1. TITLE PAGE

Vaccine Name and Compound Number:	BNT162 RNA-Based COVID-19 Vaccines, Compound Number: PF-07302048
Report Title:	Interim Report – 6 Month Update: 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
Protocol Number:	Protocol C4591001
Sponsor:	BioNTech SE
Sponsor Agent:	Pfizer Inc
Phase of Development:	Phase 1/2/3
First Subject First Visit:	29 April 2020
Primary Completion Date:	Not applicable
Data Cutoff Date:	13 March 2021
Serology Completion Dates:	22 March 2021 (Phase 1, Visit 8 [post-Dose 2 blood draw] assay completed)
Name and Affiliation of Coordinating/Leading Investigator:	Stephen Thomas, MD SUNY Upstate Medical University 725 Irving Ave, Ste. 311 Syracuse, NY 13210 The names of the principal investigators, site addresses, and number of participants enrolled at each site are provided in the appendix titled List and Description of Investigators and Service Providers, Appendix 16.1.4.
Sponsor's Signatories:	John L. Perez, MD, MBA, MA Vice President, Vaccines Clinical Research and Development, Pfizer Inc

	Kenneth Koury, PhD Clinical Biostatistics Head, Vaccines Clinical Research and Development, Pfizer Inc Ugur Sahin, MD Chief Executive Officer, BioNTech SE
Internal Reports Referenced:	Final Analysis Interim CSR: C4591001 dated 03 December 2020
Date of Current Version:	29 April 2021
Date(s) of Previous Report(s):	Not applicable

GCP STATEMENT

This study was conducted in compliance with Good Clinical Practice (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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4. LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation	Definition
AE	adverse event
AESI	adverse event of special interest
BDR	blinded data review
BLQ	below the level of quantitation
BMI	body mass index
CDC	Centers for Disease Control and Prevention (United States)
COVID-19	coronavirus disease 2019
CRF	case report form
CRO	contract research organization
CSR	clinical study report
CV	curriculum vitae
DCT	data collection tool
DMC	data monitoring committee
e-diary	electronic diary
ECMO	extracorporeal membrane oxygenation
EU	European Union
FiO_2	fraction of inspired oxygen
FSFV	first subject 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
HCV Ab	hepatitis C virus antibody
HIV	human immunodeficiency virus
HR	heart rate
IA	interim analysis
ICD	informed consent document
ICH	International Council for Harmonisation
ICU	intensive care unit
IEC	independent ethics committee
IgG	immunoglobulin G
IND	Investigational New Drug
IRB	institutional review board
IRC	internal review committee
IRR	illness rate ratio
IRT	interactive response technology
LLOQ	lower limit of quantitation
LNP	lipid nanoparticle
MedDRA	Medical Dictionary for Regulatory Activities
modRNA	nucleoside-modified messenger ribonucleic acid
NAAT	nucleic acid amplification test

Abbreviation	Definition
N-binding	SARS-CoV-2 nucleoprotein binding
NT50	neutralizing titer 50
P2 S	SARS-CoV-2 full-length, P2 mutant, prefusion spike glycoprotein
PaO_2	partial pressure of oxygen, arterial
PD	protocol deviation
PT	preferred term
PY	person-years
QA	quality assurance
QTL	quality tolerance limit
RBD	receptor-binding domain
RCDC	reverse cumulative distribution curve
RDC	remote data capture
RNA	ribonucleic acid
RR	respiratory rate
SAE	serious adverse event
SAP	statistical analysis plan
SARS	severe acute respiratory syndrome
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SMQ	standardized MedDRA queries
SOC	system organ class
SpO_2	oxygen saturation as measured by pulse oximetry
TME	targeted medical event
US	United States
VE	vaccine efficacy
VOC	variant of concern
WBC	white blood cell

5. ETHICS

5.1. Independent Ethics Committee or Institutional Review Board

The final protocol, any amendments (Appendix 16.1.1), and ICD (Appendix 16.1.3.2) were reviewed and approved by the IRBs and/or IECs for each of the investigational centers participating in the study. The IRBs and IECs are listed in Appendix 16.1.3.1.

5.2. Ethical Conduct of the Study

This study was conducted in compliance with the ethical principles originating in or derived from the Declaration of Helsinki and in compliance with all ICH GCP guidelines. In addition, all local regulatory requirements were followed, in particular, those affording greater protection to the safety of trial participants.

5.3. Participant Information and Consent

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

A signed and dated informed consent was required before any study-specific activity was performed. If the participant was not able to legally sign consent, the investigator, or a person designated by the investigator, obtained a signed and dated ICD from each participant’s parent(s)/guardian(s) before any study-specific activity was performed. Informed consent was collected as detailed in the protocol. Refer to Appendix 16.1.1, Protocol Section 10.1.2 for further information regarding informed consent.

6. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

The study was 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 the study intervention, and for ensuring accurate completion of the CRFs and DCTs supplied by Pfizer.

This study was undertaken by Pfizer and BioNTech and conducted at 153 sites: 131 in the United States, 9 in Turkey, 6 in Germany, 4 in South Africa, 2 in Brazil, and 1 in Argentina (Appendix 16.1.4.1).

Refer to Appendix 16.1.4 for a list of investigators and sites (including participants by country) and a list of service providers and external clinical testing laboratories involved in this study. Refer to Appendix 16.1.10 for a list of internal and external clinical testing laboratories involved in this study, with the tests that they performed.

No sites were terminated from the study to date.

7. INTRODUCTION

This study is ongoing, and participants are continuing to be evaluated. The final analysis interim C4591001 CSR dated 03 December 2020, reported ongoing Phase 1 and Phase 2 safety and immunogenicity data, combined Phase 2/3 safety data, and completed prespecified hypothesis testing of efficacy. Efficacy analyses were event-driven, based on accrued events for all Phase 2/3 participants ≥12 years of age. The prespecified interim analysis was

conducted on an accrued 94 evaluable COVID-19 cases for the first primary efficacy endpoint (data cutoff date: 04 November 2020), and the final analysis was conducted on an accrued 170 evaluable COVID-19 cases for the first primary efficacy endpoint (data cutoff date: 14 November 2020).

Phase 1 evaluation of safety and immunogenicity dose-level finding results in participants 18 through 55 and 65 through 85 years of age led to the selection of 1 of 2 vaccine candidates, BNT162b1 and BNT162b2. Both constructs were safe and well tolerated (except for BNT162b1 at 100 µg). Given that the reactogenicity profile for BNT162b2 was more favorable than BNT162b1 in both younger and older adults with similar immunogenicity results, and with non-human primate challenge studies showing that BNT162b2 led to earlier virus clearance and no evidence of virus in the lung[1], BNT162b2 at the 30 µg dose level was selected and advanced into the Phase 2/3 expanded cohort and efficacy evaluation.

Phase 2 of the study (for which enrollment has completed) comprised the evaluation of safety and immunogenicity data for the first 360 participants 18 through 85 years of age (180 from active vaccine group and 180 from placebo group) that entered the study after completion of Phase 1 to evaluate BNT162b2 30 µg in a larger cohort. Overall, Phase 2 safety and immunogenicity results were consistent with those observed in Phase 1.

Phase 2/3 evaluated the efficacy of BNT162b2 30 µg, and provided additional safety, efficacy, and immunogenicity data in a larger population. Prespecified efficacy (event-driven) in participants ≥12 years of age (relatively few participants 12 through 15 years of age had enrolled in the study, and no COVID-19 cases in this age group accrued at that time) and ongoing safety data in participants ≥16 years of age with a median of at least 2 months of follow-up after Dose 2 and up to the data cutoff date of 14 November 2020 were previously reported in the final analysis interim CSR dated 03 December 2020.

At the time of the final analysis interim CSR dated 03 December 2020, the first 37,706 participants 16 through 91 years of age were analyzed for safety. Individuals 12 through 15 years of age were later permitted to enroll in the study, and results for these participants will be reported separately.

