5	2	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	3	1	N	N	Resolved (PPD)	Study Treatment	4	2	N
4	3	1	N	N	Resolved (PPD)	Study Treatment	3	4	N
5	5	2	N	N	Resolved (PPD)	Study Treatment	5	2	N
6	4	2	TC/P	N	Resolved (PPD)	Study Treatment	1	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

Narrative Comment
Subject PPD, a 30-year-old PPD with no pertinent medical history, received Dose 1 on PPD.
The subject experienced urticaria (hives, upper chest) on PPD, 3 days after receiving Dose 1.
On PPD (Day 7), the urticaria resolved.
The subject was discontinued from the study intervention on PPD because of the urticaria and remained in the study to be evaluated for safety, immunogenicity, and efficacy.
In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 147), PPD (Day 167), and PPD (Day 393), respectively, and completed the study follow-up phase on PPD.
In the opinion of the investigator, there was a reasonable possibility that the urticaria was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	INJ&P	PPD	PPD	PPD (1)	PPD	ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1			P	N	Yes	NOT RELATED/OTHER: PPD	.	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	PPD
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 3	BNT162b2	PPD (172)	PPD
VACCINATION 4	BNT162b2	PPD (193)	PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	VASC	Hypertension	PPD	PPD (20)	PPD	PPD (41)		22	1	TC/P

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (PPD)	NOT RELATED/OTHER: UNDERLYING MEDICAL CONDITION	1	20	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	PROTOCOL DEVIATION

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD.
The subject experienced worsening hypertension on PPD, 19 days after receiving Dose 1.
On PPD (Day 41), the worsening hypertension resolved.
The subject was discontinued from the study intervention on PPD because of the worsening hypertension.
In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 172) and PPD (Day 193), respectively.
The subject was withdrawn from the study on PPD because of the receipt of a nonstudy COVID-19 vaccine (protocol deviation).
In the opinion of the investigator, there was no reasonable possibility that the worsening hypertension was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	SKIN	Diabetic foot	PPD	PPD (20)		ONGOING	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		1	TCN/P/W	N	Yes	NOT RELATED/OTHER: PPD	1	20	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD , a 50-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD .
The subject was diagnosed with a diabetic foot ulcer (right foot) on PPD , 19 days after receiving Dose 1.
The subject was withdrawn from the study on PPD because of the diabetic foot ulcer (right foot), which was ongoing at the time of withdrawal.
In the opinion of the investigator, there was no reasonable possibility that the diabetic foot ulcer was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 3	BNT162b2	PPD (202)	PPD
VACCINATION 4	BNT162b2	PPD (223)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (429)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (1)		PPD (40)		40
2	RESP	Oropharyngeal pain		PPD (53)		PPD (55)		3
3	INFEC	Urinary tract infection		PPD (162)		PPD (170)		9

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		P	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	1	Y
2	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: Personal illness	1	53	N
3	1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	1	162	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	PPD
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain upper	PPD	PPD ()		PPD (20)			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	P	N	Resolved (PPD)	NOT RELATED/OTHER: GALLBLADDER DISEASE	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD. On an unspecified date in PPD, the subject experienced upper abdominal pain (right quadrant). On PPD (Day 20), the upper abdominal pain resolved. The subject was discontinued from the study intervention on PPD because of the upper abdominal pain. The subject requested withdrawal from the study on PPD. In the opinion of the investigator, there was no reasonable possibility that the upper abdominal pain was related to the study intervention, but rather it was related to gallbladder disease.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	SKIN	Pruritus	PPD	PPD (2)		PPD (2)	
2	CARD	Tachycardia		PPD (2)		PPD (2)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	3	TC	N	Resolved (PPD)	Study Treatment	1	2	N
2	1	3	TC/P	N	Resolved (PPD)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject PPD, a 60-year-old PPD with no pertinent medical history, received Dose 1 on PPD. On PPD, 1 day after receiving Dose 1, the subject reported tachycardia, which resolved the same day. On the same day (Day 2), the subject also experienced generalized pruritus, which resolved on the same day. The subject was discontinued from the study intervention on PPD because of the tachycardia, and the subject requested withdrawal from the study on PPD. In the opinion of the investigator, there was a reasonable possibility that the tachycardia was related to the study intervention.

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	PPD	PPD (1)		PPD (2)	
2	NERV	Headache		PPD (1)		PPD (2)	
3	MUSC	Myalgia		PPD (1)		PPD (2)	
4	GENRL	Pyrexia		PPD (1)		PPD (2)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	2	TC/P	N	Resolved (PPD)	Study Treatment	1	1	Y
2	2	3	TC/P	N	Resolved (PPD)	Study Treatment	1	1	Y
3	2	2	TC	N	Resolved (PPD)	Study Treatment	1	1	N
4	2	2	TC/P	N	Resolved (PPD)	Study Treatment	1	1	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	PROTOCOL DEVIATION

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD. On PPD, after Dose 1 administration, the subject experienced chills, headache, and pyrexia. On the same day (Day 1), the subject also experienced myalgia. On PPD (Day 2), the chills, headache, pyrexia, and myalgia resolved. The subject was discontinued from the study intervention on PPD (Day 2) because of the chills, headache, and pyrexia and was withdrawn from the study on PPD because of the receipt of a nonstudy PPD vaccine (protocol deviation). In the opinion of the investigator, there was a reasonable possibility that the chills, headache, and pyrexia were related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GASTR	Diarrhoea	PPD	PPD (2)		PPD (5)	
2	GENRL	Fatigue		PPD (2)		PPD (8)	
3	NERV	Headache		PPD (2)		PPD (8)	
4	MUSC	Myalgia		PPD (2)		PPD (8)	
5	GASTR	Nausea		PPD (2)		PPD (5)	
6	GASTR	Vomiting		PPD (5)		PPD (5)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	3	TC/W	N	Resolved (PPD)	Study Treatment	1	2	Y
2	7	2	P	N	Resolved (PPD)	Study Treatment	1	2	Y
3	7	2	TC	N	Resolved (PPD)	Study Treatment	1	2	N
4	7	2	TC	N	Resolved (PPD)	Study Treatment	1	2	N
5	4	2	TC	N	Resolved (PPD)	Study Treatment	1	2	N
6	1	2	N	N	Resolved (PPD)	Study Treatment	1	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_CSR_Safety_Narrative/profile. (Database Snapshot Date: 07MAR2023) Date of Generation: 18APR2023 (17:51)

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment

Subject PPD , a ≥75-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD .

On PPD , 1 day after receiving Dose 1, the subject experienced diarrhea and fatigue.

On PPD (Day 2), the subject also experienced headache, myalgia, and nausea. On PPD (Day 5), PPD experienced vomiting, with the resolution of the diarrhea, nausea, and vomiting on the same day (Day 5). On PPD (Day 8), the symptoms of fatigue, headache, and myalgia resolved.

The subject was discontinued from the study intervention on PPD because of the fatigue and was withdrawn from the study on PPD because of the diarrhea.

In the opinion of the investigator, there was a reasonable possibility that the diarrhea and fatigue were related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NERV	Cerebrovascular accident	PPD	PPD (39)	PPD	PPD (41)		3	2	TC	Y
2	NERV	Cerebrovascular accident		PPD (184)		PPD (184)		1	3	TC/W	Y
3	PSYCH	PPD		PPD (39)		PPD (40)		2	2	TC	Y
4	GASTR	Gastrooesophageal reflux disease		PPD (39)	PPD	PPD (41)		3	1	TC	Y
5	VASC	Hypertensive emergency		PPD (39)		PPD (41)		3	2	TC	Y
6	VASC	Hypertensive emergency		PPD (184)	PPD	PPD (184)		1	3	TC	Y
7	METAB	Hypokalaemia		PPD (39)		PPD (41)		3	2	TC	Y
8	GENRL	Treatment noncompliance		PPD (39)	PPD	PPD (41)		3	2	TC	Y

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (PPD)	NOT RELATED/OTHER: history of PPD	2	20	N
2	Resolved (PPD)	NOT RELATED/OTHER: stroke-SAE submitted	2	165	Y
3	Resolved (PPD)	NOT RELATED/OTHER: history of PPD	2	20	N
4	Resolved (PPD)	NOT RELATED/OTHER: Disease process	2	20	N
5	Resolved (PPD)	NOT RELATED/OTHER: history of PPD	2	20	N
6	Resolved (PPD)	NOT RELATED/OTHER: Disease process	2	165	N
7	Resolved (PPD)	NOT RELATED/OTHER: History of PPD	2	20	N
8	Resolved (PPD)	NOT RELATED/OTHER: Subject not consistently taking prescribed medications	2	20	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Narrative Comment
PPD

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GASTR	Abdominal pain	PPD	PPD (21)		PPD (22)		2	2
2	GASTR	Gastritis		PPD (18)		PPD (56)		39	2
3	PSYCH	PPD		PPD (14)		PPD (22)		9	3
4	GASTR	Vomiting		PPD (18)		PPD (22)	PPD	5	3

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: ACUTE GASTRITIS	1	21	N
2	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: UNKNOWN ETIOLOGY	1	18	N
3	TC/TCN/P	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	14	Y
4	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: ACTUE GASTRITIS	1	18	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	REPEAT SCREENING 1	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Diarrhoea	PPD	PPD (2)		PPD (4)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	3	TC/P/WN	N	Resolved (PPD)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment
Subject PPD a 70-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD.
The subject experienced diarrhea on PPD, 1 day after receiving Dose 1.
The subject was withdrawn from the study on PPD (Day 4) because of the diarrhea, which resolved on the same day (Day 4).
In the opinion of the investigator, there was a reasonable possibility that the diarrhea was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≤24	PPD		

Vital Signs - Baseline
No Vital Signs - Baseline

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered):
Date of First Dose: N/A; Date of Last Dose: N/A

==========

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Presyncope	PPD	PPD (1)		PPD (1)		1
2	GASTR	Vomiting		PPD (1)		PPD (1)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	W	N	Resolved (PPD)	NOT RELATED/OTHER: blood draw	.	.	Y
2	1	W	N	Resolved (PPD)	NOT RELATED/OTHER: blood draw	.	.	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	PHYSICIAN DECISION

Narrative Comment
Subject PPD, a ≤24-year-old PPD with no reported medical history, reported presyncope and vomiting during the prevaccination blood sample collection on PPD (Day 1), which resolved that same day. The study vaccination was not administered per the physician's decision, and the subject was withdrawn from the study on PPD (Day 1) because of the presyncope and vomiting. In the opinion of the investigator, there was no reasonable possibility that the presyncope and vomiting were related to the study intervention, but rather they were related to the blood sample collection.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Headache	PPD	PPD (2)		PPD (2)	
2	GENRL	Injection site pain		PPD (2)		PPD (2)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	3	TCP	N	Resolved (PPD)	Study Treatment	1	2	Y
2	1	3	P	N	Resolved (PPD)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	FOLLOW-UP	PPD	

Narrative Comment
Subject PPD, a ≤24-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD. The subject experienced severe headache and injection site pain on PPD, 1 day after receiving Dose 1. On the same day (Day 2), the headache and injection site pain resolved. The subject was discontinued from the study intervention on PPD (Day 2) because of the headache and injection site pain and completed the study follow-up phase on PPD. In the opinion of the investigator, there was a reasonable possibility that the headache and injection site pain were related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD
VACCINATION 3	BNT162b2	PPD (148)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INFEC	Acute sinusitis	PPD	PPD (3)	PPD	PPD (8)	PPD	6
2	MUSC	Myalgia		PPD (149)		PPD (150)		2
3	GASTR	Nausea		PPD (148)	PPD	PPD (148)	PPD	1
4	SKIN	Urticaria		PPD (148)	PPD	PPD (149)		2
5	IMMUN	Allergy to vaccine		PPD (148)	PPD	PPD (149)		2

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
6	VASC	Flushing	PPD	PPD (148)	PPD	PPD (149)		2
7	GENRL	Swelling face		PPD (148)	PPD	PPD (149)		2

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: UNKNOWN	1	3	N
2	1	N	N	Resolved (PPD)	Study Treatment	3	2	N
3	1	TC/TCN	N	Resolved (PPD)	Study Treatment	3	1	N
4	1	TC/TCN	N	Resolved (PPD)	Study Treatment	3	1	N
5	2	TC/TCN/P	N	Resolved (PPD)	Study Treatment	3	1	Y
6	2	TC/TCN	N	Resolved (PPD)	Study Treatment	3	1	N
7	2	TC/TCN	N	Resolved (PPD)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD
		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Withdrawn	OPEN LABEL TREATMENT	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA

Narrative Comment
Subject PPD , a 30-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 20). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first dose of BNT162b2 on PPD (Day 148). The subject experienced an allergic reaction to vaccine on PPD , the day of receiving Dose 3 (the first dose of BNT162b2). On PPD (Day 148), 5 minutes after the first dose of BNT162b2 administration, the subject developed facial swelling and facial flushing considered to be an allergic reaction to the vaccine. The subject also experienced nausea, 1 hour 18 minutes after the first dose of BNT162b2 administration, and

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Narrative Comment
urticaria (hives on abdomen), 3 hours 18 minutes after the first dose of BNT162b2 administration. On the same day (Day 148), the nausea resolved. On PPD (Day 149), the urticaria, facial flushing, facial swelling, and allergic reaction to the vaccine resolved. The subject was discontinued from the study intervention on PPD because of the allergic reaction to vaccine and was withdrawn from the study on PPD because the subject no longer met the eligibility criteria. In the opinion of the investigator, there was a reasonable possibility that the allergic reaction to vaccine was related to BNT162b2.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NEOPL	Breast cancer	PPD	PPD ()		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		3	TC/W	N	Yes	NOT RELATED/OTHER: Breast Cancer	2	42	Y

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
PPD		PPD	ONGOING	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment
Subject PPD, a 50-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 22). The subject was diagnosed with breast cancer on an unspecified date in PPD, approximately 41 days after receiving Dose 2. The subject started treatment with PPD. The subject was withdrawn from the study on PPD because of the breast cancer, which was ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the breast cancer was related to the study intervention.

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD

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Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	ENDO	Adrenal mass	PPD	PPD (294)		ONGOING			1	N	N
2	VASC	Aortic aneurysm		PPD (294)		ONGOING			2	N	N
3	CARD	Arrhythmia		PPD (423)	PPD	ONGOING			2	W	N
4	NEOPL	B-cell small lymphocytic lymphoma stage IV		PPD (373)		ONGOING			2	N	Y
5	RESP	Emphysema		PPD (294)		ONGOING			1	N	N
6	VASC	Hypotension		PPD (263)		PPD (265)		3	2	N	N
7	RESP	Pulmonary mass		PPD (294)		ONGOING			1	N	N
8	NERV	Transient ischaemic attack		PPD (263)		PPD (265)		3	3	TC	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Yes	NOT RELATED/OTHER: UNKNOWN	2	275	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	Yes	NOT RELATED/OTHER: PPD and ASCVD	2	275	N
3	Yes	NOT RELATED/OTHER: HISTORY OF PPD	2	404	Y
4	Yes	NOT RELATED/OTHER: History of PPD	2	354	N
5	Yes	NOT RELATED/OTHER: unknown	2	275	N
6	Resolved (PPD)	NOT RELATED/OTHER: Blood Pressure side effects	2	244	N
7	Yes	NOT RELATED/OTHER: unknown	2	275	N
8	Resolved (PPD)	NOT RELATED/OTHER: Decreased cerebral blood flow and carotid artery stenosis and hypotension	2	244	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT
Withdrawn	REPEAT SCREENING 3	PPD	OTHER

Narrative Comment

Subject PPD , a ≥75-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 20).

Concomitant medications included PPD for carotid artery stenosis.

The subject experienced arrhythmia on PPD , 403 days after receiving Dose 2.

The subject was withdrawn from the study on PPD (Day 423) because of the arrhythmia, which was ongoing at the time of withdrawal.

In the opinion of the investigator, there was no reasonable possibility that the arrhythmia was related to the study intervention, but rather it was related to the history of PPD .

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (177)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	CARD	Angina pectoris	PPD	PPD (177)	PPD	PPD (218)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	42	2	P	N	Resolved (PPD)	Study Treatment	3	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	OPEN LABEL TREATMENT	PPD	ADVERSE EVENT
Completed	REPEAT SCREENING 1	PPD	
Completed	FOLLOW-UP	PPD	

Narrative Comment

Subject PPD , a 60-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD and Dose 2 on PPD (Day 22).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first dose of BNT162b2 on PPD (Day 177).

The subject experienced cardiac chest pain (angina pectoris) on PPD , the day of receiving Dose 3 (the first dose of BNT162b2).

The subject was discontinued from the study intervention on PPD (Day 177) because of the angina pectoris, which was ongoing at the time of withdrawal. The subject completed the follow-up phase of the study on PPD .

In the opinion of the investigator, there was a reasonable possibility that the angina pectoris was related to BNT162b2.

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GASTR	Abdominal discomfort	PPD	PPD (2)		PPD (29)	
2	GASTR	Diarrhoea		PPD (2)		PPD (2)	
3	GASTR	Diarrhoea		PPD (2)		PPD (29)	
4	EYE	Eye pain		PPD (2)		PPD (29)	
5	GENRL	Fatigue		PPD (2)		PPD (29)	
6	NERV	Headache		PPD (2)		PPD (2)	
7	NERV	Headache		PPD (2)		PPD (2)	
8	MUSC	Muscular weakness		PPD (2)		PPD (29)	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	28	2	TC	N	Resolved (PPD)	Study Treatment	1	2	N
2	1	1	N	N	Resolved (PPD)	Study Treatment	1	2	N
3	28	2	N	N	Resolved (PPD)	Study Treatment	1	2	N
4	28	2	P	N	Resolved (PPD)	Study Treatment	1	2	Y
5	28	2	N	N	Resolved (PPD)	Study Treatment	1	2	N
6	1	1	N	N	Resolved (PPD)	Study Treatment	1	2	N
7	1	2	TC	N	Resolved (PPD)	Study Treatment	1	2	N
8	28	2	N	N	Resolved (PPD)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

Narrative Comment

Subject PPD, a 40-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD.

The subject reported right eye pain on PPD, 1 day after receiving Dose 1.

On PPD (Day 2), the subject also experienced fatigue, headache (2 episodes), abdominal discomfort, diarrhea, loose stools, and muscular weakness. The diarrhea and headache resolved on the same day (Day 2). On PPD (Day 29), the abdominal discomfort, loose stools, right eye pain, fatigue, and muscular weakness resolved.

The subject was discontinued from the study intervention on PPD because of the right eye pain, and the subject requested withdrawal from the study follow-up phase on PPD.

In the opinion of the investigator, there was a reasonable possibility that the right eye pain was related to the study intervention.