On 14 December 2020, the process of disclosing vaccine assignments for all trial participants ≥16 years of age began. Hence, for each trial participant, there are 2 periods in the study: enrollment into the observer-blind phase until the date of vaccine disclosure and the time in the study after disclosure. Participants who originally were randomized to BNT162b2, are continuing to be followed for safety as specified in the protocol. The safety data for participants who originally were randomized to and received placebo prior to disclosure of vaccine assignment are standard blinded data that contribute to controlled assessment of safety compared to individuals who were randomly assigned to BNT162b2. After vaccine treatment disclosure and the administration of BNT162b2, the placebo participants can no longer be used for direct comparison with those who originally were randomized to BNT162b2. Given that individuals were unblinded on different days after 14 December 2020, the analysis of the observer-blinded, placebo-controlled portion of the study as well as the open-label portion displays rates of AEs adjusted for exposure time.

Based on a data cutoff date of 13 March 2021, this interim C4591001 CSR summarizes 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)

8. STUDY OBJECTIVES AND ENDPOINTS

8.1. Phase 1

Refer to the final analysis interim C4591001 CSR dated 03 December 2020, Section 8 for the study objectives, estimands, and endpoints reported based on Appendix 16.1.1, Protocol Amendment 9.

The study objectives, estimands, and endpoints presented in Table 1 are from Appendix 16.1.1, Protocol Amendment 14. Only the primary safety (Dose 1 to unblinding date [up to approximately 6 months after Dose 2]) and partial secondary immunogenicity (6 months after Dose 2) objectives for the BNT162b2 30 µg or corresponding placebo are presented in this interim CSR. Exploratory objectives, estimands, and endpoints will be summarized at a later time.

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 • AEs from Dose 1 to 1 month after the last dose • SAEs from Dose 1 to 6 months after the last dose 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	• 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 Hematology and chemistry laboratory parameters detailed in Appendix 16.1.1, Protocol Section 10.2	Interim data for local reactions and systemic events reported up to 7 days after each dose, and AEs and SAEs are reported from Dose 1 to 1 month after the last dose for all groups evaluated, and to the cutoff date after Dose 2 for the BNT162b2 30 µg group only in 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 this CSR. Interim data are reported in final analysis interim CSR dated 03 December 2020.
Secondary:	**Secondary:**	**Secondary:**	
To describe the immune responses elicited by prophylactic BNT162 vaccines in healthy adults after 1 or 2 doses	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, 6, 12, and 24 months after Dose 2 • GMTs at each time point • 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	Interim data reported up to 1 month after Dose 2 in final analysis interim CSR dated 03 December 2020. Interim data up to 6 months after Dose 2 for the BNT162b2 30 µg group only are reported in this CSR.

Table 1. Phase 1 Objectives, Estimands, and Endpoints

Objectives	Estimands	Endpoints	Reference
	• 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	Interim data reported up to 1 month after Dose 2 in final analysis interim CSR dated 03 December 2020. Interim data of S1-binding IgG levels up to 6 months after Dose 2 for the BNT162b2 30 µg group only are reported in this CSR.
	• 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	Interim data reported up to 1 month after Dose 2 in final analysis interim CSR dated 03 December 2020. Interim data for SARS-CoV-2 neutralizing titers to S1-binding IgG levels up to 6 months after Dose 2 for the BNT162b2 30 µg group only are reported in this CSR.
Exploratory:	**Exploratory:**	**Exploratory:**	
To describe the immune responses elicited by a third dose of prophylactic BNT162b2 administered to healthy adults 6 to 12 months after the second dose of either BNT162b1 or BNT162b2	• GMC/GMT and GMFR at the time of Dose 3 and 7 days and 1 month after Dose 3.	• SARS-CoV-2 reference-strain neutralizing titers • SARS-CoV-2 SA-variant neutralizing titers • Full-length S-binding or S1-binding IgG levels	Data will be reported at a later time.
	• 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	Data will be reported at a later time.
	• 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	Data will be reported at a later time.

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	Data will be reported at a later time.

Source: Appendix 16.1.1, Protocol Section 3.1.

8.2. Phase 2/3

Refer to the final analysis interim C4591001 CSR dated 03 December 2020, Section 8 for the study objectives, estimands, and endpoints reported based on Appendix 16.1.1, Protocol Amendment 9.

The study objectives, estimands, and endpoints presented in Table 2 are from Appendix 16.1.1, Protocol Amendment 14. This report summarizes results as described in Section 7.

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 this CSR.
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	Interim data are reported in final analysis interim CSR dated 03 December 2020. Updated efficacy data are reported in this CSR.
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.

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

Objectives[a]	Estimands	Endpoints	Reference
To define the safety profile of prophylactic BNT162b2 in <u>all participants</u> 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: o Local reactions (pain at the injection site, redness, and swelling) o 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 are reported in this 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	Data will be reported separately.
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 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	Data will be reported at a later time.

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 compared to after 2 doses of BNT162b2, in the same individuals	GMR of reference strain NT 1 month after the third dose of BNT162b2 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 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) of past SARS-CoV-2 infection	Data will be reported at a later time.
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	Data will be reported at a later time.
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	Data will be reported at a later time.

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.
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 this CSR.
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 this CSR.
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.

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 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	Data will be reported at a later time.
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	Data will be reported at a later time.
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	Data will be reported separately.
BNT162b2-experienced participants			
To demonstrate the noninferiority of the anti-SA immune response after a third dose of BNT162b2 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 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 and seroresponse to the	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) of past SARS-CoV-2 infection	Data will be reported at a later time.

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

Objectives[a]	Estimands	Endpoints	Reference
	reference strain at 1 month after the second dose of BNT162b2		
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	Data will be reported at a later time.
To descriptively compare the anti-SA immune response after 1 dose of BNT162b2$_{SA}$ and a third dose of BNT162b2	GMR of SA NT 1 month after 1 dose of BNT162b2$_{SA}$ to 1 month after the third 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 1 month after the third dose of BNT162b2	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) of past SARS-CoV-2 infection	Data will be reported at a later time.
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	Data will be reported at a later time.
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	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	Data will be reported at a later time.

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

Objectives[a]	Estimands	Endpoints	Reference
	BNT162b2$_{SA}$ and 1 month after the second dose of BNT162b2		
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 BNT162b2$_{SA}$ 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	Data will be reported at a later time.
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 this CSR.
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 who received BNT162b2 (at initial randomization or subsequently): 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 will be reported at a later time.
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. Phase 2/3 data will be reported at a later time.

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

Objectives[a]	Estimands	Endpoints	Reference
To describe the incidence of non-S seroconversion to SARS-CoV-2 through the entire study follow-up period in participants who received BNT162b2 at initial randomization	In participants who received BNT162b2 at initial randomization: Incidence per 1000 person-years of follow-up	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	Data will be reported at a later time.
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	Data will be reported at a later time.
To describe the serological responses to the BNT vaccine candidate and characterize the SARS-CoV-2 isolate in cases of: • Confirmed COVID-19 • Confirmed severe COVID-19 • SARS-CoV-2 infection without confirmed COVID-19		• Full S-binding or S1-binding IgG levels • SARS-CoV-2 neutralizing titers • Identification of SARS-CoV-2 variants(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 only in participants with confirmed stable HIV disease are reported in this CSR.
To describe the safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with study intervention produced by manufacturing "Process 1" or "Process 2"[b]		• AEs • SAEs • SARS-CoV-2 neutralizing titers	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 be reported at a later time.
To describe the cell-mediated immune response, and additional humoral immune response parameters, to the			Data will be reported at a later time.

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

Objectives[a]	Estimands	Endpoints	Reference
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			

a. HIV-positive participants in Phase 3 were not included in analyses of the objectives, with the exception of the specific exploratory objective.
b. See Appendix 16.1.1, Protocol Section 6.1.1 for a description of the manufacturing process.
Source: Appendix 16.1.1, Protocol Section 3.2.

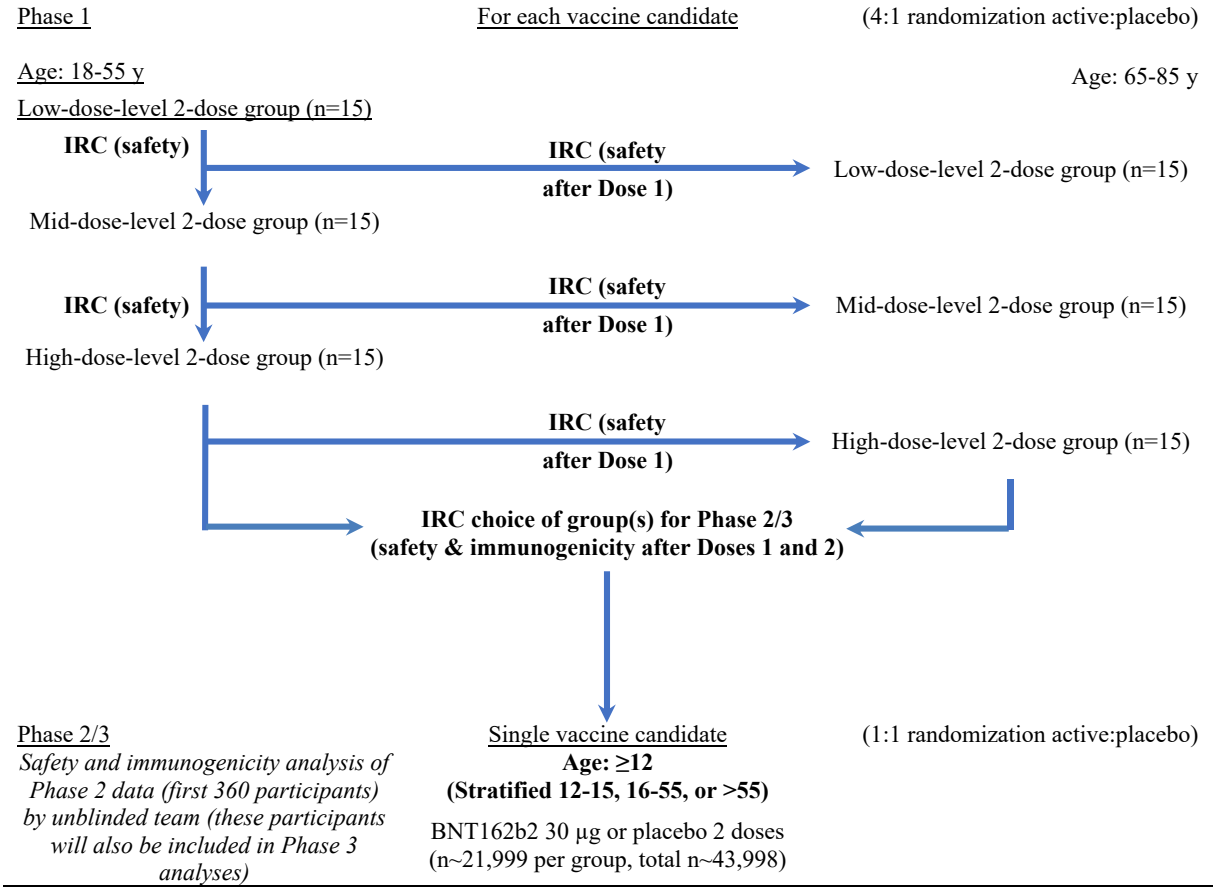
9. INVESTIGATIONAL PLAN

9.1. Overall Study Design and Plan

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

The study consists 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



Source: Appendix 16.1.1, Protocol Section 1.2
Note: Participants ≥16 years of age who originally received placebo were offered the opportunity to receive BNT162b2 at defined points as part of the study.

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; (data will be reported at a later time)
- 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 staff were unblinded to vaccine allocation for the participants in Phase 1, and remain blinded for the Phase 2/3 portion of study except those who were designated for unblinded activities following the protocol and the data blinding plan.

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

Planned Booster and Variant Strain Evaluation

Planned booster and VOC evaluation are not included in this report and will be reported at a later time.

Refer to Appendix 16.1.1, Protocol Section 4.1.1 for further details on the booster dose for Phase 1, and Appendix 16.1.1, Protocol Section 4.1.2 for further details on the booster dose and new cohort for Phase 2/3 to evaluate potential homologous and heterologous protection against emerging SARS-CoV-2 VOCs.

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, as follows:

- Phase 1 (after Visit 8).
- Phase 2/3, ≥16 years of age (after Visit 4).
- Phase 3, 12 through 15 years of age (after Visit 4).
- Original Phase 3 participants rerandomized to assess boostability and protection against emerging VOCs (after Visit 306) (data will be reported at a later time).

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.

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).

9.1.1. Phase 1

Each group (vaccine candidate/dose level/age group) was comprised of 15 participants randomized 4:1 to receive active vaccine or placebo (12 participants randomized to active vaccine and 3 to placebo, such that the placebo participants across the groups would produce a roughly comparably-sized cohort).

For each vaccine candidate/dose level/age group, safety precautions included: additional safety assessments (Section 9.5.2 and Appendix 16.1.1, Protocol Section 8.2), controlled enrollment, application of stopping rules, and IRC review of safety data to determine if dose escalation could proceed.

Groups of participants 65 to 85 years of age were not started until safety data for the RNA platform were deemed acceptable at the same, or a higher, dose level in the 18 to 55 years of age group by the IRC.

In this phase, 13 groups were studied, corresponding to a total of 195 participants.

Following review of all available safety and immunogenicity data through 14 days after Dose 2 for BNT162b1 and BNT162b2, both vaccine constructs were considered strong candidates to proceed to Phase 2/3. See Section 9.4.4 for details on selection of final candidate and dose for Phase 2/3.

Planned Evaluations

- A third dose of BNT162b2 30 µg will be given to Phase 1 participants approximately 6 to 12 months after their second dose of BNT162b1 or BNT162b2 to evaluate safety and immunogenicity for boostability and potential heterologous protection against emerging VOCs (Appendix 16.1.1, Protocol Section 4.1.1).

Participants were expected to participate for up to a maximum of approximately 26 months. Refer to Appendix 16.1.1, Protocol Section 4.1.1 for further details on the Phase 1 study design.

9.1.2. Phase 2/3

Safety and immunogenicity data generated during the Phase 1 portion of this study and the BioNTech study conducted in Germany (BNT162-01) supported BNT162b2 at a dose of 30 µg as the vaccine candidate to proceed into Phase 2/3 (see Section 9.4.4).

The Phase 2 part of the study was comprised of the first 360 participants enrolled (1:1 randomization between BNT162b2 and placebo, stratified by age groups [18 through 55 years and >55 through 85 years] with approximately 50% in each age stratum) to assess safety data through 7 days after Dose 2 and immunogenicity data through 1 month after Dose 2 from these Phase 2 360 participants. Enrollment continued during Phase 2 and these participants are included in the efficacy evaluation in the Phase 3 part of the study.

Participants in the ongoing Phase 3 part of the study are ≥12 years of age (stratified as 12 through 15, 16 through 55, or >55 years of age). The 12- through 15- year stratum comprised up to approximately 2000 participants enrolled at selected investigational sites. It was planned to enroll a minimum of 40% of participants in the >55 years of age stratum. Participants in Phase 3 were randomized 1:1 to receive either active vaccine or placebo.

Efficacy analyses for Phase 2/3 part of the study were event-driven. The prespecified interim analysis was conducted on an accrued 94 evaluable COVID-19 cases for the first primary efficacy endpoint (data cutoff date: 04 November 2020), and the final analysis was conducted on an accrued 170 evaluable COVID-19 cases for the first primary efficacy endpoint (data cutoff date: 14 November 2020). These data are reported in the final analysis interim CSR dated 03 December 2020 and included all study participants in the efficacy populations ≥12 years of age.