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Chest discomfort	PPD	PPD (5)		PPD (12)		8
2	NERV	Headache		PPD (2)		PPD (9)		8
3	METAB	Hypokalaemia		PPD (5)		PPD (7)		3
4	GENRL	Injection site pain		PPD (1)		PPD (5)		5
5	MUSC	Pain in extremity		PPD (3)		PPD (8)		6

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Resolved (PPD)	Study Treatment	1	5	N
2	2	TC/P	N	Resolved (PPD)	Study Treatment	1	2	Y
3	1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: IDIOPATHIC	1	5	N
4	3	N	N	Resolved (PPD)	Study Treatment	1	1	N
5	3	TC	N	Resolved (PPD)	Study Treatment	1	3	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP

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Narrative Comment
Subject PPD, a 40-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD. The subject experienced a worsening headache on PPD, 1 day after receiving Dose 1. The subject experienced severe injection site pain, worsening headache, pain in extremity (left arm pain), and chest discomfort on PPD (Day 1), PPD (Day 2), PPD (Day 3), and PPD (Day 5), respectively. On PPD (Day 5), the subject was discontinued from the study intervention because of the worsening headache. The injection site pain, pain in extremity, worsening headache, and chest discomfort resolved on PPD (Day 5), PPD (Day 8), PPD (Day 9), and PPD (Day 12), respectively. The subject was withdrawn from the study on PPD because the subject was lost to follow-up. In the opinion of the investigator, there was a reasonable possibility that the worsening headache was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2SA (30 µg, 2 Doses)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (23)	PPD
VACCINATION 3	BNT162b2SA	PPD (205)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	MUSC	Arthralgia	PPD	PPD (206)		PPD (206)	
2	GENRL	Chills		PPD (206)	PPD	PPD (206)	
3	GENRL	Fatigue		PPD (205)	PPD	PPD (205)	
4	GENRL	Fatigue		PPD (206)		PPD (206)	
5	GENRL	Fatigue		PPD (207)		PPD (207)	
6	NERV	Headache		PPD (206)		PPD (206)	
7	GENRL	Injection site pain		PPD (205)	PPD	PPD (207)	
8	GENRL	Injection site pain		PPD (208)		PPD (208)	
9	MUSC	Myalgia		PPD (206)		PPD (206)	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2SA (30 µg, 2 Doses)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events

AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	1	TC/P	N	Resolved (PPD)	Study Treatment	3	2	Y
2	1	2	TC/P	N	Resolved (PPD)	Study Treatment	3	2	Y
3	1	1	P	N	Resolved (PPD)	Study Treatment	3	1	Y
4	1	2	TC/P	N	Resolved (PPD)	Study Treatment	3	2	Y
5	1	1	TC/P	N	Resolved (PPD)	Study Treatment	3	3	Y
6	1	1	TC/P	N	Resolved (PPD)	Study Treatment	3	2	Y
7	3	2	TCN/P	N	Resolved (PPD)	Study Treatment	3	1	Y
8	1	1	P	N	Resolved (PPD)	Study Treatment	3	4	Y
9	1	1	TC/P	N	Resolved (PPD)	Study Treatment	3	2	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2SA (30 µg, 2 Doses)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 2	PPD	
Withdrawn	SUBSTUDY	PPD	ADVERSE EVENT
Completed	FOLLOW-UP	PPD	

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Narrative Comment
Subject PPD, a 30-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 23). The subject received a nonstudy PPD on PPD. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible to enter a subset group for evaluation of boostability and protection against emerging COVID-19 variants of concern. It was confirmed that the subject had originally received 2 doses of BNT162b2; the subject therefore received an additional dose of BNT162b2$_{SA}$ (South African variant) at PPD on PPD (Day 205). The subject experienced injection site pain (moderate severity) and fatigue (mild severity) at PPD on PPD, approximately 5.5 hours after receiving Dose 3 (the first dose of BNT162b2$_{SA}$). The subject subsequently developed arthralgia, chills, headache, and myalgia on PPD, 1 day after receiving the first dose of BNT162b2$_{SA}$. On PPD (Day 206), the arthralgia, chills, headache, and myalgia resolved, but the severity of fatigue worsened from mild to moderate on the same day. On PPD (Day 207), the severity of the fatigue improved from moderate to mild and resolved on the same day. On PPD (Day 208), the severity of the injection site pain improved from moderate to mild and resolved on the same day. The subject was discontinued from the subset group dosing on PPD because of the events and completed the study follow-up phase on PPD. In the opinion of the investigator, there was a reasonable possibility that the events were related to BNT162b2$_{SA}$.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (157)	PPD
VACCINATION 4	BNT162b2	PPD (177)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	BLOOD	Anaemia	PPD	PPD (290)		PPD (295)		6	3
2	PSYCH	PPD		PPD (356)		PPD (356)		1	1
3	GASTR	Constipation		PPD (356)		PPD (356)		1	1
4	METAB	Diabetic ketoacidosis		PPD (352)		PPD (356)		5	3

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
5	GASTR	Dyspepsia	PPD	PPD ()		ONGOING			1
6	GASTR	Gastric ulcer haemorrhage		PPD (290)		PPD (295)		6	3
7	NEOPL	Lung neoplasm malignant		PPD (358)		ONGOING			3
8	GENRL	Non-cardiac chest pain		PPD (290)		PPD (295)		6	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: bleeding gastric ulcer	4	114	N
2	TC	N	Resolved (PPD)	NOT RELATED/OTHER: situational	4	180	N
3	TC	N	Resolved (PPD)	NOT RELATED/OTHER: diet	4	180	N
4	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	176	N
5	TC	N	Yes	NOT RELATED/OTHER: gastro-esophageal reflux disease	2	72	N
6	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	114	N
7	TC/TCN/W	Y	Yes	NOT RELATED/OTHER: lung cancer, UNKNOWN	4	182	Y
8	TC	N	Resolved (PPD)	NOT RELATED/OTHER: gastric ulcer	4	114	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD, and a family medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 157) and PPD (Day 177), respectively.

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Narrative Comment
Concomitant medications received within 2 weeks prior to the onset of the malignant lung neoplasm included PPD .
On PPD (Day 352), a laboratory test result showed glucose of 778 mg/dL (normal range [NR]: 70-180 mg/dL), and a SARS-CoV-2 test result was negative. On the same day (Day 352), the subject was diagnosed with diabetic ketoacidosis.
On PPD , a chest x-ray showed bilateral perihilar peribronchial thickening with central congestive/bronchitic changes and no acute cardiopulmonary abnormality.
On PPD , a chest x-ray showed mild patchy bibasilar peripheral pulmonary opacities without significant interval change.
On PPD (Day 356), the subject experienced PPD and constipation. The subject's laboratory test results showed glucose and potassium levels of 209 mg/dL and 3.3 mmol/L (NR: 3.6-5.2 mmol/L), respectively. On the same day (Day 356), the diabetic ketoacidosis, PPD , and constipation were considered resolved.
The subject was diagnosed with a malignant lung neoplasm on PPD , 181 days after receiving Dose 4 (the second dose of BNT162b2).
On PPD , a chest x-ray was ordered due to an elevated white blood cell count (date and values were not reported), and the results revealed faintly increased bilateral airspace opacities and slightly nodular left upper lobe opacity. During hospitalization, the subject was treated with PPD .
The subject was withdrawn from the study on PPD because of the malignant lung neoplasm, which was ongoing at the time of withdrawal.
In the opinion of the investigator, there was no reasonable possibility that the malignant lung neoplasm was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Guillain-Barre syndrome	PPD	PPD (103)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCTCN/W	Y	Yes	NOT RELATED/OTHER: secondary to COVID-19	2	84	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment

Subject PPD, a 50-year-old PPD with a pertinent medical history of PPD), received Dose 1 on PPD and Dose 2 on PPD (Day 20).

Concomitant medications received within 2 weeks prior to the onset of the Guillain-Barre syndrome included PPD .

The subject was diagnosed with Guillain-Barre syndrome on PPD, 83 days after receiving Dose 2.

On PPD, the subject developed a mildly productive cough. On PPD (Day 103), the subject had a sudden onset of ascending paresthesia with bilateral numbness of the feet and hands. On PPD, the subject developed lower extremity weakness and difficulty walking. The subject had no previous history of these symptoms. On PPD, the subject was hospitalized because of the dry cough and tingling and numbness of the fingers and toes, and was subsequently diagnosed with Guillain-Barre syndrome. The subject was hypertensive with a blood pressure (BP) reading of 159/97 (units not reported). The subject had shortness of breath (SOB); the subject's oxygen saturation was 98% on room air. The subject felt more comfortable with 2 L

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Narrative Comment
oxygen delivered via a nasal cannula. Considering the subject's upper respiratory symptoms and history of PPD, the subject was tested for COVID-19, and the result was positive. The subject's primary investigations, including a complete blood count, glucose, electrolytes, troponin, and blood urea nitrogen (BUN), were all within normal limits. The subject was admitted to the hospital with an impression of COVID-19 pneumonia and transverse myelitis; however, after further testing, both diagnoses were ruled out. On PPD, the subject's laboratory test results showed a white blood cell (WBC) count of $7.3\times10^3/mm^3$ (normal range [NR]: $4.0\text{-}11.0\times10^3/mm^3$), neutrophil of 71.6% (NR not provided), lymphocyte of 15.8% (NR not provided), potassium of 3.7 mEq/L (NR: 3.5-5.0 mEq/L), low sodium of 133 mEq/L (NR: 135-145 mEq/L), calcium of 9.0 mg/dL (NR: 8.6-10.3 mg/dL), high lactate dehydrogenase of 209 IU/L (normal high: 181 IU/L), high fibrinogen of 509 mg/dL (NR: 218-441 mg/dL), elevated D-dimer of 1.33 µg FEU/mL (normal high: 0.50 µg FEU/mL), elevated creatine phosphokinase of 712 U/L (NR: 39-308 U/L), elevated C-reactive protein (CRP) of 6.3 mg/dL (NR: 0.0-3.0 mg/dL), and high ferritin of 417 mg/mL (NR: 24-336 mg/mL). A chest x-ray showed clear lungs, no pleural effusion, and the cardiomediastinal silhouette was unremarkable. A computed tomography scan of the head without contrast showed no focal brain lesion, hemorrhage, extra-axial fluid collection, infarction, or mass. A cervical-thoracic-lumbar magnetic resonance imaging without contrast showed alignment, spinal cord signal, and an incidental renal and hepatic cyst. There was no significant thoracic central or neural foraminal narrowing. Multilevel degenerative changes were seen. Moderate to severe canal stenosis at L4-L5 was noted. The subject's neurology evaluation revealed symmetric allodynia in the shins and wrist, minimal upper extremity dysmetria, decreased muscle power and tone, and absent reflexes throughout. Babinski and Hoffman signs were negative. An acute viral illness with sensorimotor deficits raised the possibility of immune-mediated polyneuropathy. A diagnosis of parainfectious Guillain-Barre syndrome was confirmed. A lumbar puncture was postponed due to the subject's frequent coughing spells, and empiric treatment with a PPD was started. The PPD was increased to PPD to control the subject's high BP. On PPD, the subject was treated with PPD was started. On PPD, a repeat chest x-ray showed a mild increase in interstitial opacities, no pleural effusion, and a cardiomediastinal silhouette. During hospitalization, the subject received PPD The subject was referred for a swallow consultation because of a history of PPD. On PPD, a chest x-ray showed minimal coarse/patchy infiltrative changes in the right lung base, a new focus of discoid atelectasis in the mid to lower left lung, and a questionable left small subpulmonic pleural effusion. The hospital records mentioned elevated creatinine and low sodium (values not provided); however, the laboratory test results were reported to be within normal limits. On PPD, the subject received PPD due to uncontrolled hypertension and an episode of supraventricular tachycardia. The subject's heart rate was 140 beats/min for 6 seconds, and it resolved spontaneously.

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Narrative Comment
On PPD, the subject was transferred to a rehabilitation care facility. On admission, the subject was asymptomatic for COVID-19 (no fever, cough, SOB, loss of taste or smell, or body aches) and had chief complaints of generalized weakness, mobility impairment, and difficulty swallowing. The subject received physical therapy 6 days a week and occupational therapy 5 days a week. The subject's antihypertensive medications were continued, and the subject's regimen was modified to include PPD. On PPD, dehydration was noticed, and PPD therapy was initiated. The subject's fluid intake and output were continuously monitored. On PPD, the laboratory test results showed BUN of 70 mg/dL (NR: 6-20 mg/dL), creatinine of 1.2 mg/dL (NR: 0.7-1.2 mg/dL), WBC of 17.94×1000/UL (NR: 4.3-11×1000/UL), neutrophil of 16.74×1000/UL (NR: 1.8-7.2×1000/UL), lymphocyte of 0.28×1000/UL (NR: 1.2-3.7×1000/UL), and CRP of >20 mg/L (NR: 0.0-4.9 mg/L). Deep vein thrombosis prophylaxis with PPD was started from PPD to PPD. The subject lost 27 pounds in 1 month. The subject's nutritionist prescribed a fortified diet, which included protein shakes. The subject gradually started to regain PPD strength. The subject's health improved sufficiently, and the subject was discharged on PPD. The subject was withdrawn from the study on PPD because of the Guillain-Barre syndrome, which was ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the Guillain-Barre syndrome was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per the investigator, the event was secondary to COVID-19.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	SKIN	Urticaria	PPD	PPD (10)		PPD (10)		1	2	TC/P/W	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (PPD)	NOT RELATED/OTHER: PPD (pre-existing on med hx)	1	10	Y

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment
Subject PPD, a 60-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD. The subject reported urticaria on PPD, 9 days after receiving Dose 1. On PPD (Day 10), the urticaria resolved. The subject was withdrawn from the study on PPD because of the urticaria. In the opinion of the investigator, there was no reasonable possibility that the urticaria was related to the study intervention, but rather it was related to preexisting PPD.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (23)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (443)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Dementia	PPD	PPD (608)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	N	Yes	NOT RELATED/OTHER: Dementia diagnosis, neurological, etiology, unknown.	3	166	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA

Narrative Comment
Subject PPD, a ≥75-year-old PPD with no pertinent medical history, received Dose 1 on PPD, Dose 2 on PPD (Day 23), and Dose 3 on PPD (Day 443). The subject was diagnosed with dementia on PPD, 165 days after receiving Dose 3. The subject was withdrawn from the study on PPD because of the dementia and as PPD no longer met the eligibility criteria. The dementia was ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the dementia was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NERV	Amnesia	PPD	PPD (17)	PPD	PPD (20)	PPD	4	1	TC/TCN/P	Y
2	EYE	Eye pain		PPD (17)		PPD (72)		56	1	N	N
3	NERV	Paraparesis		PPD (17)	PPD	ONGOING			3	TC/TCN/P	N
4	EYE	Visual impairment		PPD (17)	PPD	PPD (19)	PPD	3	3	P/W	Y

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (PPD)	NOT RELATED/OTHER: unknown at this time	1	17	Y
2	Resolved (PPD)	NOT RELATED/OTHER: visual correction improved which was the cause (corrected vision with glasses)	1	17	N
3	Yes	NOT RELATED/OTHER: Unknown at this time	1	17	Y
4	Resolved (PPD)	NOT RELATED/OTHER: Spontaneous resolution, cause is unknown	1	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment

Subject PPD , a 50-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD .

Concomitant medications within 2 weeks prior to the onset of the amnesia, visual impairment, and worsening of chronic spastic paraparesis included PPD .

The subject experienced amnesia (short-term memory loss), visual impairment, and worsening of chronic spastic paraparesis on PPD , 16 days after receiving Dose 1.

On PPD (Day 17), the subject visited the emergency room because of a sudden onset of change in visual perception and short-term memory loss. On the same day (Day 17), PPD was diagnosed with worsening of chronic spastic paraparesis and bilateral eye pain. PPD was hospitalized for further blood workup, a lumbar puncture, and imaging studies. A blood test on PPD (Day 17) showed C-reactive protein of 2.1 mg/L (upper limit of normal [ULN]: <8 mg/L), blood copper of 96 µg/dL (normal range [NR]: 72-166 µg/dL), blood folate of 10.47 ng/mL (lower limit of normal: 4.77 ng/mL), and vitamin B_{12} of 753 pg/mL (NR: 211-946 pg/mL). A nonenhanced head computed tomography scan showed no intracranial hemorrhage or acute territorial infarction. There was mild asymmetry of the lateral ventricles with dilatation of the atrium of the right lateral ventricle; however, the remainder of the ventricles were normal in size and configuration. A computed tomography angiogram (CTA) scan of the head showed that the intracranial segments of the internal carotid arteries and basilar, anterior, middle, and posterior cerebral arteries were patent without flow-limiting stenosis. No aneurysm or arteriovenous malformation was visualized. The CTA of the neck was unremarkable. The imaging results of the lungs, thyroid, and bones were unremarkable. A magnetic resonance imaging (MRI) of the brain to evaluate possible encephalitis in comparison with the CTA of the head performed on PPD (Day 17) showed no abnormality within the brain parenchyma. A developmental venous anomaly was observed in the right frontal lobe. There was asymmetric enlargement of the atrium and occipital horn of the right lateral ventricle. There were no intraventricular masses seen, and the basal cisterns were patent. Mild mucosal thickening was present in the maxillary, ethmoid, sphenoid, and frontal sinuses.