At the time of the final analysis of efficacy, relatively few participants 12 through 15 years of age had enrolled in the study, and no COVID-19 cases in this age group accrued at that time. Updated efficacy analyses during blinded placebo-controlled follow-up period were conducted on cases accrued up to the data cutoff date of 13 March 2021 to evaluate duration of protection. This report presents these analyses of all confirmed COVID-19 cases and any cases meeting protocol- and CDC-defined criteria for severe cases.

It is planned that participants would participate for approximately 26 months.

Planned Evaluations

Phase 2/3 (which is ongoing) includes additional planned analyses which are not included in this report and will be reported separately.

- In Phase 3, noninferiority of immune response to prophylactic BNT162b2 in participants 12 through 15 years of age to response in participants 16 through 25 years of age will be assessed based on the GMR of SARS-CoV-2 neutralizing titers using a 1.5-fold margin.

- The safety and immunogenicity of prophylactic BNT162b2 in individuals 16 through 55 years of age vaccinated with BNT162b2 manufactured with “Process 1” and each lot of BNT162b2 manufactured with “Process 2”, which was developed to support an increased scale of manufacture (Appendix 16.1.1, Protocol Section 6.1.1).

- Boostability and homologous/heterologous protection against emerging VOCs will allow the evaluation of safety and immunogenicity of BNT162b2$_{SA}$ (Appendix 16.1.1, Protocol Sections 4.1.1 and 4.1.2).

- An intensive period of surveillance to evaluate the efficacy of BNT162b2 against asymptomatic SARS CoV-2 infection is being conducted at selected sites among Phase 2/3 participants (Appendix 16.1.1, Protocol Section 8.1.5).

Refer to Appendix 16.1.1, Protocol Section 4.1.2 for further detail on the Phase 2/3 study design, including the planned analyses.

9.2. Discussion of Study Design, Including Choice of Control Groups

The purpose of the study is to describe the safety, tolerability, and immunogenicity of 2 BNT162 RNA-based COVID-19 vaccine candidates against COVID-19, and the efficacy of one (selected) candidate, in healthy individuals. To assess boostability in a subset of Phase 3 participants, a third candidate, will also be assessed against emerging SARS-CoV-2 VOCs.

The study is observer-blinded, as the physical appearance of the investigational vaccine candidates and the placebo may differ. The participant, investigator, study coordinator, and other site staff are blinded. At the study site, only the dispenser(s)/administrator(s) are unblinded.

The study consists of 3 placebo-controlled phases. Placebo is used as the control, as there is no licensed comparator vaccine available.

Phase 1 was designed to identify preferred vaccine candidate(s) and dose level(s) for further development based on safety, tolerability, and immunogenicity.

Phase 2 was designed to expand knowledge of the safety and immunogenicity of the vaccine candidate selected from Phase 1.

Phase 2/3 was designed to evaluate the efficacy of the vaccine candidate selected for development, and to provide additional safety and immunogenicity data in a larger population, including adolescents (adolescents were later permitted to enroll as part of Phase 3; data will be reported separately). Boostability will also be assessed.

Refer to Appendix 16.1.1, Protocol Section 4.2 for further detail of the rationale of the study design.

9.3. Participant Selection

Refer to the final analysis interim C4591001 CSR dated 03 December 2020, Sections 9.3.1, 9.3.2, 9.3.3, and 9.3.4 for inclusion criteria, exclusion criteria, criteria for temporarily delaying vaccine administration, and details for withdrawal of participants from the study, respectively, based on Appendix 16.1.1, Protocol Amendment 9. There were no changes to inclusion and exclusion criteria from Protocol Amendments 10 through 13. Refer to Appendix 16.1.1, Protocol Amendment 14, for updated inclusion and exclusion criteria of the subset of participants receiving the booster dose against emerging VOCs.

9.4. Investigational Product

9.4.1. Vaccines Administered

The vaccine candidate selected for Phase 2/3 evaluation was BNT162b2 at a dose of 30 µg. This report evaluated a 2-dose (separated by 21 days) schedule of the following for active immunization against COVID-19 or saline placebo:

- BNT162b2 (BNT162 RNA-LNP vaccine containing modRNA that encodes P2 S): 30 µg
- Normal saline (0.9% sodium chloride solution for injection)

Refer the final analysis interim C4591001 CSR dated 03 December 2020 for BNT162b1 and BNT162b2 other candidate dose levels previously evaluated.

Refer to Appendix 16.1.1, Protocol Sections 6.1 and 6.1.2 for details of the study intervention(s) and study intervention administration, including the planned BNT162b2$_{SA}$ variant.

9.4.2. Identity of Investigational Product(s)

Refer to Appendix 16.1.1, Protocol Section 6.2 for details on preparation, storage, and dispensing.

A list of the study interventions administered in this study and their respective lot numbers is provided in Table 3 below.

Table 3. Investigational Product Lot Numbers – Interim – 6 Month Update

Investigational Product	Phase	Manufacturer	Vendor Lot Number (Manufacturer)	Lot Number[a] (Pfizer)
BNT162b1 (10 µg, 20 µg, 30 µg, and 100 µg)	1	BioNTech	BCV10320-A	E220395-0001L
BNT162b2 (10 µg, 20 µg, and 30 µg)	1	BioNTech	BCV40420-A	E220395-0004L
Normal saline (0.9% sodium chloride solution for injection)	1	Pfizer	DK1589	20-001592
BNT162b2 (30 µg)	2/3	BioNTech	BCV40420-A	E220395-0006L003/P220395-0012L
			BCV40420-A	E220395-0035L002/P220395-0048L
			BCV40420-A	E220395-0035L003/P220395-0048L
			BCV40420-A	EU2065896/E220395-0004L

Table 3. Investigational Product Lot Numbers – Interim – 6 Month Update

			BCV40420-A	PA2070104/P220395-0008L
			BCV40620-A	PA2071394/P220395-0029L
			BCV40620-A	PA2072393/P220395-0019L
			BCV40620-B	PA2071395/P220395-0016L
			BCV40620-B	PA2072396/P220395-0016L
			BCV40620-C	PA2071396/P220395-0047L
			BCV40620-C	PA2072439/P220395-0047L
			BCV40620-D	PA2072442/P220395-0042L
			BCV40620-D	PA2072765/P220395-0042L
			BCV40720-A	PA2074172/P220395-0053L
			BCV40720-A	PA2074998/P220395-0060L
			BCV40720-B	PA2074173/P220395-0051L
			BCV40720-C	PA2074071/P220395-0052L
			ED3938	PA2074300/P220395-0021L
			ED3938	EU2074330/E220395-0036L
			ED3938	PA2074300/P220395-0022L
			ED3938	PA2074300/P220395-0023L
			EE3813	PA2074838/P220395-0024L
			EE3813	PA2074838/P220395-0020L
			EE8493Z	PA2077905/P220395-0026L
			EE3813	NC2075485/P220395-0068L
			EE3813	NC2075485/P220395-0074L
			EE3813	NC2075485/P220395-0077L
			EJ0553Z	PA2085061/P220395-0070L
Normal saline (0.9% sodium chloride solution for injection)	2/3	Pfizer	DK1589;20 - 001592	PA2064251/P220395-0005L
			DK1589;20 - 001776	PA2065311/P220395-0007L
			DK2074;20 - 002029	

Table 3. Investigational Product Lot Numbers – Interim – 6 Month Update

	DK2074;20 - 002108	PA2067775/P220395-0030L
	DK2074;20 - 002221	PA2067774/P220395-0013L
	DK2074;20 - 002221	PA2069407/P220395-0031L
	DK2074;20 - 002221	PA2069407/P220395-0032L
	DK2074;20 - 002221	PA2069407/P220395-0033L
	DK2074;20 - 002221	PA2069407/P220395-0034L
	DK2074;20 - 002221	PA2069407/P220395-0044L
	DK2074;20 - 002221	PA2069407/P220395-0045L
	DK2074;20 - 002221	PA2069407/P220395-0046L
	DK2074;20 - 002221	PA2069407/P220395-0054L
	DK2074;20 - 002221	PA2069407/P220395-0055L
	DK2074;20 - 002221	PA2069407/P220395-0056L
	DK2074;20 - 002221	PA2069407/P220395-0062L
	DK2074;20 - 002221	PA2069407/P220395-0065L
		PA2069407OTH/E220395-0049L

Note: C4591001 End of Study Information and Quality Control (QC) Record for Study Drug Appendix (Section D) dated 17Mar2021 was used to create this table.
a. Lot number assigned to the investigational product by Pfizer Global Clinical Supply.
Protocol C4591001 Investigational Product Lot Numbers Table – Interim – 6 Month Update, Final, Version 1.0, 18Mar2021.

9.4.3. Method of Assigning Participants to Treatment Groups

Allocation (randomization) of participants to vaccine groups proceeded through the use of an IRT system (IWR).

Refer to Appendix 16.1.1, Protocol Section 6.3.1 for details on investigational product assignment.

9.4.4. Selection of Dose Levels/Regimen

9.4.4.1. Phase 1

Section 9.4.1 provides details on the doses administered in Phase 1.

Refer to Appendix 16.1.1, Protocol Section 6 for details of the dose and regimen.

9.4.4.2. Phase 2/3

The totality of data from Phase 1 as reported in the final analysis interim C4591001 CSR dated 03 December 2020 identified BNT162b2 at 30 µg as the candidate for Phase 2/3 evaluation.

Refer to Appendix 16.1.1, Protocol Section 6 for details of the dose and regimen.

9.4.5. Blinding

The study staff receiving, storing, dispensing, preparing, and administering the study interventions were unblinded. All other study and site personnel, including the investigator, investigator staff, and participants, were blinded to study intervention assignments.

To facilitate rapid review of data in real time, Pfizer and BioNTech staff were unblinded to study intervention allocation for the participants in the Phase 1 portion of the study. The majority of sponsor staff and all personnel directly involved in study conduct were and remain blinded to study intervention allocation in Phase 2/3. All laboratory testing personnel performing serology assays remain blinded to study intervention assigned/received throughout all phases of the study. The following sponsor staff were unblinded in Phase 2/3 (further details are provided in a data blinding plan):

- Those study team members who were involved in ensuring that protocol requirements for study intervention preparation, handling, allocation, and administration are fulfilled at the site were unblinded at the site level for the duration of the study (eg, unblinded study manager, unblinded clinical research associate).

- Unblinded clinician(s), who were not direct members of the study team and did not participate in any other study-related activities, reviewed unblinded protocol deviations.

- An unblinded statistical team supporting interactions with, and interim analyses for, the DMC (see Appendix 16.1.1, Protocol Section 9.6) and the final analysis interim CSR (03 December 2020). This is comprised of a statistician, programmer(s), a clinical scientist, and a medical monitor who reviewed cases of severe COVID-19 as they were received, and reviewed AEs at least weekly for additional potential cases of severe COVID-19 (see Section 9.5.2.3).

- An unblinded submissions team was responsible for preparing documents to support regulatory activities that may have been required while the study is ongoing. This team was only unblinded at the group level and did not have access to individual participant assignments. The programs that produced the summary tables were developed and validated by the blinded study team, and these programs were run by the same unblinded statistical team supporting DMC reviews. The submissions team did not have access to unblinded COVID-19 cases unless efficacy was achieved at either an interim analysis or the final analysis, as determined by the DMC.

- After the formal data release of the final efficacy analysis of at least 164 first primary-endpoint cases, which was considered the primary completion of the study

efficacy objectives, additional limited statisticians and programmers were unblinded at the participant level to prepare unblinded analyses and other regulatory activities. A group of statisticians and programmers remained blinded as part of the blinded study team and continue supporting the blinded conduct of the study.

- After the study data used for submission became public, the blinded study team also had access to those data, and was unblinded at the group level.

- When a participant who originally received placebo received BNT162b2 per Appendix 16.1.1, Protocol Section 1.3.3, the study team was unblinded to the participant's original study intervention allocation.

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, as follows:

- Phase 1 (after Visit 8).

- Phase 2/3, ≥16 years (after Visit 4).

- Phase 3, 12 through 15 years (after Visit 4).

- Original Phase 3 participants rerandomized to assess boostability and protection against emerging VOCs (after Visit 306) (data will be reported at a later time).

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.

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, and Protocol Section 6.3.4 for circumstances when the blind could be broken.

9.4.6. Prior and Concomitant Vaccines, Medications, and Procedures

Prohibited During the Study

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

Refer to Appendix 16.1.1, Protocol Section 6.5 for details on prior and concomitant vaccines, medications and procedures that were allowed or prohibited.

9.4.7. Vaccine Compliance

Participants dosed at the site received study intervention directly from the investigator or designee, under medical supervision.

Refer to Appendix 16.1.1, Protocol Section 6.4 for details of compliance with study intervention.

9.5. Efficacy, Immunogenicity, and Safety Evaluations

9.5.1. Efficacy and Immunogenicity Evaluations

Efficacy (prespecified) was assessed for potential cases of COVID-19 and described in the final analysis interim C4591001 CSR dated 03 December 2020. The prespecified interim analysis was conducted on an accrued 94 evaluable COVID-19 cases (data cutoff date: 04 November 2020), and the final analysis was conducted on an accrued 170 evaluable COVID-19 cases for the first primary efficacy endpoint (data cutoff date: 14 November 2020). These analyses included data from all participants in Phase 3 age groups (12-15, 16-55, and >55 years of age) at the time of the analyses. Prespecified primary and secondary efficacy endpoint analyses were completed per protocol as of 14 November 2020, and no additional formal hypothesis testing of clinically confirmed COVID-19 cases is planned. At the time of the final analysis, there were relatively few participants 12-15 years of age enrolled in the study and no COVID-19 cases in this age group accrued at that time (14 November 2020). In this report, efficacy was assessed based on all cases in all participants ≥12 years of age accrued in blinded follow-up to a data cutoff date of 13 March 2021.

For immunogenicity testing, the following assays were performed in Phase 1 and Phase 2 and will be performed in Phase 2/3 with exception of the RBD-binding IgG assay:

- SARS-CoV-2 neutralization assay (reference strain and SA variant [data from SA variant will be reported at a later time])
- Full length S-binding or S1-binding IgG levels (most relevant to BNT162b2 which encodes P2 S)
- RBD-binding IgG level assay (most relevant to BNT162b1, which encodes the RBD, Phase 1 only, and previously reported in the final analysis interim C4591001 CSR dated 03 December 2020)

Refer to Appendix 16.1.1, Protocol Section 8.1 for details on efficacy and immunogenicity evaluations.

9.5.2. Safety Evaluations

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

9.5.2.1. Clinical Safety Laboratory Evaluations (Phase 1 Participants Only)

Clinical safety laboratory evaluations were only conducted for Phase 1 participants and described in Appendix 16.1.1, Protocol Section 8.2.1, and reported in the final analysis interim CSR dated 03 December 2020. The laboratory tests performed are described in Appendix 16.1.1, Protocol Appendix 2.

9.5.2.2. Electronic Diary

All participants in Phase 1 and a subset of at least the first 6000 participants randomized in Phase 2/3 recorded local reactions, systemic events, and antipyretic/pain medication usage for 7 days, following administration of study intervention using an e-diary. Any participants in Phase 3 who are HIV-positive or 12 through 15 years of age may also have been included in this subset. In addition, participants 16 through 17 years of age enrolled under Protocol Amendment 9 (finalized 29 October 2020) and onwards were included in the reactogenicity subset. All other participants, including those who originally received placebo and then received BNT162b2 under Protocol Amendment 10 and onwards, did not complete an e-diary but had their local reactions and systemic events reported as AEs in accordance with Appendix 16.1.1, Protocol Section 8.3.2 (see also Section 9.5.2.5).