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Narrative Comment
On PPD, the subject was seen by a neurologist, at which time the subject reported the symptoms of mental fogginess associated with visual changes that were described as poor depth perception. PPD also reported subtle unsteadiness and admitted to having a long history of PPD. On examination, PPD was noted to have mild spasticity in the legs, brisk reflexes in the legs, and bilateral Babinski sign. PPD gait was slightly abnormal because of subtle circumduction of the right leg, and PPD had mild issues with tandem gait. On PPD, a syphilis immunoglobulin M/immunoglobulin G (IgM/IgG) screen test (*Treponema* test) was nonreactive, and the human T-lymphotropic virus-1/-2 antibody test was negative. Autoimmune workup performed on PPD was within normal limits. The subject's visual correction improved with eyeglasses. The visual impairment was considered resolved on PPD (Day 19). On PPD (Day 20), the hepatitis panel (hepatitis A, B, and C virus) and human immunodeficiency virus (antigen/antibody combination) tests were nonreactive. An MRI of the cervical spine was performed (unknown date), which showed no evidence of transverse myelitis or other acute or chronic process in the spinal cord. Mild multilevel spinal canal stenosis secondary to disc bulging and small disc protrusions were present at C2-C3 and C4-C5 through C6-C7. There was no spinal cord impingement. Diffuse degenerative disc desiccation was noted. An MRI of the thoracic spine was obtained (unknown date) with and without gadolinium contrast for possible myelopathy, which revealed minimal to mild degenerative changes in the thoracic spine. Vertebral body heights were maintained, and the bone marrow signals were within normal limits. No spondylolisthesis or high-grade central canal or neural foraminal stenosis was observed. The spinal cord demonstrated normal signal intensity. No evidence of abnormal enhancement was noted. There were no intradural or extradural masses, and the paraspinal soft tissues were unremarkable. On PPD (Day 20), a lumbar puncture was performed, and the cerebrospinal fluid (CSF) analysis showed clear and colorless CSF with a red blood cell count of 114/µL (ULN: <2/µL), total nucleated cells of <3/µL (ULN: <5/µL); white blood cell count of 3+, CSF glucose of 66, and protein of 51 (units and normal ranges not provided). The Gram stain showed no organisms, and culture results showed no growth for 5 days. The amnesia was considered resolved on PPD (Day 20). On PPD, the subject reported that PPD might have had mild injection site discomfort for 3 days after receiving Dose 1; however, PPD did not report it to the site at that time. The subject was discontinued from the study intervention on PPD because of the amnesia, visual impairment, and worsening of chronic spastic paraparesis. The eye pain was considered resolved on PPD (Day 72). The subject was withdrawn from the study on PPD because of the visual impairment. The worsening of chronic spastic paraparesis was ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the worsening of chronic spastic paraparesis was related to the study intervention. In the opinion of the investigator, there was no reasonable possibility that the amnesia and visual impairment were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 3	BNT162b2	PPD (138)	PPD
VACCINATION 4	BNT162b2	PPD (159)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Parkinsonism	PPD	PPD (15)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	P	N	Yes	NOT RELATED/OTHER: natural progression of parkinsonism	1	15	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

Narrative Comment
Subject PPD, a 60-year-old PPD with no pertinent medical history, received Dose 1 on PPD.
The subject was diagnosed with parkinsonism on PPD, 14 days after receiving Dose 1.
The subject was discontinued from the study intervention on PPD because of the parkinsonism, which was ongoing at the time of study completion.
In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 138) and PPD (Day 159), respectively, and completed the study follow-up phase on PPD.
In the opinion of the investigator, there was no reasonable possibility that the parkinsonism was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Pyrexia	PPD	PPD (2)	PPD	PPD (4)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	4	TC/P	N	Resolved (PPD)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		PPD
		PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	FOLLOW-UP	PPD	

Narrative Comment
Subject PPD, a ≤24-year-old PPD with no reported medical history, received Dose 1 on PPD. The subject developed pyrexia (fever [104.7°F]) on PPD, 1 day after receiving Dose 1. The subject was discontinued from the study intervention on PPD (Day 4) because of the pyrexia, which resolved on the same day (Day 4). The subject completed the study follow-up phase on PPD. In the opinion of the investigator, there was a reasonable possibility that the pyrexia was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
UNPLANNED VACCINATION	BNT162b2	PPD (341)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (550)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	EAR	Deafness unilateral	PPD	PPD (20)		PPD (29)	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	10	3	TC/P	N	Resolved (PPD)	Study Treatment	1	20	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	REPEAT SCREENING 3	PPD	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

Narrative Comment
Subject PPD, a 60-year-old PPD with no pertinent medical history, received Dose 1 on PPD, Dose 2 on PPD (Day 341), and Dose 3 on PPD (Day 550). The subject was diagnosed with unilateral deafness (right ear) on PPD, 19 days after receiving Dose 1. On PPD (Day 29), the unilateral deafness resolved. The subject was discontinued from the study intervention on PPD because of the unilateral deafness and completed the study follow-up phase on PPD. In the opinion of the investigator, there was a reasonable possibility that the unilateral deafness was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	PPD	PPD	PPD (1)	PPD	PPD (189)		189		P	N

Adverse Events				
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (PPD)	NOT RELATED/OTHER: THERE IS NOT AN UNDERLYING CAUSE. THIS EVENT IS A STANDARD PPD.	.	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	PPD
Completed	FOLLOW-UP	PPD	

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (24)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INV	Blood glucose increased	PPD	PPD (432)		PPD (434)		3	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/W	Y	Resolved (PPD)	NOT RELATED/OTHER: Diabetes Type II	2	409	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

Narrative Comment
Subject PPD, a 50-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 24). Concomitant medications received within 2 weeks prior to the onset of the increased blood glucose included PPD for type 2 diabetes mellitus. The subject reported increased blood glucose on PPD, 408 days after receiving Dose 2. The subject was hospitalized due to the event on PPD (Day 432). It was reported that the subject was diagnosed with type 2 diabetes mellitus on PPD and was initially prescribed with unknown oral medications. PPD failed to disclose this information to the site staff during PPD last visit on PPD. On PPD (Day 434), the increased blood glucose resolved, and PPD was discharged on the same day. The subject requested withdrawal from the study on PPD (Day 434) because of the increased blood glucose. In the opinion of the investigator, there was no reasonable possibility that the increased blood glucose was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (166)	PPD
VACCINATION 4	BNT162b2	PPD (186)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	SKIN	Dermatitis allergic	PPD	PPD (2)	PPD	PPD (19)	
2	IMMUN	Drug hypersensitivity		PPD (2)	PPD	PPD (19)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	18	2	TC	N	Resolved (PPD)	Study Treatment	1	2	N
2	18	2	TC/P	N	Resolved (PPD)	Study Treatment	1	2	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

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Narrative Comment
Subject PPD, a 30-year-old PPD with no reported medical history, received Dose 1 on PPD.
The subject developed drug hypersensitivity (allergic reaction to the study intervention) on PPD, 1 day after receiving Dose 1.
On PPD (Day 2), the subject developed allergic dermatitis (allergic reaction upper body rash).
The subject was discontinued from the study intervention on PPD (Day 2) because of the drug hypersensitivity.
The drug hypersensitivity and allergic dermatitis resolved on PPD (Day 19). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 166) and PPD (Day 186), respectively.
The subject requested withdrawal from the study on PPD.
In the opinion of the investigator, there was a reasonable possibility that the drug hypersensitivity was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Present
		PPD	Present
		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 3	BNT162b2	PPD (212)	PPD
VACCINATION 4	BNT162b2	PPD (235)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (467)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Dizziness	PPD	PPD (1)	PPD	PPD (1)	PPD

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	P	N	Resolved (PPD)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	SCREENING	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Narrative Comment
Subject PPD, a 50-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD. On PPD, approximately half an hour after receiving Dose 1, the subject reported mild dizziness at PPD, which resolved on the same day at PPD. The subject was discontinued from the study intervention on PPD (Day 1) because of the dizziness. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 212), PPD (Day 235), and PPD (Day 467), respectively. The subject completed the study follow-up phase on PPD. In the opinion of the investigator, there was a reasonable possibility that the dizziness was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (27)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	INJ&P	PPD	PPD	PPD ()		ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1			W	N	Yes	NOT RELATED/OTHER: PPD	2	55	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	PPD

Narrative Comment
PPD

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past
		PPD	Past
		PPD	Present
		PPD	Past
		PPD	Past
		PPD	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD		PPD	Past
		PPD	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD
VACCINATION 3	BNT162b2	PPD (180)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	SKIN	Angioedema	PPD	PPD (182)	PPD	PPD (187)	
2	SKIN	Urticaria		PPD (181)	PPD	PPD (187)	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	6	1	TC/P	N	Resolved (PPD)	Study Treatment	3	3	Y
2	7	2	TC/P	N	Resolved (PPD)	Study Treatment	3	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	OPEN LABEL TREATMENT	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA

Narrative Comment

Subject PPD, a 50-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 20).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first dose of BNT162b2 on PPD (Day 180).

The subject experienced urticaria on the forehead, posterior neck, bilateral posterior hands, and bilateral plantar areas on PPD, 1 day after receiving Dose 3 (the first dose of BNT162b2).

PPD developed angioedema on the forehead on PPD, 2 days after receiving the first dose of BNT162b2.

The urticaria and angioedema resolved on PPD (Day 187).

The subject was discontinued from the study intervention on PPD because of the urticaria and angioedema, and was withdrawn from the study on PPD as PPD no longer met the eligibility criteria.

In the opinion of the investigator, there was a reasonable possibility that the urticaria and angioedema were related to BNT162b2.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2SA (30 µg, 2 Doses)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2SA (30 µg, 2 Doses)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (20)	PPD
VACCINATION 3	BNT162b2SA	PPD (217)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	GENRL	Chills	PPD	PPD (21)	PPD	PPD (21)	PPD
2	GENRL	Injection site pain		PPD (1)	PPD	PPD (2)	
3	BLOOD	Lymphadenopathy		PPD (218)		PPD (223)	
4	GENRL	Pain		PPD (21)	PPD	PPD (21)	PPD

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	1	N	N	Resolved (PPD)	Study Treatment	2	2	N
2	2	1	N	N	Resolved (PPD)	Study Treatment	1	1	N
3	6	1	P	N	Resolved (PPD)	Study Treatment	3	2	Y
4	1	1	N	N	Resolved (PPD)	Study Treatment	2	2	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 2	PPD	
Withdrawn	SUBSTUDY	PPD	ADVERSE EVENT
Completed	FOLLOW-UP	PPD	

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Narrative Comment
Subject PPD, a 40-year-old PPD with no reported medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 20). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible to enter a subset for evaluation of boostability and protection against emerging COVID-19 variants of concern. It was confirmed that the subject had originally received 2 doses of BNT162b2; the subject therefore received the first dose of $BNT162b2_{SA}$ (South African variant) on PPD (Day 217). The subject was diagnosed with lymphadenopathy (left axillary adenopathy) on PPD, 1 day after receiving Dose 3 (the first dose of $BNT162b2_{SA}$). The lymphadenopathy resolved on PPD (Day 223). The subject was withdrawn from the subset dosing on PPD because of the lymphadenopathy and completed the study follow-up phase on PPD. In the opinion of the investigator, there was a reasonable possibility that the lymphadenopathy was related to $BNT162b2_{SA}$.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered):
Date of First Dose: N/A; Date of Last Dose: N/A

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered):
Date of First Dose: N/A; Date of Last Dose: N/A

==========

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INV	Blood pressure increased	PPD	PPD (1)	PPD	PPD (1)		1	2	W	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (PPD)	NOT RELATED/OTHER: Blood pressure values of volunteer were high during vaccine preparation period.	.	.	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered):
Date of First Dose: N/A; Date of Last Dose: N/A

==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT
Completed	SCREENING	PPD	

Narrative Comment
Subject PPD, a 40-year-old PPD with no reported medical history, experienced increased blood pressure before the administration of study intervention on PPD, which resolved on the same day. The subject was withdrawn from the study before the administration of study intervention on PPD (Day 1) because of the increased blood pressure. In the opinion of the investigator, there was no reasonable possibility that the increased blood pressure was related to the study intervention.

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NEOPL	Hormone receptor positive breast cancer	PPD	PPD (257)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TCN/W	Y	Yes	NOT RELATED/OTHER: Breast cancer diagnosis	2	236	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment

Subject PPD, a 60-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 22).

The subject was diagnosed with hormone receptor-positive breast cancer (ER-positive intraductal carcinoma of left breast) on PPD, 235 days after receiving Dose 2.

On PPD (Day 257), the subject noticed a mass in PPD left breast. A breast ultrasonography scan showed a 19×12 mm solid lesion. A fine needle biopsy of the lesion was performed, and the histopathology report on PPD revealed an intraductal carcinoma. On PPD, the subject underwent a mastectomy and segmental regional lymph node resection procedure for the breast cancer. The subject was diagnosed with carcinoma in situ without lymph node involvement. The subject did not receive any hormonal therapy for the breast cancer. On PPD, the subject was discharged from the hospital. Histopathology results on PPD were consistent with ER-positive intraductal carcinoma. The subject received protective radiotherapy on PPD.

The subject was withdrawn from the study on PPD because of the hormone receptor-positive breast cancer, which was ongoing at the time of withdrawal.

In the opinion of the investigator, there was no reasonable possibility that the hormone receptor-positive breast cancer was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)

Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (207)	PPD
VACCINATION 4	BNT162b2	PPD (230)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD		PPD (1)		PPD (263)	PPD	263
2	GASTR	Food poisoning	PPD	PPD (154)		PPD (154)		1
3	GENRL	Injection site pain		PPD (207)	PPD	PPD (208)	PPD	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		P	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	1	Y
2	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD poisoning	1	154	N
3	1	N	N	Resolved (PPD)	Study Treatment	3	1	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	PPD
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_CSR_Safety_Narrative/profile. (Database Snapshot Date: 07MAR2023) Date of Generation: 18APR2023 (17:51)

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (162)	PPD
VACCINATION 4	BNT162b2	PPD (183)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (407)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INV	Blood pressure increased	PPD	PPD (1)		PPD (18)	
2	GASTR	Diarrhoea		PPD (1)		PPD (14)	
3	GENRL	Fatigue		PPD (1)		PPD (10)	
4	INV	Heart rate irregular		PPD (1)		PPD (18)	
5	GENRL	Pyrexia		PPD (1)		PPD (10)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	18	2	N	N	Resolved (PPD)	Study Treatment	1	1	N
2	14	2	N	N	Resolved (PPD)	Study Treatment	1	1	N
3	10	2	N	N	Resolved (PPD)	Study Treatment	1	1	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	18	2	P	N	Resolved (PPD)	Study Treatment	1	1	Y
5	10	2	N	N	Resolved (PPD)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	REPEAT SCREENING 1	PPD	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

Narrative Comment
Subject PPD, a 30-year-old PPD with no pertinent medical history, received Dose 1 on PPD. The subject was diagnosed with an irregular heart rate on PPD, the day of Dose 1 administration. On PPD (Day 1), the subject also experienced increased blood pressure, diarrhea, fatigue, and pyrexia. The fatigue and pyrexia resolved on PPD (Day 10). The subject was withdrawn from the study intervention on PPD because of the irregular heart rate. The diarrhea resolved on PPD (Day 14), and the increased blood pressure and irregular heart rate resolved on PPD (Day 18). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 162), PPD (Day 183), and PPD (Day 407), respectively, and completed the study follow-up phase on PPD. In the opinion of the investigator, there was a reasonable possibility that the irregular heart rate was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	MUSC	Myalgia	PPD	PPD (8)		ONGOING

Adverse Events										
AE Number	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			2	TC/P/W	N	Yes	Study Treatment	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment
Subject PPD, a 40-year-old PPD with a pertinent medical history of PPD received Dose 1 on PPD. The subject experienced myalgia (shoulders and neck, on the right body side) on PPD, 7 days after receiving Dose 1. The subject was discontinued from the study intervention on PPD and was withdrawn from the study on PPD because of the myalgia, which was ongoing at the time of withdrawal. In the opinion of the investigator, there was a reasonable possibility that the myalgia was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (-1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past
			Past
			Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD		PPD (22)	PPD	PPD (239)	PPD	218

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		P	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	PPD
Completed	FOLLOW-UP	PPD	

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered):
Date of First Dose: N/A; Date of Last Dose: N/A
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered):
Date of First Dose: N/A; Date of Last Dose: N/A

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	NERV	Syncope	PPD	PPD (1)	PPD	PPD (1)	PPD	1	2
2	GASTR	Vomiting		PPD (1)	PPD	PPD (1)	PPD	1	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TCN/P/W	N	Resolved (PPD)	NOT RELATED/OTHER: post phlebotomy	.	.	Y
2	TCN/P/W	N	Resolved (PPD)	NOT RELATED/OTHER: post sincopal recovery	.	.	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered):
Date of First Dose: N/A; Date of Last Dose: N/A
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT
Completed	SCREENING	PPD	

Narrative Comment
Subject PPD, a 40-year-old PPD with no reported medical history, experienced syncope and vomiting after the prevaccination phlebotomy on PPD (Day 1), which resolved on the same day. The subject was withdrawn from the study before the administration of study intervention on PPD (Day 1) because of the syncope and vomiting. In the opinion of the investigator, there was no reasonable possibility that the syncope and vomiting were related to the study intervention, but rather they were related to the phlebotomy.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered):
Date of First Dose: N/A; Date of Last Dose: N/A
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered):
Date of First Dose: N/A; Date of Last Dose: N/A
==========

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	NERV	Syncope	PPD	PPD (1)	PPD	PPD (1)	PPD	1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	W	N	Resolved (PPD)	NOT RELATED/OTHER: Post blood extraction	.	.	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT
Completed	SCREENING	PPD	

Narrative Comment
Subject PPD, a 30-year-old PPD with no reported medical history, experienced syncope during the prevaccination blood sample collection on PPD (Day 1); the syncope resolved on the same day. The subject was withdrawn from the study before the administration of study intervention on PPD (Day 1) because of the syncope. In the opinion of the investigator, there was no reasonable possibility that the syncope was related to the study intervention, but rather it was related to blood sample collection.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Injection site pain	PPD	PPD (1)	PPD	PPD (18)	PPD

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	18	2	TC/P/W	N	Resolved (PPD)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment
Subject PPD, a 40-year-old PPD with no reported medical history, received Dose 1 on PPD.
The subject reported moderate injection site pain on PPD, after Dose 1 administration.
The injection site pain resolved on PPD (Day 18).
The subject was withdrawn from the study on PPD because of the injection site pain.
In the opinion of the investigator, there was a reasonable possibility that the injection site pain was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	VASC	Hypertension	PPD	PPD (23)	PPD	PPD (51)	PPD	29

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	P	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	1	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	FOLLOW-UP	PPD	

Narrative Comment
Subject PPD, a 50-year-old PPD with no reported medical history, received Dose 1 on PPD.
The subject experienced hypertension on PPD, 22 days after receiving Dose 1.
The subject was discontinued from the study intervention on PPD (Day 23) because of the hypertension, which resolved on PPD (Day 51). On PPD, the subject completed the study follow-up phase.
In the opinion of the investigator, there was no reasonable possibility that the hypertension was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	PPD		PPD (23)			

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			P	N		NOT RELATED/OTHER: PPD	1	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	PPD
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	PPD	PPD		PPD ()		PPD ()		
2	INJ&P			PPD (22)	PPD	PPD ()		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	1	62	N
2		P	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	PPD
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD		PPD	Present
		PPD	Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 3	BNT162b2	PPD (182)	PPD
VACCINATION 4	BNT162b2	PPD (203)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (491)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Chills	PPD	PPD (182)	PPD	PPD (185)		4
2	INJ&P	PPD		PPD (23)		PPD (57)		35
3	GENRL	Injection site pain		PPD (182)	PPD	PPD (185)		4
4	GENRL	Injection site pain		PPD (203)	PPD	PPD (204)		2
5	MUSC	Myalgia		PPD (182)	PPD	PPD (185)		4
6	MUSC	Myalgia		PPD (203)	PPD	PPD (204)		2
7	GENRL	Pyrexia		PPD (203)	PPD	PPD (204)		2
8	PPD	PPD		PPD (57)		PPD (57)		1
9	REPRO	PPD		PPD (48)		PPD (57)		10

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (PPD)	Study Treatment	3	1	N
2		P	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	23	Y
3	1	N	N	Resolved (PPD)	Study Treatment	3	1	N
4	1	N	N	Resolved (PPD)	Study Treatment	4	1	N
5	1	N	N	Resolved (PPD)	Study Treatment	3	1	N
6	1	N	N	Resolved (PPD)	Study Treatment	4	1	N
7	1	TC	N	Resolved (PPD)	Study Treatment	4	1	N
8	3	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	57	N
9	1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	48	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	PPD
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	PROTOCOL DEVIATION

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Past
			Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	SKIN	Urticaria	PPD	PPD (10)		PPD (36)	
2	SKIN	Urticaria		PPD (2)	PPD	PPD (5)	PPD

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	27	2	TC/P	N	Resolved (PPD)	Study Treatment	1	10	Y
2	4	3	TC	N	Resolved (PPD)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	FOLLOW-UP	PPD	

Narrative Comment
Subject PPD, a 50-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD. The subject reported urticaria on 2 occasions after receiving Dose 1. The subject had an initial episode of urticaria on PPD (Day 2) lasting until PPD (Day 5). The second episode took place on PPD (Day 10) lasting until PPD (Day 36). The subject was discontinued from the study intervention on PPD because of the additional episode of urticaria. On PPD, the subject completed the study follow-up phase. In the opinion of the investigator, there was a reasonable possibility that the urticaria was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, Ischaemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, Ischaemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 3	BNT162b2	PPD (140)	PPD
VACCINATION 4	BNT162b2	PPD (161)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (464)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	NERV	Cerebellar infarction	PPD	PPD (24)	PPD	ONGOING			1	N	N
2	NERV	Cerebral atrophy		PPD (24)	PPD	ONGOING			1	N	N
3	NERV	Cerebral infarction		PPD (22)		PPD (161)		140	3	TC/TCN/P	Y
4	GENRL	Injection site pain		PPD (141)		PPD (148)		8	1	N	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, Ischaemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: CT finding	1	24	Y
2	Yes	NOT RELATED/OTHER: CT Findings	1	24	N
3	Resolved (PPD)	NOT RELATED/OTHER: Pt.70 years old; and PPD history of PPD as risk factors for event.	1	22	Y
4	Resolved (PPD)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

Narrative Comment

Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD and PPD, received Dose 1 on PPD.