Use of an e-diary allowed recording of these assessments within a fixed time window and provided an accurate representation of the participant's experience at that time. For participants who were not in the reactogenicity subset, local reactions and systemic events consistent with reactogenicity were reported as AEs (Section 9.5.2.5).

Refer to Appendix 16.1.1, Protocol Section 8.2.2 for additional details on use of the e-diary, including details for participants receiving the booster dose against emerging VOCs. Refer to Appendix 16.1.1, Protocol Section 8.2.2.2, Protocol Section 8.2.2.3, Protocol Section 8.2.2.4, Protocol Section 8.2.2.5 for details on grading of prompted local reactions, systemic events, fever, and use of antipyretic/pain medications, respectively.

9.5.2.3. Phase 1 Stopping Rules

Stopping rules were in place for all Phase 1 participants, based on review of AE data and e-diary reactogenicity data, until the start of Phase 2/3 or 30 days after the administration of the second dose of study intervention in Phase 1, whichever was later. These data were monitored on an ongoing basis by the investigator (or medically qualified designee), Pfizer, and BioNTech in order to promptly identify and flag any event that potentially contributes to a stopping rule.

Refer to Appendix 16.1.1, Protocol Section 8.2.3 for details on Phase 1 stopping rules.

9.5.2.4. Surveillance of Events That Could Represent Vaccine-Associated Enhanced COVID-19 and Phase 2/3 Stopping Rule

Participants in all phases of the study were surveilled for potential COVID-19 illness from Visit 1 onwards. If a participant experienced any potential symptoms for COVID-19 illness, a COVID-19 illness and subsequent convalescent visit (in-person or telehealth) occurred. As part of these visits, samples (nasal [midturbinate] swab and blood) were taken for antigen and antibody assessment as well as recording of COVID-19–related clinical and laboratory information (including local diagnosis).

During Phase 1, Pfizer and BioNTech conducted unblinded reviews of the data, including for the purpose of safety assessment. All NAAT-confirmed cases in Phase 1 were reviewed contemporaneously by the IRC and the DMC.

In Phase 2/3, the unblinded team supporting the DMC, including an unblinded medical monitor, reviewed cases of severe COVID-19 as they were received and reviewed AEs at least weekly for additional potential cases of severe COVID-19. At any point, the unblinded team may have discussed with the DMC chair whether the DMC should review cases for an adverse imbalance of cases of COVID-19 and/or severe COVID-19 between the vaccine and placebo groups.

The stopping rule was triggered when the 1-sided probability of observing the same or a more extreme case split was 5% or less when the true incidence of severe disease was the same for vaccine and placebo participants, and alert criteria were triggered when this probability was less than 11%. In addition, when the total number of severe cases was low (15 or less), the unblinded team supporting the DMC implemented the alert rule when a reverse case split of 2:1 or worse was observed.

When the total number of severe cases was 20 or less, the stopping rule and alert rules in Appendix 16.1.1, Protocol Table 10 and Table 11, respectively, applied.

Refer to Appendix 16.1.1, Protocol Section 8.13 for details on COVID-19 surveillance, and Protocol Section 8.2.4 for details on Phase 2/3 stopping rules.

9.5.2.5. Adverse Events and Serious Adverse Events

AEs were collected during the study from the signing of the ICD through and including 1 month after Dose 2 (Visit 7 for Phase 1 participants and Visit 3 for Phase 2/3 participants).

Acute reactions (immediate AEs) were collected within the first 4 hours after administration of the study intervention (for the first 5 participants vaccinated in each Phase 1 group), and within the first 30 minutes (for the remainder of participants).

SAEs were collected from the signing of the ICD to approximately 6 months after the last dose of study intervention (Visit 8 for Phase 1 participants and Visit 4 for Phase 2/3 participants).

Additionally, for those participants who originally received placebo but went on to receive BNT162b2 at Vaccinations 3 and 4, AEs were collected from the time the participant

provided informed consent (for receipt of Vaccinations 3 and 4) through and including Visit 103. SAEs were collected from the time the participant provides informed consent (for receipt of Vaccinations 3 and 4) to approximately 6 months after the second dose of BNT162b2 (Visit 104).

Refer to Appendix 16.1.1, Protocol Section 8.3 for additional details for collecting AEs and SAEs, including details for participants receiving the booster dose against emerging VOCs.

9.5.2.6. Events of Special Interest

While AESIs were not prespecified in the protocol, Pfizer utilizes a safety review as part of the signal detection processes that highlights specified TMEs of clinical interest. TMEs are specific AE terms reviewed on an ongoing basis by routine safety data review procedures throughout the clinical study. Although not prespecified in the protocol, TMEs are maintained in a separate list as part of the Safety Surveillance Review Plan for the vaccine program. By definition, TMEs are considered to be AESIs specific for a product or program's protocol(s). They are based on review of known pharmacology, toxicology findings, possible class effects, published literature, and potential signals arising from safety data assessments.

The list of TMEs is customized for each development program and is dynamic. For this study, the list of TMEs includes events of interest because of their association with COVID-19 and terms of interest for vaccines in general. Terms are chosen from the MedDRA dictionary and may include PTs, high level term, high level group terms, or standardized MedDRA queries (SMQs; all evaluated as broad and narrow).

Other events of clinical interest identified by the sponsor were also reviewed and summarized (Section 12.2.4.4).

9.6. Data Quality Assurance

A number of steps were taken in the planning and implementation of this study to ensure that the data collected were accurate, consistent, complete, and reliable. This study used an RDC system and handheld diary device or application. The CRFs were designed to be used with ease.

Investigators were required to review the diary data online at frequent intervals to evaluate participant compliance and as part of the ongoing safety review. Furthermore, diary data were made available to Pfizer and Pfizer's representative online to enable ongoing review.

Representatives of Pfizer conducted routine reviews, using both on-site and remote access options with the investigational sites while the study was in progress to check the accuracy and completeness of the data being entered into the RDC system. During these visits, critical data were verified against participant source documents, and queries regarding missing or contradictory data were resolved. In addition, study procedures were reviewed, and protocol deviations were discussed with the investigator. Telephone and email contact was maintained with the investigators between site visits. In addition, the overall study conduct was subject to internal quality review by Pfizer.

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.

The accuracy of the clinical database was verified through a series of processes. Potential errors were identified through the generation of automatic queries during data entry and manual queries during data review. Clinical data were reviewed on an ongoing basis, and a BDR was conducted to identify any undetected data issues or concerns requiring correction. Once all participant data had been entered and all data queries closed, a final data management review was performed, and the database was declared ready for statistical analysis.

This CSR has been subject to quality control review by Pfizer or Pfizer's designee.

Quality assurance audits were performed at selected sites by Pfizer's own independent quality assurance group or by a CRO and/or individual contract personnel under the group's direction. These audits were conducted according to Pfizer's procedures and GCP guidelines.

Refer to the final analysis interim C4591001 CSR dated 03 December 2020 for previously reported data quality issues.

9.7. Statistical Methods Planned in the Protocol

9.7.1. Statistical and Analytical Plans

Detailed methodology for summarization and statistical analyses of the data collected in this study is documented in the SAP (Appendix 16.1.9). Any major modifications of the primary endpoint definition and/or its analysis subsequent to the protocol finalization were reflected in a protocol amendment.

9.7.1.1. Analysis Sets

The analysis populations presented in this report are defined in Table 4.

Refer to Appendix 16.1.9, SAP Section 4 for details of all other planned analysis sets, including planned immunogenicity populations for the booster dose and efficacy populations for seroconversion and asymptomatic surveillance.