Concomitant medications received within 2 weeks prior to the onset of the cerebral and cerebellar infarctions included PPD

The subject was diagnosed with a cerebral infarction (left middle cerebral artery infarct) on PPD, 21 days after receiving Dose 1, and a cerebellar infarction on PPD, 23 days after receiving Dose 1. On PPD (Day 22), the subject had slurred speech and presented to the emergency department. The clinical examination revealed expressive aphasia and a left facial droop. That same day (Day 22), PPD vital signs included a blood pressure of 134/57 mmHg, heart rate of 119 beats/min, body temperature of 35.7°C, respiratory rate of 20 breaths/min, and oxygen saturation of 96% on room air. An electrocardiogram showed p-pulmonale, which was not clinically significant. Laboratory test results showed a platelet count of 290×10^9/L, glucose of 5.5 mmol/L, and high urea level of 8.4 mmol/L (normal ranges not reported), with all other laboratory test results within normal limits. The subject was hospitalized and was treated with PPD since PPD (Day 22). A computed tomography scan on

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Narrative Comment
PPD (Day 24) revealed an acute infarct in the middle cerebral artery distribution on the left side, along with chronic cerebellar infarcts and cerebral atrophy. The subject was diagnosed with cerebral infarction (left middle cerebral artery infarct) with an onset date of PPD (Day 22), and cerebellar infarction and cerebral atrophy with an onset date of PPD (Day 24). PPD also received physiotherapy, occupational therapy, and speech therapy. PPD clinical condition and speech improved. PPD was discharged on PPD and was advised to follow-up with speech therapy. No COVID-19 test was performed. The subject was discontinued from the study intervention on PPD (Day 22) because of the cerebral infarction, which resolved with sequelae (minimal expressive dysphasia) on PPD (Day 161). The cerebral atrophy and cerebellar infarction were ongoing at the time of withdrawal. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 140), PPD (Day 161), and PPD (Day 464), respectively, and completed the study follow-up phase on PPD. In the opinion of the investigator, there was no reasonable possibility that the cerebral infarction was related to the study intervention, concomitant medications, or clinical trial procedures, but rather related to the age of the subject and history of PPD. Pfizer concurred with the investigator's causality assessment. In the opinion of the investigator, there was no reasonable possibility that the cerebellar infarction was related to the study intervention.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Past
			Past
			Past

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (118)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Bell's palsy	PPD	PPD (126)		PPD ()	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		2	TC/P	N	Resolved (PPD)	Study Treatment	3	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Withdrawn	OPEN LABEL TREATMENT	PPD	ADVERSE EVENT
Completed	FOLLOW-UP	PPD	

Narrative Comment

Subject PPD , a ≤24-year-old PPD with a pertinent history of PPD received Dose 1 on PPD and Dose 2 on PPD (Day 21).

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first dose of BNT162b2 on PPD (Day 118).

The subject developed recurrent Bell's palsy (left facial hemiparesis) on PPD , 8 days after receiving Dose 3 (the first dose of BNT162b2).

The subject was discontinued from the study intervention on PPD because of the Bell's palsy, which was considered resolved in PPD .

On PPD , the subject completed the study follow-up phase.

In the opinion of the investigator, there was a reasonable possibility that the Bell's palsy was related to BNT162b2.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered):
Date of First Dose: N/A; Date of Last Dose: N/A

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)
No Study Vaccination(s)

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered):
Date of First Dose: N/A; Date of Last Dose: N/A

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	NERV	Syncope	PPD	PPD (1)	PPD	PPD (1)	PPD	1	2
2	GASTR	Vomiting		PPD (1)	PPD	PPD (2)	PPD	2	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	W	N	Resolved (PPD)	NOT RELATED/OTHER: Study Procedure (phlebotomy)	.	.	Y
2	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	.	.	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered):
Date of First Dose: N/A; Date of Last Dose: N/A
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment

Subject PPD, a 30-year-old PPD with no reported medical history, experienced vasovagal syncope during the prevaccination blood sample collection on PPD (Day 1). The vasovagal syncope resolved on the same day (Day 1).

On PPD (Day 1), the subject also reported vomiting, which resolved on PPD (Day 2).

The study intervention was not administered and the subject was withdrawn from the study on PPD (Day 2) because of the vasovagal syncope.

In the opinion of the investigator, there was no reasonable possibility that the vasovagal syncope was related to the study intervention, but rather it was related to the study procedure (phlebotomy).

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Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present
			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	PPD		PPD (182)		PPD (182)		1	4

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	W	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	161	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	REPEAT SCREENING 1	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA
Withdrawn	FOLLOW-UP	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Past
			Present
			Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
UNPLANNED VACCINATION	BNT162b2	PPD (279)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain upper	PPD	PPD (4)	PPD	PPD (4)	PPD	1	2
2	SKIN	Alopecia		PPD ()		ONGOING			1
3	INV	Body temperature increased		PPD (2)	PPD	PPD (3)	PPD	2	1
4	INV	Body temperature increased		PPD (3)	PPD	PPD (4)		2	2
5	GENRL	Chills		PPD (279)	PPD	PPD (284)		6	2
6	GENRL	Chills		PPD (1)	PPD	PPD (14)		14	1
7	EYE	Eye irritation		PPD (1)	PPD	PPD (3)		3	1
8	NERV	Headache		PPD (279)	PPD	PPD (281)		3	2
9	NERV	Headache		PPD (4)		PPD (14)		11	2
10	INJ&P	PPD		PPD (1)		PPD (109)	PPD	109	
11	GASTR	Nausea		PPD (15)		PPD (109)		95	1
12	EYE	Ocular hyperaemia		PPD (1)	PPD	PPD (3)		3	1

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
13	REPRO	Ovarian cyst ruptured	PPD	PPD (216)		PPD (272)		57	1
14	GENRL	Pyrexia		PPD (3)	PPD	PPD (3)	PPD	1	2
15	GENRL	Pyrexia		PPD (279)	PPD	PPD (282)		4	2
16	INV	Weight decreased		PPD (9		ONGOING			1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: unknown etiology but due to gas	1	4	N
2	N	N	Yes	NOT RELATED/OTHER: PPD	1	20	N
3	N	N	Resolved (PPD)	Study Treatment	1	2	N
4	TC	N	Resolved (PPD)	Study Treatment	1	3	N
5	N	N	Resolved (PPD)	Study Treatment	2	1	N
6	N	N	Resolved (PPD)	Study Treatment	1	1	N
7	N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown etiology	1	1	N
8	TC	N	Resolved (PPD)	Study Treatment	2	1	N
9	TC	N	Resolved (PPD)	Study Treatment	1	4	N
10	P	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	1	Y
11	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	15	N
12	N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown etiology	1	1	N
13	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	216	N
14	TC	N	Resolved (PPD)	Study Treatment	1	3	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
15	TC	N	Resolved (PPD)	Study Treatment	2	1	N
16	N	N	Yes	NOT RELATED/OTHER: PPD	1	20	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	NERV	Headache	PPD	PPD (1)	PPD	PPD (4)	PPD
2	GENRL	Injection site pain		PPD (22)	PPD	PPD (24)	PPD
3	GENRL	Injection site pain		PPD (1)	PPD	PPD (4)	PPD
4	PPD	PPD		PPD (282)		PPD (306)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	4	2	TC	N	Resolved (PPD)	Study Treatment	1	1	N
2	3	2	TC	N	Resolved (PPD)	Study Treatment	2	1	N
3	4	2	TC	N	Resolved (PPD)	Study Treatment	1	1	N
4	25	2	W	N	Resolved (PPD)	Study Treatment	2	261	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present
			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present
			Present
			Present
			Present
			Present
			Present
			Present
			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	RESP	Pulmonary embolism	PPD	PPD (21)		ONGOING		

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC/P	Y	Yes	NOT RELATED/OTHER: PPD	1	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

Narrative Comment

Subject PPD , a 70-year-old PPD with a pertinent medical history of PPD , received Dose 1 on PPD .

Concomitant medications received within 2 weeks prior to the onset of the pulmonary embolism included PPD

The subject was diagnosed with a pulmonary embolism on PPD , 20 days after receiving Dose 1.

On PPD , the subject presented to the emergency department (ED) because of shortness of breath and cough starting on PPD and chest tightness since PPD (Day 21). The subject thought these symptoms were related to the smoke in the air and PPD were not helping. A SARS-CoV-2 test result was negative and troponin I level was <0.02 ng/mL (normal range [NR]: <0.04 ng/mL). The subject received an PPD On PPD , PPD went home against medical advice, as PPD was admitted to the COVID-19 area of the emergency room.

After PPD was back home, the symptoms improved but were still present; therefore, the subject returned to the ED on PPD . A computed tomography angiogram of the chest performed on PPD was positive for acute pulmonary embolism. On PPD , troponin I was <0.02 ng/mL, prothrombin time (PT) was 15.5 seconds (NR: 11.7-14.3 seconds), and international normalized ratio (INR) was 1.3 (NR: 2.0-3.0). The subject discontinued treatment with PPD PPD was discharged home on the same day in stable condition, with a prescription for PPD and was referred to hematology/oncology. The subject continued to experience shortness of breath since PPD and chest tightness since PPD . PPD was advised to postpone travel for 6 weeks, continue PPD with PPD

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Narrative Comment
PPD and monitor PT/INR values. On PPD, the PT was 21.7 seconds, and the INR was 2.0. On PPD, the PT was 23.6 seconds, and the INR was in therapeutic range at 2.2, and the subject was advised to discontinue treatment with PPD and continue PPD. PPD continued to have shortness of breath, fatigue, and mild cough on PPD. On PPD, a repeat SARS-CoV-2 NAAT result was negative; the PT was 33.2 seconds, and the INR was above therapeutic range at 3.3. On PPD, the PT was 32.9 seconds, and the INR was 3.3; the PPD doses were titrated. On PPD, the INR was in therapeutic range (value not reported), and a trial weekly dose of PPD was recommended. On PPD, the PT was 22.6 seconds, and the INR was in therapeutic range at 2.1. On PPD, the PT was 19.9 seconds, and the INR was subtherapeutic at 1.8, and the subject was instructed to increase the dose of PPD and recheck the INR in 1 week. The subject was discontinued from the study intervention on PPD because of the pulmonary embolism. The subject requested withdrawal from the study on PPD. The pulmonary embolism was ongoing at the time of withdrawal. In the opinion of the investigator, there was no reasonable possibility that the pulmonary embolism was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to the subject's medical history of PPD. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	INJ&P	PPD		PPD (1)		ONGOING	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1			P	N	Yes	NOT RELATED/OTHER: not applicable	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal, PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	PPD
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

Narrative Comment
PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	PPD		PPD (19)	PPD	ONGOING			3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	P/W	N	Yes	NOT RELATED/OTHER: Basic psychiatric pathology PPD	1	19	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	ADVERSE EVENT
Withdrawn	FOLLOW-UP	PPD	ADVERSE EVENT

Narrative Comment
PPD

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Reason(s) for Narrative: Myocarditis/Pericarditis
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Past
			Past
			Present
			Past
			Present
			Present

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Reason(s) for Narrative: Myocarditis/Pericarditis
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (119)	PPD
VACCINATION 4	BNT162b2	PPD (140)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (485)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Pericarditis	PPD	PPD (291)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Yes	NOT RELATED/OTHER: likely viral etiology	4	152	Y

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Reason(s) for Narrative: Myocarditis/Pericarditis
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Narrative Comment
Subject PPD, a 50-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 22). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 119), PPD (Day 140), and PPD (Day 485), respectively. Concomitant medications received within 2 weeks prior to the onset of the pericarditis included PPD The subject was diagnosed with pericarditis on PPD, 151 days after receiving Dose 4 (the second dose of BNT162b2). On PPD (Day 291), the subject experienced chest pain and pressure with sweats after a workout. PPD reported fatigue and mild shortness of breath the next day, PPD. Due to the persistence of symptoms, PPD went to the emergency room on PPD. On the same day, the chest x-ray, abdominal x-ray, and echocardiogram results were all normal. PPD also underwent 2 electrocardiograms, one of which showed changes consistent with pericarditis. A COVID-19 polymerase chain reaction test (nasal swab) and influenza A+B screen on PPD showed negative results. PPD electrolytes and chemistry panel were normal, except glucose, which was elevated at 104 (units and normal range [NR] not reported). Laboratory test results on the same day included troponin I of <0.04 ng/mL (NR: <0.05 ng/mL), D-dimer of <0.27 µg/mL (NR: <0.60 µg/mL), brain natriuretic peptide of 29 pg/mL (NR: <100 pg/mL), antinuclear antibody of <1:40 (NR: <1:40), rheumatoid factor of <10 IU/mL (NR: <25 IU/mL), erythrocyte sedimentation rate of 4 mm/hr (NR: <25 mm/hr), blood thyroid stimulating hormone of 4.0 mIU/L (NR: 0.3-4.7 mIU/L), and a total white blood cells count of 3.73×10^9/µL (NR: 4.16-9.95$\times10^9$/µL). On an unspecified date, the C-reactive protein was <0.3 mg/dL (NR: <0.8 mg/dL). PPD was admitted overnight for observation and to complete the evaluation and was discharged on PPD. On the same day, PPD was started on treatment with PPD. The site contacted the subject by phone on PPD, and PPD reported continued intermittent chest pressure related to PPD pericarditis, along with some decrease in exercise tolerance. PPD was taking PPD, as needed, for the chest pressure. PPD denied chest pain, shortness of breath, or palpitations. PPD last echocardiogram 4-5 months ago showed a small amount of pericardial fluid. PPD continued to be followed up by PPD cardiologist, who now considers PPD pericarditis to be chronic and most likely viral in histology. The pericarditis was ongoing at the time of study completion (on PPD). In the opinion of the investigator, there was no reasonable possibility that the pericarditis was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per the investigator, the event was most likely related to viral etiology.

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Reason(s) for Narrative: Myocarditis/Pericarditis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: Myocarditis/Pericarditis
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (133)	PPD
VACCINATION 4	BNT162b2	PPD (153)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CARD	Myopericarditis	PPD	PPD (155)	PPD	PPD (156)		2	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: Rhinovirus infection	4	3	Y

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
PPD				

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

Narrative Comment
Subject PPD, a ≤24-year-old PPD with no pertinent medical history, received Dose 1 on PPD and Dose 2 on PPD (Day 21). In accordance with the protocol allowance, the subject's PPD agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on PPD (Day 133) and PPD (Day 153), respectively. The subject was diagnosed with myopericarditis on PPD, 2 days after receiving Dose 4 (the second dose of BNT162b2).

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Narrative Comment
Approximately 1 week before the onset of myopericarditis, the subject reported a body temperature of 100.5°F associated with some cough and rhinorrhea, which resolved on unreported dates. On PPD (Day 155), the subject reported chest tightness and pain at PPD PM after PPD ; the subject's PPD offered a PPD at home, but PPD had no relief. Later in the evening, the PPD took PPD to the hospital's emergency department (ED) for chest pain, and PPD body temperature at the ED was 100.1°F. On the same day (Day 155), an electrocardiogram (ECG) result showed diffuse ST elevations; further testing showed troponin levels of 0.27 (units not reported). The subject was treated with PPD , resulting in almost immediate relief of chest pain on PPD (Day 156) at PPD . On the same day (Day 156), PPD was transferred to another hospital and remained hospitalized for further evaluation. On the same day (Day 156), the subject's laboratory examinations showed troponin T of 0.18 ng/mL and 0.71 ng/mL (normal range: <0.01 ng/mL) at PPD and PPD , respectively. The polymerase chain reaction test results were positive for rhinovirus (respiratory) and negative for enterovirus (blood), parvovirus B19 (blood), and SARS-CoV-2 RNA (nasopharyngeal). PPD received PPD on PPD (Day 156). Additionally, PPD received PPD , and protocol-prohibited PPD , all from PPD (Day 156). The subject was doing well and remained without chest pain. PPD denied fevers, chills, or shortness of breath. The myopericarditis was considered resolved on PPD (Day 156). PPD was continued on PPD until discharge on PPD , after which PPD was planned, ending with PPD until PPD . PPD was discharged from the hospital on PPD , with a close follow-up scheduled with a pediatric cardiologist. At discharge, PPD was prescribed PPD until PPD) and PPD until PPD , followed by PPD from PPD to PPD). The subject was actively followed as a cardiologist outpatient at the time of reporting. PPD did not report a recurrence of cough or rhinorrhea. An ECG on PPD showed minimal ST elevations, significantly improved in comparison to the ECG on PPD . A 2D echocardiogram showed normal biventricular function, and a left ventricular global longitudinal strain (LV GLS) of 19%, which had decreased from an initial 20% on the previous echocardiogram. The strain was lower in the basal anterior, anteroseptal, inferoseptal, and inferior segments (lower strain in the septal from anterior to the inferior segments). The subject's coronaries were normal without dilation. Troponin T was <0.01 ng/mL. A follow-up magnetic resonance imaging scan of the heart on PPD revealed mildly decreased left ventricular (LV) systolic function (LV ejection fraction [EF] of 47%) and borderline right ventricular (RV) systolic function (RVEF of 46%); there were no significant valvular abnormalities. PPD LVEF and RVEF were previously reported to be 58% and 55%, respectively. It was noted that the stroke volume had decreased, and mitral regurgitation had improved. Another follow-up transthoracic echocardiogram performed on PPD showed LV GLS of 20.2%. As of PPD , the subject had reportedly resumed gym exercises. On PPD , it was reported that PPD was feeling well and could resume PPD . In the opinion of the investigator, there was no reasonable possibility that the myopericarditis was related to BNT162b2 or clinical trial procedures, but rather it was considered related to the rhinovirus infection. Pfizer did not concur with the investigator's causality assessment. Per Pfizer, there was a reasonable possibility that myopericarditis was related to vaccine administration, based on the plausible temporal relationship.

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Reason(s) for Narrative: Myocarditis/Pericarditis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: Myocarditis/Pericarditis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (23)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (512)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Abdominal distension	PPD	PPD (16)	PPD	PPD (16)	PPD	1
2	GASTR	Abdominal pain		PPD (16)	PPD	PPD (16)	PPD	1
3	CARD	Myocarditis		PPD (419)	PPD	PPD (486)	PPD	68

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: UNKNOWN	1	16	N
2	1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: UNKNOWN	1	16	N
3	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: UNKNOWN	2	397	Y

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Reason(s) for Narrative: Myocarditis/Pericarditis
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Narrative Comment
Subject PPD, a 70-year-old PPD with no reported medical history, received Dose 1 on PPD, Dose 2 on PPD (Day 23), and Dose 3 on PPD (Day 512). The subject experienced suspected myocarditis on PPD, 396 days after receiving Dose 2. The event was considered resolved on PPD (Day 486). In the opinion of the investigator, there was no reasonable possibility that the suspected myocarditis was related to the study intervention.

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Reason(s) for Narrative: Myocarditis/Pericarditis
Unique Subject ID: PPD ; **Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; **Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Past
			Past

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Reason(s) for Narrative: Myocarditis/Pericarditis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD
VACCINATION 3	BNT162b2	PPD (194)	PPD
VACCINATION 4	BNT162b2	PPD (216)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (463)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Myocarditis	PPD	PPD (25)	PPD	PPD (25)	PPD	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Unkonwn	2	6	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Myocarditis/Pericarditis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: Myocarditis/Pericarditis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Narrative Comment
Subject PPD, a 30-year-old PPD with a pertinent medical history of PPD, received Dose 1 on PPD and Dose 2 on PPD (Day 20). The subject was diagnosed with myocarditis (right retro-atrial inflammation) at PPD on PPD, 5 days after receiving Dose 2. The event resolved at PPD on the same day (PPD [Day 25]). In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether the subject was eligible for receipt of BNT162b2. It was confirmed that the subject had originally received placebo; the subject therefore received the first, second, and third doses of BNT162b2 on PPD (Day 194), PPD (Day 216), and PPD (Day 463), respectively. In the opinion of the investigator, there was no reasonable possibility that the myocarditis was related to the study intervention.

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Reason(s) for Narrative: Myocarditis/Pericarditis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: Myocarditis/Pericarditis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (20)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (440)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Gastrooesophageal reflux disease	PPD	PPD (61)	PPD	PPD (103)	PPD	43
2	CARD	Pericarditis		PPD (48)	PPD	PPD (264)	PPD	217

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Unknown	2	42	N
2	2	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	29	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Myocarditis/Pericarditis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Narrative Comment
Subject PPD, a 70-year-old PPD with a pertinent medical history of PPD (dates unknown), received Dose 1 on PPD, Dose 2 on PPD (Day 20), and Dose 3 on PPD (Day 440). The subject was diagnosed with pericarditis on PPD, 28 days after receiving Dose 2. On PPD (Day 48), the subject experienced dyspnea. The next day, the subject was admitted to the hospital due to dyspnea, fever (maximum temperature of 38°C), and myalgia for a potential COVID-19 illness. On PPD and PPD, swabs for COVID-19 were negative. The subject was discharged on PPD. On PPD, another COVID-19 test was performed due to the subject's persistent symptoms, but the result was negative. The subject followed up with a pneumologist as an outpatient. On PPD, as cough and dyspnea persisted, the subject was readmitted to another hospital for further evaluation due to pericarditis. On PPD, a Doppler echocardiogram showed parietal pericardium thickening and pericardial mass with a heterogeneous density structure without restrictive physiology at the time of the study. During the hospitalization, the subject presented with fever twice (maximum temperature of 38°C on PPD) without evident focus. The results of blood cultures (twice; dates unknown), a urine culture (date unknown), and a COVID-19 test (PPD) were all negative. The subject was treated with PPD, without oxygen requirement. A noncontrast chest computed tomography scan on PPD showed moderate pericardial and left pleural effusions associated with atelectasis of the underlying segments. The hospital's thoracic surgeon recommended a pericardial biopsy using a pleuropericardial window, but it was not performed in that hospital due to a lack of necessary equipment. The subject was discharged on PPD to continue the outpatient study and treatment. On PPD, the subject remained afebrile but had a persistent cough and mild dyspnea. Additional laboratory tests performed on unknown dates included the following: a tuberculin test result was negative; a sputum test result was negative for tuberculosis; blood test results were unremarkable; a venereal disease research laboratory test result was negative; a human immunodeficiency virus rapid test result was negative; and an electrocardiogram showed sinus rhythm, a heart rate of 100 beats/min, septal inactivation, negative T from V4 to V6, and a QT interval of 0.36. On PPD, the subject was feeling well, but cough and mild dyspnea were persistent. On the same day, the subject had a thoracic surgery review. A blood test was performed on PPD; the results were unremarkable. On PPD, the subject reported feeling well but was having productive coughs. On PPD, the subject was admitted for a pericardial biopsy, which was successfully completed without complications. A drainage tube was placed for the left pleural drainage. After the procedure, the subject was admitted to the intensive care unit. The subject remained clinically stable. A pericardial culture performed on PPD showed "no acid/alcohol-resistant bacilli were observed in 200 fields." The pericardial biopsy report showed the following: macroscopy findings showed a fibrous fragment measuring 3×1.2×0.7 cm, off-white, and elastic; microscopy findings of the histopathological sections showed a fibroconnective and adipose wall with fibrosis, vasocongestion, hemorrhages, and moderate chronic lymphoplasmacytic inflammation with few polymorphonuclear cells, and there were no

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Narrative Comment
neoplastic changes observed. The diagnosis was chronic pericarditis with mild activity. On PPD, a COVID-19 test result was negative. On PPD, the drainage tube was withdrawn without complications, and the subject was discharged. On PPD, the subject had a consultation with a pulmonologist; the subject was advised to rest at home and follow up with a rheumatologist . On PPD, the subject reported feeling asymptomatic. The subject's exercise fatigue had improved, and the subject had gained weight. The subject was resting at home without medications. The subject had an appointment with a rheumatologist, who requested blood tests. On PPD, a blood test was performed with the following results: antinuclear antibodies were negative; erythrocyte sedimentation rate of 5 mm (normal range [NR] not reported); total bilirubin of 0.42 mg% (NR: up to 1 mg%), direct bilirubin of 0.12 mg% (NR: up to 0.20 mg%), alkaline phosphatase of 231 µL (NR: 65 to 300 µL), pyruvic transaminase of 18 µL (NR: 3 to 40 µL), oxaloacetic transaminase of 18 µL (NR: 1 to 35 µL), and hemoglobin of 15.9 g% (NR not reported). The pericarditis was considered resolved on PPD (Day 264). In the opinion of the investigator, there was no reasonable possibility that the pericarditis was related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	60	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Past
			Present
			Present
			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (128)	PPD
VACCINATION 4	BNT162b2	PPD (149)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (499)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Brain stem infarction	PPD	PPD (268)		PPD (280)		13
2	NERV	Headache		PPD (2)	PPD	PPD (2)	PPD	1
3	VASC	Hot flush		PPD (2)	PPD	PPD (6)	PPD	5
4	GENRL	Injection site swelling		PPD (500)		PPD (501)		2
5	INJ&P	Procedural pain		PPD (175)		PPD (237)		63

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: Stroke	4	120	Y
2	1	N	N	Resolved (PPD)	Study Treatment	1	2	N
3	1	N	N	Resolved (PPD)	Study Treatment	1	2	N
4	1	N	N	Resolved (PPD)	Study Treatment	5	2	N
5	1	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: UNKNOWN	4	27	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Past
			Present
			Past
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present
			Present
			Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (21)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (402)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Fatigue	PPD	PPD (2)	PPD	PPD (4)		3
2	GENRL	Injection site pain		PPD (1)	PPD	PPD (4)		4
3	NERV	Ischaemic stroke		PPD (27)	PPD	PPD (29)		3

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Unique Subject ID: PPD ; Country: PPD
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Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (PPD)	Study Treatment	1	2	N
2	1	N	N	Resolved (PPD)	Study Treatment	1	1	N
3	2	N	Y	Resolved (PPD)	NOT RELATED/OTHER; unknown	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present
			Present
			Present
			Present
			Past

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Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Past
			Present
			Present
			Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (402)	PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	CARD	Cardiac failure congestive	PPD	PPD (17)	PPD	PPD (19)		3	2	TC

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
2	NERV	Cerebellar infarction	PPD	PPD (310)		PPD ()			2	TC
3	METAB	Hypoglycaemia		PPD (514)		PPD (522)		9	3	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (PPD)	NOT RELATED/OTHER: Progression of cardiovascular disease	1	17	N
2	Y	Resolved (PPD)	NOT RELATED/OTHER: cerebrovascular disease	2	289	Y
3	Y	Resolved (PPD)	NOT RELATED/OTHER: Per Sub I event is not related to study drug.	3	113	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (413)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	CONG	PPD	PPD	PPD (725)		ONGOING			3
2	METAB	Hypercholesterolaemia		PPD (609)	PPD	ONGOING			2
3	VASC	Hypertension		PPD (698)	PPD	ONGOING			2
4	NERV	Ischaemic stroke		PPD (722)		PPD (722)		1	3
5	SOCCI	PPD		PPD ()		ONGOING			1
6	NERV	Syncope		PPD (724)		PPD (724)		1	3
7	NEOPL	Uterine leiomyoma		PPD ()		ONGOING			1
8	NEOPL	Uterine leiomyoma		PPD (705)	PPD	ONGOING			2

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Yes	NOT RELATED/OTHER: CARDIOVASCULAR	3	313	N
2	TC	N	Yes	NOT RELATED/OTHER: cardiovascular	3	197	N
3	TC	N	Yes	NOT RELATED/OTHER: cardiovascular	3	286	N
4	TC	Y	Resolved (PPD)	NOT RELATED/CONCOMITANT DRUG TREATMENT	3	310	Y
5	TC	N	Yes	NOT RELATED/OTHER: GYNOCOLOGY	2	144	N
6	N	N	Resolved (PPD)	NOT RELATED/OTHER: CARDIOVASCULAR	3	312	N
7	N	N	Yes	NOT RELATED/OTHER: GYN	2	144	N
8	TC	N	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	3	293	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	FOLLOW-UP	PPD	
Completed	OPEN LABEL TREATMENT	PPD	

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	50	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present
			Past
			Present
			Past
			Present

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present
			Past
			Present
			Present
			Past
			Present
			Present
			Present
			Present
			Present
			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (129)	PPD
VACCINATION 4	BNT162b2	PPD (148)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (364)	PPD

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Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	VASC	Arteriosclerosis	PPD	PPD (0)		ONGOING			1
2	MUSC	Arthritis		PPD (48)		ONGOING			2
3	NERV	Basilar artery occlusion		PPD (255)		PPD (286)		32	2
4	NERV	Basilar artery stenosis		PPD (633)		ONGOING			2
5	GENRL	Chills		PPD (365)	PPD	PPD (368)		4	2
6	GENRL	Chills		PPD (148)	PPD	PPD (150)	PPD	3	2
7	GENRL	Fatigue		PPD (148)	PPD	PPD (151)		4	2
8	NERV	Headache		PPD (203)		PPD (222)		20	1
9	NERV	Headache		PPD (14)	PPD	PPD (15)	PPD	2	3
10	METAB	Hypokalaemia		PPD (14)	PPD	PPD (14)	PPD	1	1
11	GENRL	Injection site pain		PPD (148)	PPD	PPD (151)	PPD	4	2
12	MUSC	Neck pain		PPD (148)	PPD	PPD (151)		4	2
13	MUSC	Neck pain		PPD (14)	PPD	PPD (15)	PPD	2	3
14	GENRL	Pain		PPD (365)	PPD	PPD (368)		4	2
15	GENRL	Pyrexia		PPD (365)	PPD	PPD (368)		4	2

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Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TCN	N	Yes	NOT RELATED/OTHER: diet/lifestyle	4	46	N
2	TC	N	Yes	NOT RELATED/OTHER: Arthritis	2	27	N
3	TC	N	Resolved (PPD)	NOT RELATED/OTHER: due to headache	4	108	Y
4	TC	N	Yes	NOT RELATED/OTHER: Atherosclerosis	5	270	N
5	N	N	Resolved (PPD)	Study Treatment	5	2	N
6	N	N	Resolved (PPD)	Study Treatment	4	1	N
7	N	N	Resolved (PPD)	Study Treatment	4	1	N
8	N	N	Resolved (PPD)	NOT RELATED/OTHER: poor sleep	4	56	N
9	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: neck pain and PPD	1	14	N
10	TC	N	Resolved (PPD)	NOT RELATED/OTHER: incident follow-up at ER visit	1	14	N
11	TC	N	Resolved (PPD)	Study Treatment	4	1	N
12	TC	N	Resolved (PPD)	Study Treatment	4	1	N
13	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: headache and PPD	1	14	N
14	TC	N	Resolved (PPD)	Study Treatment	5	2	N
15	TC	N	Resolved (PPD)	Study Treatment	5	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Past
			Past

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Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (127)	PPD
VACCINATION 4	BNT162b2	PPD (148)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (386)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Embolic stroke	PPD	PPD (519)	PPD	PPD (527)		9	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: Cerebrovascular Disease	5	134	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	PHYSICIAN DECISION

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past
			Past
			Present
			Present
			Present

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (42)	PPD
VACCINATION 4	BNT162b2	PPD (63)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	GENRL	Chills	PPD	PPD (63)	PPD	PPD (64)	PPD	2	1	N	N
2	NERV	Headache		PPD (63)	PPD	PPD (64)	PPD	2	1	N	N
3	NERV	Ischaemic stroke		PPD (184)	PPD	PPD (187)		4	3	N	Y
4	GENRL	Pyrexia		PPD (63)	PPD	PPD (64)	PPD	2	1	N	N
5	INJ&P	Skin laceration		PPD (41)		PPD (45)		5	1	N	N

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (PPD)	Study Treatment	4	1	N
2	Resolved (PPD)	Study Treatment	4	1	N
3	Resolved (PPD)	NOT RELATED/OTHER: known PPD	4	122	Y
4	Resolved (PPD)	Study Treatment	4	1	N
5	Resolved (PPD)	NOT RELATED/OTHER: accidental injury from PPD	2	20	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	REPEAT SCREENING 1	PPD	
Withdrawn	VACCINATION	PPD	OTHER
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	OTHER

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (454)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Ischaemic stroke	PPD	PPD (116)	PPD	PPD (150)		35	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: history of PPD	2	95	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≥75	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past
			Past
			Past
			Present
			Present
			Past
			Present

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Past
			Past
			Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (165)	PPD
VACCINATION 4	BNT162b2	PPD (184)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (456)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CARD	Atrial fibrillation	PPD	PPD (488)	PPD	PPD (512)	PPD	25
2	NERV	Ischaemic stroke		PPD (486)	PPD	PPD (535)	PPD	50

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	5	33	N
2	3	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	5	31	Y

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	PROTOCOL DEVIATION

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past
			Past
			Present

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (198)	PPD
VACCINATION 4	BNT162b2	PPD (217)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (470)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	CONG	PPD	PPD	PPD (614)	PPD	PPD (719)	PPD	106
2	GENRL	Injection site pain		PPD (22)	PPD	PPD (61)	PPD	40
3	GENRL	Injection site pain		PPD (471)	PPD	PPD (477)	PPD	7
4	GENRL	Injection site pruritus		PPD (56)		PPD (56)		1
5	NERV	Ischaemic stroke		PPD (586)	PPD	PPD (670)	PPD	85

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	5	145	N

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	1	N	N	Resolved (PPD)	Study Treatment	2	2	N
3	2	N	N	Resolved (PPD)	Study Treatment	5	2	N
4	1	N	N	Resolved (PPD)	Study Treatment	2	36	N
5	3	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	5	117	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	50	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (186)	PPD
VACCINATION 4	BNT162b2	PPD (226)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (474)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Ischaemic stroke	PPD	PPD (75)	PPD	PPD (152)	PPD	78
2	INFEC	Pneumonia		PPD (297)	PPD	PPD (306)	PPD	10
3	METAB	Type 2 diabetes mellitus		PPD (287)	PPD	PPD (362)	PPD	76

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	55	Y

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	3	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	4	72	N
3	2	TC	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	4	62	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (21)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (443)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Ischaemic stroke	PPD	PPD (257)	PPD	PPD (291)	PPD	35

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	237	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD
VACCINATION 3	BNT162b2	PPD (157)	PPD
VACCINATION 4	BNT162b2	PPD (178)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (451)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Ischaemic stroke	PPD	PPD (43)	PPD	PPD (47)	PPD	5

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	24	Y

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	Not Reported	PPD	

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Past
			Present
			Past
			Past
			Present
			Past

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present
			Present
			Present
			Present
			Present
			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (154)	PPD
VACCINATION 4	BNT162b2	PPD (175)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (402)	PPD

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	NERV	Ischaemic stroke	PPD	PPD (734)	PPD	PPD (737)	PPD	4	3	N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (PPD)	NOT RELATED/OTHER: Past medical history of PPD	5	333	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	60	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD
VACCINATION 3	BNT162b2	PPD (149)	PPD
VACCINATION 4	BNT162b2	PPD (168)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (442)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Cognitive disorder	PPD	PPD (318)	PPD	PPD (384)	PPD	67
2	NERV	Ischaemic stroke		PPD (318)	PPD	PPD (383)	PPD	66

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (PPD)	NOT RELATED/OTHER: Ischemic stroke	4	151	N
2	3	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	4	151	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

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Reason(s) for Narrative: Ischemic Stroke
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: Anaphylaxis
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	70	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past
			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: Anaphylaxis
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD
VACCINATION 3	BNT162b2	PPD (149)	PPD
VACCINATION 4	BNT162b2	PPD (171)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (427)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	IMMUN	Anaphylactic shock	PPD	PPD (38)		PPD (38)		1	4
2	INJ&P	Arthropod bite		PPD (38)	PPD	PPD (39)		2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: anaphylactic shock to PPD	2	19	Y
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: NA	2	19	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: Anaphylaxis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: Anaphylaxis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: Anaphylaxis
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (25)	PPD
VACCINATION 3	BNT162b2	PPD (95)	PPD
VACCINATION 4	BNT162b2	PPD (115)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (389)	PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	IMMUN	Anaphylactic reaction	PPD	PPD (231)	PPD	PPD (231)	PPD	1	4	TC
2	INJ&P	Arthropod bite		PPD (231)	PPD	PPD (231)	PPD	1	4	TC

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Y	Resolved (PPD)	NOT RELATED/OTHER: Anaphylaxis secondary to insect bite	4	117	Y
2	Y	Resolved (PPD)	NOT RELATED/OTHER: anaphylaxis secondary to insect bite	4	117	N

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Reason(s) for Narrative: Anaphylaxis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: Anaphylaxis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: Anaphylaxis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: Anaphylaxis
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (21)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (427)	PPD

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	IMMUN	Anaphylactic reaction	PPD	PPD (29)	PPD	PPD (29)	PPD	1	4	TC
2	INFEC	Infected bite		PPD (31)	PPD	PPD (41)	PPD	11	2	TC
3	GENRL	Injection site pain		PPD (1)	PPD	PPD (2)	PPD	2	1	N
4	GENRL	Injection site swelling		PPD (1)	PPD	PPD (2)	PPD	2	2	N

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Reason(s) for Narrative: Anaphylaxis
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (PPD)	NOT RELATED/OTHER: Subject with history of PPD	2	9	Y
2	N	Resolved (PPD)	NOT RELATED/OTHER: Subject with history of PPD	2	11	N
3	N	Resolved (PPD)	Study Treatment	1	1	N
4	N	Resolved (PPD)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: Anaphylaxis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: Anaphylaxis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	70	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present
			Present