Table 4. Analysis Populations

Population	Description
Enrolled	All participants who had a signed ICD.
Randomized	All participants who were assigned a randomization number in the IWR system.
Dose 1 evaluable immunogenicity	For Phase 1 only, all eligible randomized participants who received the vaccine to which they were randomly assigned at the first dose, had at least 1 valid and determinate immunogenicity result from the blood collection within an appropriate window after Dose 1 (same as visit window, ie, within 19-23 days after Dose 1) and had no other important protocol deviations as determined by the clinician.
Dose 2 evaluable immunogenicity	All eligible randomized participants who received 2 doses of the vaccine to which they were randomly assigned, with Dose 2 received within the predefined window (19-42 days after Dose 1), had at least 1 valid and determinate immunogenicity result from the

Table 4. Analysis Populations

Population	Description
	blood collection within an appropriate window after Dose 2 (6-8 days after Dose 2 for Phase 1 and 28-42 days after Dose 2 for Phase 2/3), and had no other important protocol deviations as determined by the clinician.
Dose 1 all-available immunogenicity	For Phase 1 only: all randomized participants who received at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 1 but before Dose 2.
Dose 2 all-available immunogenicity	All randomized participants who received at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 2.
Evaluable efficacy (7 days)	All eligible randomized participants who received all vaccination(s) as randomized, with Dose 2 received within the predefined window (19-42 days after Dose 1) and had no other important protocol deviations as determined by the clinician on or before 7 days after Dose 2.
Dose 1 all-available efficacy	All randomized participants who received at least 1 vaccination.
Dose 2 all-available efficacy	All randomized participants who completed 2 vaccination doses.
Safety	All randomized participants who received at least 1 dose of the study intervention.

9.7.2. 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.

9.7.3. Efficacy Analysis

The efficacy assessment in Phase 2/3 portion of the study was event-driven. VE with respect to the first primary efficacy endpoint was assessed at the first interim analysis (at least 62 cases) at 94 cases (data cutoff date: 04 November 2020). At the final analysis VE with respect to the first primary efficacy endpoint (at least 164 cases) was assessed on an accrued 170 evaluable COVID-19 cases(data cutoff date: 14 November 2020) and also included VE for the second primary and all secondary efficacy endpoints. No additional formal hypothesis testing of clinically confirmed COVID-19 cases is planned.

Assessment of VE of BNT162b2 was performed for confirmed COVID-19 cases observed at least 7 days after the receipt of Dose 2 onwards among participants either without or with or without serological or virological evidence (up to 7 days after receipt of the second dose) of past SARS-CoV-2 infection. VE was estimated by 100% × (1 – IRR), where IRR was the ratio of COVID-19 illness rate in the BNT162b2 group to the corresponding illness rate in the placebo group (Appendix 16.1.9, SAP Appendix 3 with details on the calculation of IRR and VE).

Updated descriptive efficacy analyses during blinded placebo-controlled follow-up were conducted based on the data cutoff date of 13 March 2021 for the primary efficacy endpoints and for the secondary efficacy endpoint of severe disease, including subgroup analyses.

The point estimate of VE in the blinded follow-up period and associated 2-sided 95% CI was derived using the Clopper Pearson method adjusted for surveillance time, and the posterior

probability (ie, P[VE >30%|data]) was provided for the primary endpoints and secondary endpoints of severe disease. In addition to the protocol definition of severe COVID-19, supportive analyses using the CDC definition of severe COVID-19 was also performed.

COVID-19 cases and severe COVID-19 cases occurring after Dose 1 were also summarized descriptively and previously reported in the final analysis interim C4591001 CSR dated 03 December 2020. Updated COVID-19 and severe COVID-19 cases after Dose 1 were summarized descriptively based on the data cutoff date of 13 March 2021.

The efficacy analysis for Phase 2/3 is also described in Appendix 16.1.1, Protocol Section 9.4.2 and Appendix 16.1.9, SAP Section 6.1.3 (primary), SAP Section 6.2.2 (secondary), and SAP Section 6.3.2 (exploratory).

9.7.4. Immunogenicity Analysis

For immunogenicity results of SARS-CoV-2 neutralizing titers and S1- or RBD-binding IgG concentrations, the GMT or GMCs were computed along with associated 95% CIs. The GMT and GMC were calculated as the means of assay results after making the logarithm transformation and then exponentiating the means to express results on the original scale. Two-sided 95% CIs were obtained by taking log transforms of assay results, calculating the 95% CIs with reference to Student's t-distribution, and then exponentiating the confidence limits.

The GMFR was calculated by exponentiating the mean of the difference of logarithmically transformed assay results (later time point – earlier time point). Two-sided CIs were obtained by calculating CIs using Student's t-distribution for the mean difference of the logarithmically transformed assay results and exponentiating the confidence limits.

The GMR was calculated as the mean of the difference of logarithmically transformed assay results (eg, SARS-CoV-2 neutralizing titers minus S1-binding IgG levels for each participant) and exponentiating the mean. Two-sided CIs were obtained by calculating CIs using Student's t-distribution for the mean difference of the logarithmically transformed assay results and exponentiating the confidence limits.

The exact 95% CIs for binary endpoints were computed using the F distribution (Clopper-Pearson method).

Titers/concentrations below the LLOQ or denoted as BLQ were set to 0.5 × LLOQ for analysis.

The immunogenicity analysis is further described in Appendix 16.1.1, Protocol Section 9.4.1, and Appendix 16.1.9, SAP Sections 6.2.1.1 through 6.2.1.3 for Phase 1, and Appendix 16.1.9, SAP Section 6.2.1.4 and SAP Section 6.3.3 for Phase 2/3.

9.7.5. Safety Analysis

The primary safety objective was evaluated by descriptive summary statistics for local reactions, systemic events, AEs/SAEs, and abnormal hematology and chemistry laboratory parameters (Phase 1 only; reported in the final analysis interim C4591001 CSR dated

03 December 2020), for each vaccine group. A 3-tier approach was used to summarize AEs in Phase 2/3. Under this approach, AEs were classified into 1 of 3 tiers:

- Tier 1 events are prespecified events of clinical importance and are identified in a list in the product's Safety Review Plan; there are no Tier 1 AEs identified for this program.
- Tier 2 events were those that were not Tier 1 but were considered "relatively common"; a MedDRA preferred term is defined as a Tier 2 event if there are at least 1% of participants with the AE term in at least 1 vaccine group.
- Tier 3 events were those that were neither Tier 1 nor Tier 2.

The safety analysis is described in Appendix 16.1.1, Protocol Section 9.4.3, and Appendix 16.1.9, SAP Section 6.1.1 (primary) and SAP Section 6.3.1 (exploratory for Phase 1 boostability assessment only).

9.7.6. Other Analyses

The safety results for individuals with confirmed stable HIV disease were summarized descriptively. Furthermore, VE may be assessed if there is a sufficient number of COVID-19 cases in this group of participants.

AEs and SAEs reported during the open-label follow-up period were summarized separately for participants who were unblinded at the time of being eligible for receipt of BNT162b2 according to recommendations detailed separately, and available in the electronic study reference portal, or no later than at approximately Visit 4. To account for different durations of follow-up time due to unblinding in the study, AEs and SAEs during the blinded follow-up period and open label follow-up period were summarized as incidence rates adjusted by exposure time.

Other analyses are described in Appendix 16.1.1, Protocol Section 9.4.4, and Appendix 16.1.9, SAP Section 6.3.4.

9.7.7. Analysis Timing

During Phase 1, Pfizer and BioNTech conducted unblinded reviews of the data for the purpose of safety assessment, facilitating dose escalation decisions, and/or supporting clinical development.

During Phase 2/3, IAs were planned to be performed by an unblinded statistical team after accrual of at least 62, 92, and 120 cases. For operational reasons, the first interim analysis was conducted after accrual of at least 62 first primary-endpoint cases (94 cases), and the final interim analysis of efficacy was conducted after accrual of at least 164 first primary-endpoint cases (170 cases).