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Reason(s) for Narrative: Anaphylaxis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (20)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (442)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	IMMUN	Anaphylactic reaction	PPD	PPD (601)	PPD	PPD (612)	PPD	12	3
2	INJ&P	Craniocerebral injury		PPD (601)	PPD	PPD (602)	PPD	2	2
3	INJ&P	Face injury		PPD (601)	PPD	PPD (622)		22	2
4	INJ&P	Fall		PPD (601)	PPD	PPD (601)	PPD	1	2
5	MUSC	Osteoarthritis		PPD (575)	PPD	PPD (686)		112	2
6	INJ&P	Tooth fracture		PPD (601)	PPD	PPD (692)		92	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD intake	3	160	Y
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: Falling from PPD own height.	3	160	N

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Reason(s) for Narrative: Anaphylaxis
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	N	N	Resolved (PPD)	NOT RELATED/OTHER: Falling from PPD own height.	3	160	N
4	N	N	Resolved (PPD)	NOT RELATED/OTHER: Anaphylactic Reaction	3	160	N
5	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Incorrect movement	3	134	N
6	N	N	Resolved (PPD)	NOT RELATED/OTHER: Falling from PPD own height.	3	160	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: Anaphylaxis
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b1 Phase 1 (10 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (-6)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD ; Country: PPD

Vaccine Group (as Administered): BNT162b1 Phase 1 (10 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD ; Date of Last Dose: PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b1	PPD (1)	PPD
VACCINATION 2	BNT162b1	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (301)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	RESP	Cough	PPD	PPD (3)		PPD (5)		3	1
2	RESP	Dyspnoea		PPD (41)		PPD (53)		13	1
3	INJ&P	PPD		PPD (314)		PPD (378)		65	
4	RESP	Throat irritation		PPD (41)		PPD (53)		13	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	Study Treatment	1	3	N
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: Reactive airway disease	2	21	N
3	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	3	14	Y
4	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	21	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b1 Phase 1 (10 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 2	PPD	
Completed	SUBSTUDY	PPD	
Withdrawn	FOLLOW-UP	PPD	PROTOCOL DEVIATION

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b1 Phase 1 (10 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (161)	PPD
VACCINATION 4	BNT162b2	PPD (182)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (430)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD		PPD (37)		PPD (294)		258	

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	15	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2SA (30 µg, 1 Dose) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2SA (30 µg, 1 Dose) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
VACCINATION 3	BNT162b2SA	PPD (230)	PPD
FOURTH DOSE BNT162b2	BNT162b2	PPD (631)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	NERV	Depressed level of consciousness	PPD	PPD (18)		PPD (25)		8	1
2	INJ&P	PPD		PPD (214)		PPD (489)		276	
3	GENRL	Injection site pain		PPD (2)		PPD (3)		2	1

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2SA (30 µg, 1 Dose) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD EXPOSURE	1	18	N
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	193	Y
3	N	N	Resolved (PPD)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2SA (30 µg, 1 Dose) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 2	PPD	
Completed	SUBSTUDY	PPD	
Completed	REPEAT SCREENING 4	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present
			Past
			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (127)	PPD
VACCINATION 4	BNT162b2	PPD (148)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (425)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Clostridium difficile infection	PPD	PPD (48)		PPD (199)		152	2
2	INJ&P	PPD		PPD (179)		PPD (448)		270	
3	GENRL	Injection site pain		PPD (127)	PPD	PPD (129)		3	1

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
4	MUSC	Osteoarthritis	PPD	PPD (642)		ONGOING			2
5	INFEC	Pharyngitis streptococcal		PPD (26)		PPD (36)		11	2
6	INJ&P	Procedural pain		PPD (137)		PPD (152)		16	3
7	MUSC	Tendonitis		PPD (642)		ONGOING			2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	27	N
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	32	Y
3	N	N	Resolved (PPD)	Study Treatment	3	1	N
4	N	N	Yes	NOT RELATED/OTHER: osteoarthritis	5	218	N
5	TC	N	Resolved (PPD)	NOT RELATED/OTHER: bacterial infection	2	5	N
6	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Tonsillectomy	3	11	N
7	N	N	Yes	NOT RELATED/OTHER: tendonitis	5	218	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (182)	PPD
VACCINATION 4	BNT162b2	PPD (204)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (455)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD		PPD (137)		PPD (394)		258	

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	116	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (100)	PPD
VACCINATION 4	BNT162b2	PPD (119)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (414)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD		PPD (414)	PPD	PPD (553)		140

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (132)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 4	BNT162b2	PPD (151)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (405)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD		PPD (405)	PPD	PPD (615)		211

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: N/A	5	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (48)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (414)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD	PPD	PPD (414)	PPD	PPD (624)		211	
2	GENRL	Fatigue		PPD (49)		PPD (52)		4	1
3	GENRL	Injection site erythema		PPD (49)		PPD (52)		4	1
4	GENRL	Injection site pain		PPD (49)		PPD (52)		4	1
5	GASTR	Toothache		PPD (11)		PPD (15)		5	1

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: N/A	3	1	Y
2	N	N	Resolved (PPD)	Study Treatment	2	2	N
3	N	N	Resolved (PPD)	Study Treatment	2	2	N
4	N	N	Resolved (PPD)	Study Treatment	2	2	N
5	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Common toothache	1	11	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)

Date of First Dose: PPD **; Date of Last Dose:** PPD

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (215)	PPD
VACCINATION 4	BNT162b2	PPD (236)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PPD	PPD	PPD	PPD ()		PPD ()			3
2	INJ&P	PPD		PPD ()		PPD ()			
3	INJ&P	PPD		PPD ()		ONGOING			1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	22	N
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	1	Y
3	N	N	Yes	NOT RELATED/OTHER: PPD	4	20	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (169)	PPD
VACCINATION 4	BNT162b2	PPD (190)	PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INJ&P	PPD		PPD (105)		PPD (380)		276		N

Adverse Events						
AE Number	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	Resolved (PPD)	NOT RELATED/OTHER: PPD occured unrelated to vaccine	2	84	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (124)	PPD
VACCINATION 4	BNT162b2	PPD (145)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	PPD	PPD	PPD	PPD (198)		PPD ()			2	TC/TCN	Y
2	INJ&P	PPD		PPD (141)		PPD ()				N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (PPD)	NOT RELATED/OTHER: Patient had a PPD, we have requested more information and will update	4	54	N
2	Resolved (PPD)	NOT RELATED/OTHER: Unrelated	3	18	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (164)	PPD
VACCINATION 4	BNT162b2	PPD (184)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (463)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	PPD	PPD	PPD	PPD (289)		PPD (296)		8	2	TCN	Y
2	INJ&P	PPD		PPD (463)	PPD	PPD (621)		159	1	N	N
3	GENRL	Injection site pain		PPD (164)	PPD	PPD (167)		4	1	N	N
4	MUSC	Myalgia		PPD (184)	PPD	PPD (185)	PPD	2	1	TC	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (PPD)	NOT RELATED/OTHER: 'most common causes genetic'	4	106	N
2	Resolved (PPD)	NOT RELATED/OTHER: Subject was cleared by PI and PCP to receive COVID booster. Report faxed PPD	5	1	Y
3	Resolved (PPD)	Study Treatment	3	1	N
4	Resolved (PPD)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD ; **Country:** PPD

Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD ; **Date of Last Dose:** PPD

==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (406)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PPD	PPD	PPD	PPD (151)		PPD ()		
2	METAB	Gout		PPD (38)	PPD	PPD (49)	PPD	12

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: Not realted	2	130	Y
2	1	TC	N	Resolved (PPD)	Study Treatment	2	17	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	PHYSICIAN DECISION

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (134)	PPD
VACCINATION 4	BNT162b2	PPD (155)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (303)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INFEC	Cellulitis	PPD	PPD (173)		PPD (183)		11	1
2	INJ&P	PPD		PPD (176)		PPD (434)		259	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: bacterial skin infection	4	19	N
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	22	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	OTHER

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present
			Present
			Present
			Present
			Present
			Past
			Present
			Present
			Past
			Present
			Past
			Past
			Past
			Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD ; Country: PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD ; Date of Last Dose: PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (131)	PPD
VACCINATION 4	BNT162b2	PPD (152)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (406)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (185)		PPD (439)		255
2	PPD	PPD		PPD (414)	PPD	PPD (438)		25
3	GENRL	Injection site pain		PPD (131)	PPD	PPD (134)	PPD	4
4	BLOOD	Lymphadenopathy		PPD (152)	PPD	PPD (157)		6

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	34	Y
2	2	N	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	9	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	2	N	N	Resolved (PPD)	Study Treatment	3	1	N
4	1	N	N	Resolved (PPD)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (95)	PPD
VACCINATION 4	BNT162b2	PPD (119)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	BLOOD	Anaemia	PPD	PPD ()		ONGOING			1
2	INJ&P	PPD		PPD (133)		PPD (415)		283	
3	ENDO	Hypothyroidism		PPD ()		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Yes	NOT RELATED/OTHER: PPD	4	203	N
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	15	Y
3	TC	N	Yes	NOT RELATED/OTHER: autoimmune	4	203	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	REPEAT SCREENING 3	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	PPD	PPD	PPD (01)		ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		N	N	Yes	NOT RELATED/OTHER: PPD	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	OTHER
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Past
			Present
			Present
			Present
			Past
			Past
			Present
			Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD
VACCINATION 3	BNT162b2	PPD (131)	PPD
VACCINATION 4	BNT162b2	PPD (154)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	PPD	PPD	PPD	PPD (159)		PPD (159)		1	3
2	INJ&P	PPD		PPD (133)		PPD (159)		27	
3	INJ&P	PPD		PPD (176)		PPD (444)		269	

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD History	4	6	N
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: n/a	3	3	Y
3	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	23	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Past
			Past

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Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD
VACCINATION 3	BNT162b2	PPD (246)	PPD
VACCINATION 4	BNT162b2	PPD (266)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (441)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD ()		PPD (311)		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	1	Y

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Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP
Withdrawn	OPEN LABEL TREATMENT	PPD	LOST TO FOLLOW-UP

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Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD	PPD	PPD (17)		PPD (288)		272	

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	17	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	OTHER
Withdrawn	FOLLOW-UP	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (173)	PPD
VACCINATION 4	BNT162b2	PPD (194)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (486)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (204)		PPD (467)		264
2	GENRL	Fatigue		PPD (174)	PPD	PPD (175)	PPD	2
3	NERV	Headache		PPD (174)	PPD	PPD (174)	PPD	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: life	4	11	Y
2	1	N	N	Resolved (PPD)	Study Treatment	3	2	N
3	1	TC	N	Resolved (PPD)	Study Treatment	3	2	N

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Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

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Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present

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Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (171)	PPD
VACCINATION 4	BNT162b2	PPD (193)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (429)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Chills	PPD	PPD (194)	PPD	PPD (194)	PPD	1	1
2	INJ&P	PPD		PPD (450)	PPD	PPD (716)		267	
3	GENRL	Fatigue		PPD (433)	PPD	PPD (434)	PPD	2	1
4	NERV	Headache		PPD (193)	PPD	PPD (193)	PPD	1	1
5	NERV	Headache		PPD (433)	PPD	PPD (434)	PPD	2	1
6	GENRL	Injection site pain		PPD (193)	PPD	PPD (195)	PPD	3	2
7	GENRL	Injection site pain		PPD (429)	PPD	PPD (433)	PPD	5	1
8	GENRL	Injection site pain		PPD (171)	PPD	PPD (175)	PPD	5	1
9	GASTR	Nausea		PPD (193)	PPD	PPD (193)	PPD	1	1
10	GENRL	Pyrexia		PPD (194)	PPD	PPD (194)	PPD	1	1

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (PPD)	Study Treatment	4	2	N
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	22	Y
3	N	N	Resolved (PPD)	Study Treatment	5	5	N
4	N	N	Resolved (PPD)	Study Treatment	4	1	N
5	N	N	Resolved (PPD)	Study Treatment	5	5	N
6	TC	N	Resolved (PPD)	Study Treatment	4	1	N
7	N	N	Resolved (PPD)	Study Treatment	5	1	N
8	N	N	Resolved (PPD)	Study Treatment	3	1	N
9	N	N	Resolved (PPD)	Study Treatment	4	1	N
10	N	N	Resolved (PPD)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (20)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (418)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Chills	PPD	PPD (418)	PPD	PPD (421)	PPD	4
2	INJ&P	PPD		PPD (169)		PPD (428)		260
3	GENRL	Fatigue		PPD (1)	PPD	PPD (2)	PPD	2
4	GENRL	Fatigue		PPD (20)	PPD	PPD (21)	PPD	2
5	GENRL	Feeling hot		PPD (1)	PPD	PPD (2)	PPD	2
6	NERV	Headache		PPD (418)	PPD	PPD (421)	PPD	4
7	GENRL	Pyrexia		PPD (20)	PPD	PPD (21)	PPD	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (PPD)	Study Treatment	3	1	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	150	Y
3	1	N	N	Resolved (PPD)	Study Treatment	1	1	N
4	1	N	N	Resolved (PPD)	Study Treatment	2	1	N
5	1	TC	N	Resolved (PPD)	Study Treatment	1	1	N
6	1	N	N	Resolved (PPD)	Study Treatment	3	1	N
7	1	TC	N	Resolved (PPD)	Study Treatment	2	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (20)	PPD
VACCINATION 3	BNT162b2	PPD (156)	PPD
VACCINATION 4	BNT162b2	PPD (177)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (434)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (183)		PPD (364)		182

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	7	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (400)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	PPD	PPD	PPD (260)		PPD (523)	
2	GENRL	Fatigue		PPD (401)		PPD (402)	
3	NERV	Headache		PPD (401)		PPD (402)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	264		N	N	Resolved (PPD)	Study Treatment	2	239	Y
2	2	1	N	N	Resolved (PPD)	Study Treatment	3	2	N
3	2	1	N	N	Resolved (PPD)	Study Treatment	3	2	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (125)	PPD
VACCINATION 4	BNT162b2	PPD (146)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (427)	PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	INJ&P	PPD	PPD	PPD (160)		PPD (445)		286		N
2	INFEC	Herpes zoster		PPD (89)		PPD (95)		7	1	TC
3	NERV	Nerve compression		PPD (170)	PPD	ONGOING			1	TC

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD ; Country: PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD ; Date of Last Dose: PPD

==========

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Resolved (PPD)		4	15	Y
2	N	Resolved (PPD)	NOT RELATED/OTHER: ACUTE HERPES ZOSTER INFECTION	2	68	N
3	N	Yes	NOT RELATED/OTHER: OVERUSE INJURY	4	25	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (209)	PPD
VACCINATION 4	BNT162b2	PPD (230)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (483)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (354)		PPD (633)	PPD	280

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	125	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (24)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	CONG	PPD	PPD	PPD (294)	PPD	PPD (295)	PPD	2	4	N
2	INJ&P	PPD		PPD (31)		PPD (294)	PPD	264		N
3	PPD	PPD		PPD (294)	PPD	PPD (295)	PPD	2	4	N
4	PPD	PPD		PPD (294)		PPD (294)		1	3	N
5	CONG	PPD		PPD (294)	PPD	PPD (295)	PPD	2	4	N

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD of unknown cause	2	271	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	N	Resolved (PPD)	NOT RELATED/OTHER: N/A	2	8	Y
3	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD of unknown cause	2	271	N
4	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	271	N
5	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD of unknown cause	2	271	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (203)	PPD
VACCINATION 4	BNT162b2	PPD (224)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	PPD	PPD	PPD (250)		ONGOING	
2	MUSC	Myalgia		PPD (224)	PPD	PPD (225)	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	Study Treatment	4	27	Y
2	2	2	N	N	Resolved (PPD)	Study Treatment	4	1	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (196)	PPD
VACCINATION 4	BNT162b2	PPD (217)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (444)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (181)		ONGOING		
2	GENRL	Injection site pain		PPD (444)	PPD	PPD (445)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Yes	NOT RELATED/OTHER: unknown	2	161	Y
2	1	N	N	Resolved (PPD)	Study Treatment	5	1	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Past
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present
			Past
			Past
			Present
			Past
			Past
			Past
			Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (120)	PPD
VACCINATION 4	BNT162b2	PPD (141)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (422)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GASTR	Diarrhoea	PPD	PPD (423)		PPD (424)	PPD	2	1
2	INJ&P	PPD		PPD (427)		PPD (678)		252	
3	BLOOD	Lymphadenopathy		PPD (422)	PPD	PPD (426)	PPD	5	1
4	INFEC	Urinary tract infection		PPD (452)		PPD (458)		7	2

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (PPD)	Study Treatment	5	2	N
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	6	Y
3	N	N	Resolved (PPD)	Study Treatment	5	1	N
4	TC	N	Resolved (PPD)	NOT RELATED/OTHER: UNKNOWN	5	31	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (99)	PPD
VACCINATION 4	BNT162b2	PPD (120)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (452)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (452)	PPD	PPD (707)		256

Adverse Events							
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	333	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present
			Past
			Past
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Past
			Present
			Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (24)	PPD
VACCINATION 3	BNT162b2	PPD (88)	PPD
VACCINATION 4	BNT162b2	PPD (108)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (479)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PSYCH	PPD	PPD	PPD (416)		ONGOING			2

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
2	INJ&P	PPD	PPD	PPD (479)	PPD	ONGOING			
3	INV	Progesterone decreased	LOW PROGESTERONE	PPD (416)		ONGOING			2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Yes	NOT RELATED/OTHER: PRIOR MEDICAL HISTORY OF PPD	4	309	N
2	TC	N	Yes	NOT RELATED/OTHER: PPD	5	1	Y
3	TC	N	Yes	NOT RELATED/OTHER: UNKNOWN PER SUB I	4	309	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (149)	PPD
VACCINATION 4	BNT162b2	PPD (170)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (511)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (523)		PPD (529)		7

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	13	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (24)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD	PPD	PPD ()		PPD (332)			2
2	SKIN	Night sweats		PPD (42)		PPD ()			1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	26	Y
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: Unknown-possibly endocrinologic	2	19	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present
			Present
			Present
			Past
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Past
			Present
			Present
			Past
			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (122)	PPD
VACCINATION 4	BNT162b2	PPD (142)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (485)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	GENRL	Chills	PPD	PPD (142)		PPD (143)		2	1	TC	N
2	METAB	Decreased appetite		PPD (122)	PPD	PPD (123)		2	1	N	N
3	INJ&P	PPD		PPD (502)		PPD (728)		227		N	Y
4	PPD	PPD		PPD (702)		PPD (728)		27	2	TC	Y
5	PPD	PPD		PPD (728)		PPD (728)		1	2	N	Y
6	PPD	PPD		PPD (702)		PPD (728)		27	2	TC	Y
7	GENRL	Pyrexia		PPD (486)		PPD (488)		3	1	TC/TCN	N
8	GENRL	Pyrexia		PPD (122)	PPD	PPD (123)		2	1	TC	N
9	GASTR	Vomiting		PPD (487)	PPD	PPD (487)	PPD	1	2	TCN	N
10	GASTR	Vomiting		PPD (142)		PPD (143)		2	1	TC	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (PPD)	Study Treatment	4	1	N
2	Resolved (PPD)	Study Treatment	3	1	N
3	Resolved (PPD)	NOT RELATED/OTHER: Subject PPD	5	18	Y
4	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	218	N
5	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	244	N
6	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	218	N
7	Resolved (PPD)	Study Treatment	5	2	N
8	Resolved (PPD)	Study Treatment	3	1	N
9	Resolved (PPD)	Study Treatment	5	3	N
10	Resolved (PPD)	Study Treatment	4	1	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications				
Investigator Text	**WHO Drug Preferred Term**	**Start Date**	**End Date**	**Route**
PPD				

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (2)		PPD (39)		38

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		TC	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	WITHDRAWAL BY SUBJECT
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Past
			Past
			Present
			Present
			Past

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (24)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (388)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (36)		PPD (301)	PPD	266

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	13	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (23)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (485)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INV	Body temperature increased	PPD	PPD (486)	PPD	PPD (487)	PPD	2
2	INJ&P	PPD		PPD (491)		PPD (758)	PPD	268
3	GENRL	Injection site erythema		PPD (486)	PPD	PPD (488)		3
4	GENRL	Injection site pain		PPD (485)	PPD	PPD (488)		4
5	GENRL	Injection site pain		PPD (23)	PPD	PPD (26)	PPD	4
6	BLOOD	Lymphadenopathy		PPD (24)	PPD	PPD (26)	PPD	3

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (PPD)	Study Treatment	3	2	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	3	7	Y
3	1	N	N	Resolved (PPD)	Study Treatment	3	2	N
4	1	N	N	Resolved (PPD)	Study Treatment	3	1	N
5	1	N	N	Resolved (PPD)	Study Treatment	2	1	N
6	1	N	N	Resolved (PPD)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (131)	PPD
VACCINATION 4	BNT162b2	PPD (152)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (404)	PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	PPD	PPD	PPD (404)	PPD	PPD (538)		135		N	N
2	GENRL	Injection site pain		PPD (152)	PPD	PPD (154)		3	1	N	N
3	GENRL	Injection site pain		PPD (404)	PPD	PPD (405)		2	1	N	N
4	PPD	PPD		PPD (544)		PPD (545)		2	4	TC/TCN	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	253	Y
2	Resolved (PPD)	Study Treatment	4	1	N
3	Resolved (PPD)	Study Treatment	4	253	N
4	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	141	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present
			Past

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (24)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (422)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PPD	PPD	PPD	PPD (134)		PPD (134)		1
2	INJ&P	PPD		PPD ()		PPD (134)		
3	INJ&P	PPD		PPD (428)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	N	Y	Resolved (PPD)	NOT RELATED/OTHER: Unknown	2	111	N
2		N	N	Resolved (PPD)	NOT RELATED/OTHER: Unknown	2	45	Y
3		N	N	Yes	NOT RELATED/OTHER: N/A	3	7	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications				
Investigator Text	WHO Drug Preferred Term	Start Date	End Date	Route
PPD				

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (20)	PPD
VACCINATION 3	BNT162b2	PPD (169)	PPD
VACCINATION 4	BNT162b2	PPD (189)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (393)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	PPD	PPD	PPD ()		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1			N	N	Yes	NOT RELATED/OTHER: PPD	4	1	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (31)	PPD
VACCINATION 3	BNT162b2	PPD (185)	PPD
VACCINATION 4	BNT162b2	PPD (207)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (476)	PPD

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	PPD	PPD	PPD	PPD (172)		PPD (172)		1	2
2	PPD	PPD		PPD (374)		PPD (378)		5	3
3	GENRL	Chills		PPD (19)		PPD (23)		5	1
4	RESP	Cough		PPD (19)		PPD (23)		5	1
5	INJ&P	PPD		PPD (34)		PPD (172)		139	
6	NERV	Headache		PPD (19)		PPD (23)		5	1
7	RESP	Oropharyngeal pain		PPD (19)		PPD (23)		5	2
8	PPD	PPD		PPD ()		ONGOING			1

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Y	Resolved (PPD)	NOT RELATED/OTHER: Other-Unknown	2	142	N
2	TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	4	168	N
3	N	N	Resolved (PPD)	NOT RELATED/OTHER: Viral Illness	1	19	N
4	N	N	Resolved (PPD)	NOT RELATED/OTHER: Viral Illness	1	19	N
5	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	4	Y
6	N	N	Resolved (PPD)	NOT RELATED/OTHER: Viral Illness	1	19	N
7	N	N	Resolved (PPD)	NOT RELATED/OTHER: Viral Illness	1	19	N
8	TC	N	Yes	NOT RELATED/OTHER: unknown	5	13	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past
			Past
			Past
			Past
			Past

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (151)	PPD
VACCINATION 4	BNT162b2	PPD (172)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (158)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Yes	NOT RELATED/OTHER: PPD	3	8	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past
			Past

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (24)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (18)		PPD ()		
2	SOCCI	PPD		PPD ()		PPD ()		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	18	Y
2	3	N	Y	Resolved (PPD)	NOT RELATED/OTHER: Unknown	2	54	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past
			Present
			Present
			Present
			Past
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (185)	PPD
VACCINATION 4	BNT162b2	PPD (206)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD ()		PPD (742)		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	3	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (154)	PPD
VACCINATION 4	BNT162b2	PPD (173)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (184)		PPD (439)		256
2	GENRL	Injection site pain		PPD (1)		PPD (1)		1
3	GENRL	Injection site pain		PPD (154)		PPD (155)		2

Adverse Events							
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	12	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	1	N	N	Resolved (PPD)	Study Treatment	1	1	N
3	1	N	N	Resolved (PPD)	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	PROTOCOL DEVIATION

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Past
			Past

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (44)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	MUSC	Bone pain	PPD	PPD (45)		PPD (231)		187
2	GENRL	Chills		PPD (2)		PPD (2)		1
3	INJ&P	PPD		PPD (32)		PPD (296)	PPD	265
4	NERV	Headache		PPD (2)		PPD (2)		1
5	GENRL	Injection site pain		PPD (2)		PPD (2)		1
6	MUSC	Myalgia		PPD (2)		PPD (2)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	2	N
2	1	N	N	Resolved (PPD)	Study Treatment	1	2	N
3		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	32	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	1	N	N	Resolved (PPD)	Study Treatment	1	2	N
5	1	N	N	Resolved (PPD)	Study Treatment	1	2	N
6	1	N	N	Resolved (PPD)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	<24	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD ; **Country:** PPD

Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD ; **Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (24)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (399)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GASTR	Abdominal pain	PPD	PPD (421)	PPD	PPD (421)	PPD	1
2	GENRL	Axillary pain		PPD (25)	PPD	PPD (27)	PPD	3
3	INJ&P	PPD		PPD (399)	PPD	PPD (481)	PPD	83
4	GENRL	Fatigue		PPD (25)	PPD	PPD (25)	PPD	1
5	NERV	Headache		PPD (25)	PPD	PPD (25)	PPD	1
6	GENRL	Injection site pain		PPD (25)	PPD	PPD (25)	PPD	1
7	MUSC	Myalgia		PPD (25)	PPD	PPD (25)	PPD	1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	N	N	Resolved (PPD)	NOT RELATED/OTHER: Unknown	3	23	N
2	2	N	N	Resolved (PPD)	Study Treatment	2	2	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	3	1	Y
4	2	N	N	Resolved (PPD)	Study Treatment	2	2	N
5	2	N	N	Resolved (PPD)	Study Treatment	2	2	N
6	2	N	N	Resolved (PPD)	Study Treatment	2	2	N
7	2	N	N	Resolved (PPD)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD ; Country: PPD

Vaccine Group (as Administered): Placebo

Date of First Dose: PPD ; Date of Last Dose: PPD

==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past
			Past
			Past
			Past

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	PPD	PPD	PPD (5)	PPD	ONGOING	

Adverse Events								
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Yes	NOT RELATED/OTHER: PPD		1	5	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): Placebo

Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (24)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (1)		PPD (20)		20

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCS	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	PROTOCOL DEVIATION

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past
			Past
			Past
			Present

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (412)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Diarrhoea	PPD	PPD (2)	PPD	PPD (4)	PPD	3	1
2	INJ&P	PPD		PPD (8)		PPD (62)		55	3
3	NERV	Headache		PPD (23)	PPD	PPD (23)	PPD	1	2
4	GENRL	Injection site pain		PPD (23)	PPD	PPD (25)	PPD	3	2
5	GASTR	Vomiting		PPD (23)	PPD	PPD (23)	PPD	1	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	Study Treatment	1	2	N
2	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	8	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	N	N	Resolved (PPD)	Study Treatment	2	2	N
4	N	N	Resolved (PPD)	Study Treatment	2	2	N
5	N	N	Resolved (PPD)	Study Treatment	2	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (174)	PPD
VACCINATION 4	BNT162b2	PPD (195)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (470)	PPD

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	INJ&P	PPD	PPD	PPD (72)		PPD (340)		269	1	N	N
2	GENRL	Injection site pain		PPD (174)	PPD	PPD (176)	PPD	3	1	N	N
3	GENRL	Injection site pain		PPD (470)	PPD	PPD (471)	PPD	2	1	N	N
4	GENRL	Malaise		PPD (196)	PPD	PPD (197)	PPD	2	1	N	N
5	GENRL	Pyrexia		PPD (196)	PPD	PPD (197)	PPD	2	1	TC	N
6	RESP	Throat irritation		PPD (32)		PPD (36)		5	1	N	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (PPD)	NOT RELATED/OTHER: PPD, not related to investigational product	2	51	Y
2	Resolved (PPD)	Study Treatment	3	1	N
3	Resolved (PPD)	Study Treatment	5	1	N
4	Resolved (PPD)	Study Treatment	4	2	N
5	Resolved (PPD)	Study Treatment	4	2	N
6	Resolved (PPD)	NOT RELATED/OTHER: related to sick contacts	2	11	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Past
			Present

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)

Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (184)	PPD
VACCINATION 4	BNT162b2	PPD (205)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD	PPD	PPD (48)		PPD (307)	PPD	260	
2	GENRL	Injection site pain		PPD (184)	PPD	PPD (185)		2	1
3	GENRL	Injection site pain		PPD (205)	PPD	PPD (206)		2	1
4	GENRL	Injection site pain		PPD (498)	PPD	PPD (499)		2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	26	Y
2	N	N	Resolved (PPD)	Study Treatment	3	1	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	N	N	Resolved (PPD)	Study Treatment	4	1	N
4	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	294	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD **; Date of Last Dose:** PPD

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (145)	PPD
VACCINATION 4	BNT162b2	PPD (166)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (479)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD	PPD	PPD (141)		PPD (395)		255	
2	GENRL	Fatigue		PPD (166)	PPD	PPD (167)		2	1
3	GENRL	Fatigue		PPD (480)		PPD (481)		2	1
4	GENRL	Injection site pain		PPD (145)	PPD	PPD (146)		2	1
5	GENRL	Injection site pain		PPD (166)	PPD	PPD (167)		2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	120	Y
2	TC	N	Resolved (PPD)	Study Treatment	4	1	N
3	N	N	Resolved (PPD)	Study Treatment	5	2	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	TC	N	Resolved (PPD)	Study Treatment	3	1	N
5	TC	N	Resolved (PPD)	Study Treatment	4	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (131)	PPD
VACCINATION 4	BNT162b2	PPD (153)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (469)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (493)		ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Yes	NOT RELATED/OTHER: PPD	5	25	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	OTHER

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 3	BNT162b2	PPD (194)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 4	BNT162b2	PPD (245)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (464)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (87)	PPD	PPD (362)	PPD	276
2	NERV	Sciatica		PPD (217)	PPD	PPD (218)	PPD	2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	1	87	Y
2	2	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Physical effort	3	24	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Past
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (208)	PPD
VACCINATION 4	BNT162b2	PPD (231)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (624)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Anaemia	PPD	PPD (604)	PPD	ONGOING	
2	INJ&P	PPD		PPD (624)	PPD	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	TC	N	Yes	NOT RELATED/OTHER: unknown	4	374	N
2			TC	N	Yes	NOT RELATED/OTHER: unknown	5	1	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (24)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (496)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	BLOOD	Anaemia	PPD	PPD (606)	PPD	PPD (679)	PPD	74
2	INJ&P	PPD		PPD (496)	PPD	PPD (678)	PPD	183

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Unknown	3	111	N
2		TC	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	3	1	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (24)	PPD
VACCINATION 3	BNT162b2	PPD (326)	PPD
VACCINATION 4	BNT162b2	PPD (346)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (542)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (87)	PPD	PPD (363)		277

Adverse Events							
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	64	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (23)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (460)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (460)	PPD	PPD (713)	PPD	254
2	PPD	PPD		PPD (706)	PPD	PPD (746)	PPD	41
3	PPD	PPD		PPD (696)	PPD	PPD (713)	PPD	18

Adverse Events							
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	3	1	Y
2	2	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	3	247	N
3	3	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	3	237	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (24)	PPD
VACCINATION 3	BNT162b2	PPD (207)	PPD
VACCINATION 4	BNT162b2	PPD (228)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (485)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Anaemia	PPD	PPD (662)	PPD	ONGOING	
2	INJ&P	PPD		PPD (485)	PPD	ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	TC	N	Yes	NOT RELATED/OTHER: PPD	5	178	N
2			N	N	Yes	NOT RELATED/OTHER: unknown	5	1	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	WITHDRAWAL BY SUBJECT

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (20)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (452)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	PPD	PPD	PPD	PPD (100)	PPD	PPD (103)	PPD	4	2
2	INFEC	Asymptomatic bacteriuria		PPD (254)	PPD	PPD (288)	PPD	35	2
3	INJ&P	PPD		PPD (200)	PPD	PPD (462)	PPD	263	
4	INJ&P	PPD		PPD (42)	PPD	PPD (103)	PPD	62	
5	HEPAT	PPD		PPD (467)	PPD	PPD (469)	PPD	3	3
6	METAB	PPD		PPD (467)	PPD	PPD (469)	PPD	3	3
7	INJ&P	PPD		PPD (462)	PPD	PPD (827)	PPD	366	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	81	N
2	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: it is unknown	2	235	N
3	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	181	Y
4	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	23	Y
5	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	3	16	N
6	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	3	16	N
7	N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	3	11	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (189)	PPD
VACCINATION 4	BNT162b2	PPD (211)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (465)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	MUSC	Back pain	PPD	PPD (43)	PPD	PPD (45)	PPD	3	1
2	GASTR	Diarrhoea		PPD (25)	PPD	PPD (25)	PPD	1	1
3	INJ&P	PPD		PPD (89)	PPD	PPD (365)		277	
4	BLOOD	Lymphadenopathy		PPD (466)	PPD	PPD (470)	PPD	5	1
5	MUSC	Neck pain		PPD (43)	PPD	PPD (45)	PPD	3	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	NOT RELATED/OTHER: muscular contracture	2	22	N
2	N	N	Resolved (PPD)	Study Treatment	2	4	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	68	Y
4	TC/TCN	N	Resolved (PPD)	Study Treatment	3	2	N
5	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: muscle contracture	2	22	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past
			Past
			Past

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (301)	PPD
VACCINATION 4	BNT162b2	PPD (321)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (526)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (103)	PPD	PPD (361)	PPD	259

Adverse Events							
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: it is unknown	2	81	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (186)	PPD
VACCINATION 4	BNT162b2	PPD (208)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (473)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PPD	PPD	PPD	PPD (551)	PPD	PPD (553)	PPD	3
2	INJ&P	PPD		PPD (473)	PPD	PPD (551)	PPD	79
3	NEOPL	Leiomyoma		PPD (537)	PPD	PPD (565)	PPD	29

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	3	TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	5	79	N
2		TC	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	5	1	Y
3	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	5	65	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (20)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (454)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	BLOOD	Anaemia	PPD	PPD (403)	PPD	PPD (486)	PPD	84
2	HEPAT	PPD		PPD (494)	PPD	PPD (496)	PPD	3
3	INJ&P	PPD		PPD (236)	PPD	PPD (507)	PPD	272
4	HEPAT	PPD		PPD (499)	PPD	PPD (507)	PPD	9

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	384	N
2	2	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	3	41	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3		TCN	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	217	Y
4	2	TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	3	46	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (198)	PPD
VACCINATION 4	BNT162b2	PPD (222)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (563)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (563)	PPD	PPD (657)	PPD	95

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		TC	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	5	1	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (186)	PPD
VACCINATION 4	BNT162b2	PPD (207)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (522)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (522)	PPD	ONGOING		
2	SKIN	Rash		PPD (26)	PPD	PPD (32)	PPD	7

Adverse Events							
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		TC	N	Yes	NOT RELATED/OTHER: unknown	5	1	Y
2	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	6	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP
Withdrawn	OPEN LABEL TREATMENT	PPD	LOST TO FOLLOW-UP

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (339)	PPD
VACCINATION 4	BNT162b2	PPD (358)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (535)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	METAB	Dehydration	PPD	PPD (289)	PPD	PPD (293)	PPD	5	3
2	INJ&P	PPD		PPD (19)	PPD	PPD (287)	PPD	269	
3	NERV	Headache		PPD (21)	PPD	PPD (29)	PPD	9	3
4	HEPAT	PPD		PPD (289)	PPD	PPD (293)	PPD	5	3
5	METAB	Hypernatraemia		PPD (289)	PPD	PPD (293)	PPD	5	3
6	INFEC	Urinary tract infection		PPD (160)	PPD	PPD (177)	PPD	18	3
7	GENRL	Injection site pain		PPD (1)	PPD	PPD (1)	PPD	1	1

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD ; Country: PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD ; Date of Last Dose: PPD

==========

Adverse Events

AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	270	N
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	19	Y
3	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Unknown	2	2	N
4	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	270	N
5	TC/TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	270	N
6	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	141	N
7	N	N	Resolved (PPD)	Study Treatment	1	1	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (20)	PPD
VACCINATION 3	BNT162b2	PPD (192)	PPD
VACCINATION 4	BNT162b2	PPD (213)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (476)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD	PPD	PPD (7)	PPD	PPD (77)		71	

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	7	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD **; Date of Last Dose:** PPD

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (252)	PPD
VACCINATION 4	BNT162b2	PPD (352)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (582)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (246)	PPD	PPD (328)	PPD	83

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	224	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD **; Date of Last Dose:** PPD

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (317)	PPD
VACCINATION 4	BNT162b2	PPD (337)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (520)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (107)	PPD	PPD (377)	PPD	271

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		TCN	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	2	86	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (33)	PPD

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD **; Date of Last Dose:** PPD

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Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (334)	PPD
VACCINATION 4	BNT162b2	PPD (356)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (533)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD	PPD	PPD (35)	PPD	PPD (324)	PPD	290	
2	INJ&P	PPD		PPD (210)	PPD	PPD (210)	PPD	1	2
3	INFEC	Urinary tract infection		PPD (135)	PPD	PPD (181)	PPD	47	3

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	3	Y
2	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	178	N
3	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: it is unknown	2	103	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (20)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (188)	PPD
VACCINATION 4	BNT162b2	PPD (214)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (466)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD	PPD	PPD (486)	PPD	PPD (549)	PPD	64	

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	21	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (170)	PPD
VACCINATION 4	BNT162b2	PPD (195)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (486)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (486)	PPD	PPD (749)		264
2	GENRL	Injection site pain		PPD (170)	PPD	PPD (171)		2
3	GENRL	Injection site pain		PPD (196)		PPD (196)		1
4	GENRL	Injection site pain		PPD (486)	PPD	PPD (487)		2

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	1	Y
2	1	N	N	Resolved (PPD)	Study Treatment	3	1	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
3	1	N	N	Resolved (PPD)	Study Treatment	4	2	N
4	1	N	N	Resolved (PPD)	Study Treatment	5	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (161)	PPD
VACCINATION 4	BNT162b2	PPD (180)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (491)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (491)	PPD	PPD (569)		79
2	INJ&P	PPD		PPD (569)		PPD ()		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	1	Y
2		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	79	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	PROTOCOL DEVIATION

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (172)	PPD
UNPLANNED VACCINATION	BNT162b2	PPD (302)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (575)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	REPRO	PPD	PPD	PPD (465)		PPD (559)		95
2	PPD	PPD		PPD (283)		PPD (283)		1
3	INJ&P	PPD		PPD (575)	PPD	PPD (626)		52
4	GENRL	Injection site pain		PPD (173)		PPD (173)		1
5	INJ&P	PPD		PPD (177)		PPD (283)		107
6	PPD	PPD		PPD (623)		PPD (628)		6

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: Unknown	4	164	N
2	1	N	Y	Resolved (PPD)	NOT RELATED/OTHER: Unknown	3	112	N
3		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	1	Y
4	1	N	N	Resolved (PPD)	Study Treatment	3	2	N
5		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	3	6	Y
6	3	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	49	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD ; Country: PPD

Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD ; Date of Last Dose: PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (23)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (474)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Injection site pain	PPD	PPD (24)		PPD (24)		1
2	GENRL	Injection site pain		PPD (474)	PPD	PPD (475)		2
3	GENRL	Malaise		PPD (24)		PPD (24)		1
4	INJ&P	PPD		PPD (474)	PPD	PPD (509)		36
5	NERV	Tension headache		PPD (51)		PPD (51)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC	N	Resolved (PPD)	Study Treatment	2	2	N
2	1	N	N	Resolved (PPD)	Study Treatment	3	1	N
3	2	TC	N	Resolved (PPD)	Study Treatment	2	2	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	3	1	Y
5	1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Tension	2	29	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	PROTOCOL DEVIATION

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (149)	PPD
UNPLANNED VACCINATION	BNT162b2	PPD (253)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (479)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	ENDO	Hypothyroidism	PPD	PPD (262)		ONGOING		
2	GENRL	Injection site pain		PPD (150)		PPD (151)		2
3	GENRL	Injection site pain		PPD (254)		PPD (254)		1
4	GENRL	Injection site pain		PPD (479)	PPD	PPD (479)		1
5	INJ&P	PPD		PPD (479)	PPD	PPD ()		
6	INJ&P	PPD		PPD (158)		PPD (414)		257

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	TC	N	Yes	NOT RELATED/OTHER: Unknown	4	10	N
2	2	N	N	Resolved (PPD)	Study Treatment	3	2	N
3	1	N	N	Resolved (PPD)	Study Treatment	4	2	N
4	1	N	N	Resolved (PPD)	Study Treatment	5	1	N
5		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	1	N
6		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	3	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (21)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (489)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Chills	PPD	PPD (22)		PPD (23)		2
2	INJ&P	PPD		PPD (489)	PPD	PPD (583)		95
3	GENRL	Pyrexia		PPD (22)		PPD (23)		2
4	NERV	Somnolence		PPD (22)		PPD (23)		2

Adverse Events							
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (PPD)	Study Treatment	2	2	N
2		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	3	1	Y
3	1	TC	N	Resolved (PPD)	Study Treatment	2	2	N
4	1	TC	N	Resolved (PPD)	Study Treatment	2	2	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD ; Country: PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD ; Date of Last Dose: PPD

==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present
			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (239)	PPD
VACCINATION 4	BNT162b2	PPD (260)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (470)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	MUSC	Back pain	PPD	PPD (63)		PPD (64)		2	2
2	GENRL	Injection site pain		PPD (260)	PPD	PPD (262)	PPD	3	1
3	INJ&P	PPD		PPD (470)	PPD	ONGOING			
4	INJ&P	PPD		PPD (49)		PPD (323)		275	
5	REPRO	PPD		PPD (18)		PPD (22)		5	2

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Occupational activity	2	42	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	N	N	Resolved (PPD)	Study Treatment	4	1	N
3	N	N	Yes	Study Treatment	5	1	N
4	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	28	Y
5	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	18	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	PROTOCOL DEVIATION

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
UNPLANNED VACCINATION	BNT162b2	PPD (239)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (451)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Injection site pain	PPD	PPD (452)		PPD (453)		2
2	INJ&P	PPD		PPD (451)	PPD	PPD (781)		331
3	INJ&P	PPD		PPD (2)		PPD (259)		258

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	N	N	Resolved (PPD)	Study Treatment	3	2	N
2		N	N	Resolved (PPD)	Study Treatment	3	1	N
3		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	2	Y

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past
			Past
			Past

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (138)	PPD
VACCINATION 4	BNT162b2	PPD (159)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (469)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (469)	PPD	PPD (581)		113
2	GENRL	Injection site pain		PPD (470)		PPD (470)		1
3	MUSC	Myalgia		PPD (160)		PPD (160)		1
4	GENRL	Pyrexia		PPD (160)		PPD (160)		1

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	1	Y
2	1	N	N	Resolved (PPD)	Study Treatment	5	2	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
3	1	TC	N	Resolved (PPD)	Study Treatment	4	2	N
4	1	TC	N	Resolved (PPD)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (24)	PPD

PFIZER CONFIDENTIAL SDTM Creation: 10MAR2023 (16:40) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_unblinded/C4591001_CSR_Safety_Narrative_AECI_AEICBER/profile. (Database Snapshot Date: 07MAR2023) Date of Generation: 26JUN2023 (14:47)

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (115)	PPD
VACCINATION 4	BNT162b2	PPD (134)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (447)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (447)	PPD	PPD (504)		58
2	PPD	PPD		PPD (433)		PPD (504)		72
3	NERV	Headache		PPD (135)		PPD (136)		2
4	GENRL	Injection site pain		PPD (135)		PPD (136)		2
5	GENRL	Injection site pain		PPD (448)		PPD (448)		1
6	INJ&P	PPD		PPD (510)		PPD (722)		213
7	GENRL	Pain		PPD (448)		PPD (448)		1

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	1	Y
2	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	300	N
3	1	TC	N	Resolved (PPD)	Study Treatment	4	2	N
4	1	TC	N	Resolved (PPD)	Study Treatment	4	2	N
5	1	TC	N	Resolved (PPD)	Study Treatment	5	2	N
6		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	64	N
7	1	TC	N	Resolved (PPD)	Study Treatment	5	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past
			Past

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 3	BNT162b2	PPD (113)	PPD
VACCINATION 4	BNT162b2	PPD (134)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (453)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (145)		PPD (399)		255
2	GENRL	Fatigue		PPD (113)	PPD	PPD (114)		2
3	NERV	Headache		PPD (113)	PPD	PPD (114)		2
4	NERV	Headache		PPD (135)		PPD (135)		1
5	INJ&P	PPD		PPD (453)	PPD	PPD ()		
6	GENRL	Pyrexia		PPD (113)	PPD	PPD (114)		2

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events

AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	12	Y
2	1	N	N	Resolved (PPD)	Study Treatment	3	1	N
3	1	N	N	Resolved (PPD)	Study Treatment	3	1	N
4	1	N	N	Resolved (PPD)	Study Treatment	4	2	N
5		N	N	Resolved (PPD)	NOT RELATED/OTHER: Unknown	5	1	N
6	1	N	N	Resolved (PPD)	Study Treatment	3	1	N

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Withdrawn	VACCINATION	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (101)	PPD
VACCINATION 4	BNT162b2	PPD (122)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (449)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	GENRL	Chills	PPD	PPD (449)	PPD	PPD (450)		2
2	METAB	Diabetes mellitus inadequate control		PPD (533)		PPD (587)		55
3	INJ&P	PPD		PPD (476)		PPD (715)		240
4	PPD	PPD		PPD (518)		PPD (587)		70
5	GENRL	Injection site pain		PPD (449)	PPD	PPD (450)		2
6	PPD	PPD		PPD (715)		PPD (718)		4
7	INFEC	Sepsis		PPD (582)		PPD (587)		6
8	REPRO	PPD		PPD (612)		PPD (715)		104
9	METAB	Type 2 diabetes mellitus		PPD (533)		ONGOING		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
10	GENRL	Injection site erythema	PPD	PPD (101)	PPD	PPD (101)	PPD	1
11	GENRL	Injection site swelling		PPD (101)	PPD	PPD (101)		1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (PPD)	Study Treatment	5	1	N
2	2	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	5	85	N
3		N	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	5	28	Y
4	3	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	70	N
5	1	N	N	Resolved (PPD)	Study Treatment	5	1	N
6	3	TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: Unknown	5	267	N
7	3	TC	Y	Resolved (PPD)	NOT RELATED/OTHER: bacterial	5	134	N
8	3	TCN	Y	Resolved (PPD)	NOT RELATED/OTHER: unknown	5	164	N
9	2	TC	N	Yes	NOT RELATED/OTHER: unknown	5	85	N
10	1	N	N	Resolved (PPD)	Study Treatment	3	1	N
11	1	N	N	Resolved (PPD)	Study Treatment	3	1	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (24)	PPD
VACCINATION 3	BNT162b2	PPD (102)	PPD
UNPLANNED VACCINATION	BNT162b2	PPD (222)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GASTR	Abdominal pain	PPD	PPD (184)		PPD (192)		9	1
2	GENRL	Injection site pain		PPD (102)	PPD	PPD (103)		2	1
3	INJ&P	PPD		PPD (95)		PPD (366)		272	
4	PPD	PPD		PPD (176)		PPD (211)		36	2
5	NEOPL	Uterine leiomyoma		PPD (131)		ONGOING			1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	NOT RELATED/OTHER: Degenerative fibroids	3	83	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
2	N	N	Resolved (PPD)	Study Treatment	3	1	N
3	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	72	Y
4	TCN	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	3	75	N
5	N	N	Yes	NOT RELATED/OTHER: Unknown	3	30	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	NO LONGER MEETS ELIGIBILITY CRITERIA

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (112)	PPD
UNPLANNED VACCINATION	BNT162b2	PPD (179)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (452)	PPD

Adverse Events										
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**
1	GASTR	Abdominal pain	PPD	PPD (162)		PPD (165)		4	2	N
2	PPD	PPD		PPD (161)		PPD (162)		2	2	TCN
3	NEOPL	Fibroadenoma of breast		PPD ()		ONGOING			1	N
4	NERV	Headache		PPD (112)	PPD	PPD (114)		3	1	N
5	GENRL	Injection site pain		PPD (112)	PPD	PPD (114)		3	1	N
6	GENRL	Injection site pain		PPD (179)	PPD	PPD (180)		2	1	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
7	INJ&P	PPD	PPD	PPD (116)		PPD (161)		46		N
8	MUSC	Myalgia		PPD (112)	PPD	PPD (114)		3	1	N
9	GENRL	Pyrexia		PPD (112)	PPD	PPD (114)		3	1	N

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Resolved (PPD)	NOT RELATED/OTHER: Secondary to PPD	3	51	N
2	Y	Resolved (PPD)	NOT RELATED/OTHER: PPD	3	50	N
3	N	Yes	NOT RELATED/OTHER: Unknown	2	1	N
4	N	Resolved (PPD)	Study Treatment	3	1	N
5	N	Resolved (PPD)	Study Treatment	3	1	N
6	N	Resolved (PPD)	Study Treatment	4	1	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
7	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	3	5	Y
8	N	Resolved (PPD)	Study Treatment	3	1	N
9	N	Resolved (PPD)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	PROTOCOL DEVIATION

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD ; **Country:** PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD ; **Date of Last Dose:** PPD

==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	≤24	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (197)	PPD
VACCINATION 4	BNT162b2	PPD (228)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (442)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	NERV	Headache	PPD	PPD (228)	PPD	PPD (228)	PPD	1
2	GENRL	Injection site pain		PPD (198)		PPD (199)		2
3	GENRL	Injection site pain		PPD (442)	PPD	PPD (442)		1
4	INJ&P	PPD		PPD (442)	PPD	ONGOING		
5	INJ&P	PPD		PPD (65)		PPD (334)		270
6	MUSC	Myalgia		PPD (198)		PPD (199)		2
7	GASTR	Nausea		PPD (198)		PPD (199)		2
8	GASTR	Nausea		PPD (228)	PPD	PPD (228)	PPD	1
9	GENRL	Pyrexia		PPD (198)		PPD (199)		2

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	TC	N	Resolved (PPD)	Study Treatment	4	1	N
2	1	TC	N	Resolved (PPD)	Study Treatment	3	2	N
3	1	N	N	Resolved (PPD)	Study Treatment	5	1	N
4		N	N	Yes	Study Treatment	5	1	N
5		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	45	Y
6	1	TC	N	Resolved (PPD)	Study Treatment	3	2	N
7	1	N	N	Resolved (PPD)	Study Treatment	3	2	N
8	1	N	N	Resolved (PPD)	Study Treatment	4	1	N
9	1	TC	N	Resolved (PPD)	Study Treatment	3	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (30)		PPD (293)		264

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		TC	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	9	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (21)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (476)	PPD

Adverse Events											
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**
1	INJ&P	PPD	PPD	PPD (46)		PPD (296)	PPD	251		N	N
2	PPD	PPD		PPD (296)	PPD	PPD (296)	PPD	1		N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	26	Y
2	Resolved (PPD)	NOT RELATED/OTHER: PPD	2	276	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	BNT162b2	PPD (1)	PPD
VACCINATION 2	BNT162b2	PPD (22)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (4)		PPD (266)		263

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	OTHER

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Past
			Past

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (187)	PPD
VACCINATION 4	BNT162b2	PPD (210)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (482)	PPD

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	INJ&P	PPD	PPD	PPD (386)		ONGOING	

Adverse Events									
AE Number	**Duration (Days)**	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		1	N	N	Yes	NOT RELATED/OTHER: PPD	4	177	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	Placebo	PPD (22)	PPD
VACCINATION 3	BNT162b2	PPD (146)	PPD
VACCINATION 4	BNT162b2	PPD (167)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (461)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	GENRL	Chills	PPD	PPD (168)	PPD	PPD (168)	PPD	1	1
2	GENRL	Injection site pain		PPD (167)	PPD	PPD (169)	PPD	3	1
3	GENRL	Injection site pain		PPD (146)	PPD	PPD (149)		4	1
4	INJ&P	PPD		PPD (461)	PPD	PPD (461)		1	
5	GASTR	Nausea		PPD (490)		PPD ()			1
6	GENRL	Pyrexia		PPD (168)	PPD	PPD (168)	PPD	1	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	Study Treatment	4	2	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
2	N	N	Resolved (PPD)	Study Treatment	4	1	N
3	N	N	Resolved (PPD)	Study Treatment	3	1	N
4	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	1	Y
5	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	5	30	N
6	N	N	Resolved (PPD)	Study Treatment	4	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Past
			Past
			Past
			Past

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): Placebo

Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD	PPD	PPD (11)		PPD (66)		56	
2	GENRL	Injection site pain		PPD (1)	PPD	PPD (2)	PPD	2	1

Adverse Events							
AE Number	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	1	11	Y
2	N	N	Resolved (PPD)	Study Treatment	1	1	N

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Withdrawn	FOLLOW-UP	PPD	LOST TO FOLLOW-UP

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	40	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
PPD			Present
			Present
			Present
			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (21)	PPD
VACCINATION 3	BNT162b2	PPD (99)	PPD
VACCINATION 4	BNT162b2	PPD (119)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (388)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**	**Toxicity Grade**
1	INJ&P	PPD	PPD	PPD (139)		PPD (398)		260	
2	GENRL	Fatigue		PPD (100)	PPD	PPD (101)	PPD	2	1
3	INFEC	Ophthalmic herpes zoster		PPD (39)		PPD (51)		13	1
4	GENRL	Injection site pain		PPD (99)	PPD	PPD (100)	PPD	2	1

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	4	21	Y
2	N	N	Resolved (PPD)	Study Treatment	3	2	N
3	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: Unknown	2	19	N
4	N	N	Resolved (PPD)	Study Treatment	3	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
PPD		

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	40	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
PPD			Present
			Present

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (23)	PPD
VACCINATION 3	BNT162b2	PPD (158)	PPD
VACCINATION 4	BNT162b2	PPD (178)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	RENAL	Dysuria	PPD	PPD (37)	PPD	PPD (50)	PPD	14
2	INJ&P	PPD		PPD (178)	PPD	ONGOING		

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	1	TC	N	Resolved (PPD)	NOT RELATED/OTHER: Unknown	2	15	N
2		N	N	Yes	NOT RELATED/OTHER: unknown	3	21	Y

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
PPD		

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Withdrawn	FOLLOW-UP	PPD	PROTOCOL DEVIATION

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
PPD	30	PPD		

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 1	BNT162b2	PPD (1)	PPD

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD ; Country: PPD

Vaccine Group (as Administered): BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD ; Date of Last Dose: PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 2	BNT162b2	PPD (20)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (442)	PPD

Adverse Events									
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	PPD	PPD	PPD	PPD (464)	PPD	PPD (482)	PPD	19
2	INJ&P	PPD		PPD (442)	PPD	PPD (697)		256
3	REPRO	PPD		PPD (571)	PPD	PPD (575)	PPD	5
4	GASTR	Vomiting		PPD (461)	PPD	PPD (512)	PPD	52

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	2	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	3	23	N
2		TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: unknown	3	1	Y
3	2	TC/TCN	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	3	130	N
4	1	N	N	Resolved (PPD)	NOT RELATED/OTHER: PPD	3	20	N

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
PPD	30	PPD		

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
PPD cm	PPD kg	PPD kg/m2	PPD (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
VACCINATION 1	Placebo	PPD (1)	PPD
VACCINATION 2	Placebo	PPD (19)	PPD

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Reason(s) for Narrative: PPD

Unique Subject ID: PPD **; Country:** PPD

Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)

Date of First Dose: PPD **; Date of Last Dose:** PPD

==========

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
VACCINATION 3	BNT162b2	PPD (193)	PPD
VACCINATION 4	BNT162b2	PPD (212)	PPD
THIRD DOSE BNT162b2	BNT162b2	PPD (437)	PPD

Adverse Events								
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**	**Duration (Days)**
1	INJ&P	PPD	PPD	PPD (193)	PPD	PPD (451)		259

Adverse Events								
AE Number	**Toxicity Grade**	**Action to Subject**	**SAE**	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1		N	N	Resolved (PPD)	NOT RELATED/OTHER: it is unknown	3	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: PPD
Unique Subject ID: PPD **; Country:** PPD
Vaccine Group (as Administered): Placebo => BNT162b2 Phase 2/3 (30 µg) => BNT162b2 (30 µg, 1 Dose)
Date of First Dose: PPD **; Date of Last Dose:** PPD
==========

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	PPD	
Completed	VACCINATION	PPD	
Completed	REPEAT SCREENING 1	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	REPEAT SCREENING 3	PPD	
Completed	OPEN LABEL TREATMENT	PPD	
Completed	FOLLOW-UP	PPD	

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