Statistical analyses were described for the following data in the final analysis interim C4591001 CSR dated 03 December 2020:

- Complete safety and immunogenicity analysis approximately 1 month after Dose 2 for Phase 1. Results for participants randomized to BNT162b1 100 μg summarized up to 3 weeks after Dose 1 for safety, and approximately 7 weeks after Dose 1 for immunogenicity.

- Safety data through 7 days after Dose 2 and immunogenicity data through 1 month after Dose 2 (immunogenicity not available at this time) from the first 360 participants enrolled (180 to active vaccine and 180 to placebo, stratified equally between 18 to 55 years and >55 to 85 years) in Phase 2/3.

- Safety data through 1 month after Dose 2 from at least 6000 participants ≥16 years of age enrolled (3000 to active vaccine and 3000 to placebo) in Phase 2/3. Additional analyses of safety data (with longer follow-up and/or additional participants) may have been conducted if required for regulatory purposes.

- An interim analysis for efficacy was conducted after accrual of at least 62 cases for the first primary endpoint (conducted at 94 cases), and the final analysis of efficacy was conducted after accrual of at least 164 cases for the first primary endpoint (conducted at 170 cases).

Statistical analyses were carried out as the following data became available and are reported in this CSR:

- Safety analysis up to approximately 6 months after Dose 2 for participants ≥16 years of age in Phase 2/3, and safety and immunogenicity analysis for Phase 1 participants in the BNT162b2 30 μg dose group.

- Updated efficacy analysis based on the data cutoff date of 13 March 2021.

Statistical analyses are or will be carried out as the following data become available and reported separately:

- Safety data through 1 month after Dose 2 and noninferiority comparison of SARS-CoV-2 neutralizing titers in participants 12 through 15 years of age compared to those in participants 16 through 25 years of age, 1 month after Dose 2.

- Descriptive analysis of immunogenicity and safety of “Process 1” and “Process 2” material, 1 month after Dose 2.

- Complete safety and immunogenicity analysis approximately 1 month after Dose 3 for Phase 3 participants included in the booster evaluation and approximately 1 month after Dose 2 for newly enrolled Phase 3 participants included in the BNT162b2$_{SA}$ evaluation.

- Analysis of efficacy against asymptomatic SARS-CoV-2 (determined by asymptomatic seroconversion of N-binding antibody and/or asymptomatic SARS-CoV-2 infection based on central laboratory–confirmed NAAT) when a sufficient number of cases have accrued to evaluate the objective(s).

- Complete immunogenicity analysis approximately 6 months after Dose 2 for all participants in Phase 2/3.

- Complete efficacy and persistence-of-immunogenicity analysis after data are available or at the end of the study.

All analyses conducted on Phase 2/3 data while the study is ongoing was performed by an unblinded statistical team.

The analysis timing is described in Appendix 16.1.1, Protocol Section 9.5, and Appendix 16.1.9, SAP Section 7.

9.8. Changes in the Conduct of Study or Planned Analyses

Changes in study conduct are described in Appendix 16.1.1, Protocol Amendment Summary of Changes Table. Changes to the original planned analysis are described in SAP v5.0 (Appendix 16.1.9, SAP Section 1).

Additional changes in study conduct or planned analysis not noted in the protocol or SAP were previously reported in Section 9.8 of the final analysis interim C4591001 CSR dated 03 December 2020. Changes in study conduct or planned analysis not noted in the protocol or SAP in this interim CSR were as follows:

- In Phase 2/3, for participants in the blinded placebo-controlled follow-up period and for original placebo participants in the open-label follow-up period who then received BNT162b2 after unblinding, summary tables of AEs within 7 days after each dose were generated in order to evaluate whether AEs reported may have been attributed to reactogenicity events in participants who did not have an e-diary to report reactogenicity. Although this was not specified in the SAP, this was prespecified in analysis and reporting plan before database release.

- Additional summary tables for efficacy were generated to evaluate the imbalance of important PDs in the BNT162b2 group compared with placebo group observed in the evaluable efficacy (7 days) population, and to assess additional subgroups by age, risk status, and comorbidity status.

10. STUDY PARTICIPANTS

10.1. Disposition of Participants

10.1.1. Phase 1

Refer to Section 10.1.1 of the final analysis interim C4591001 CSR dated 03 December 2020 for disposition of all Phase 1 participants up through the data cutoff date of 24 August 2020.

Disposition of all Phase 1 participants randomized to the BNT162b2 30 µg or corresponding placebo are presented in Supplemental Table 14.1. All participants in each age group (18 through 55 and 65 through 85 years) randomized to the BNT162b2 group completed the visit at 6 months after Dose 2, with most of these visits occurring during the open-label

follow-up period. All participants in each age group randomized to the placebo group received both doses of BNT162b2 (Dose 3 and Dose 4 in the study) during the open-label period and completed the visit at 1 month after Dose 4, as of the data cutoff date of 13 March 2021. No participants were withdrawn from the study up to the data cutoff date.

10.1.2. Phase 2/3 Participants ≥16 Years of Age

The disposition of all Phase 2/3 participants randomized is presented for the blinded placebo-controlled and open-label follow-up periods in Table 5. In this ongoing study, tables summarizing participant withdrawals may include some participants who were reported as withdrawn but remain in the study and are continuing to be evaluated. These participants are documented in the Errata.

10.1.2.1. Blinded Placebo-Controlled Follow-Up Period

During the blinded placebo-controlled follow-up period, most participants randomized received Dose 1 (99.8%) and Dose 2 (98.1%). There were 352 (1.6%) participants in the BNT162b2 group and 528 (2.4%) participants in the placebo group who discontinued from the vaccination period (Dose 1 to 1 month after Dose 2) (Table 5). Most participants completed the visit at 1 month post-Dose 2 (≥96.4%). Few participants in the BNT162b2 and placebo groups were withdrawn from the study (1.6% and 2.2%, respectively), and most were due to withdrawals by the participant, or they were lost to follow-up.

There were 7 participants with special data issues: 8 participant identification numbers from 4 participants who enrolled into the study more than once and 3 participants whose vaccine assignment was not confirmed in the IRT at the time of data cutoff.

- Three participants who were randomized and vaccinated, but actual vaccine assignment was not confirmed in IRT at the time of data cutoff (Appendix 16.2.5.2). Participants were vaccinated as per CRF, but due to the inability to confirm consistency between the data in the CRF and IRT, these participants were not assigned to any actual dosing group. Safety data from these 3 participants were excluded from safety summary tables but their safety data are listed separately(Table 8, Appendix 16.2.7.2.3, Appendix 16.2.7.3.3, and Appendix 16.2.7.4.3).

- During the conduct of this study, 4 participants were each randomized twice with different participant identification numbers at 2 different sites. Because the significant misconduct of these participants compromised the integrity of the study data, results from these participants were excluded from all efficacy and safety analyses, including disposition and demographic tabulations. These participants who were discontinued from vaccination and/or from the study are listed separately (Appendix 16.2.1.2).

10.1.2.2. Open-Label Follow-Up Period

Individuals ≥16 years of age have been 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 continue to be followed in an open-label manner. Unblinded recipients originally randomized to placebo are offered BNT162b2

vaccination (Doses 3 and 4 [first and second dose of BNT162b2 30 µg, respectively]) and thereafter followed in an open-label manner.

Most participants in the BNT162b2 (96.8%) and placebo (96.4%) groups completed the 1 month post-Dose 2 visit before unblinding (Table 5).

A total of 87 (0.4%) Phase 2/3 original BNT162b2 participants received Dose 1 of BNT162b2 during the blinded placebo-controlled follow-up period and then received Dose 2 of BNT162b2 30 µg during the open-label follow-up period (when they were unblinded). There were 105 (0.5%) participants withdrawn from the study, and most were due to withdrawals by the participant or because of a protocol deviation.

During the open-label follow-up period, most participants originally randomized in the placebo group received Doses 3 and 4 (88.8% and 72.4%, respectively) of BNT162b2. There were few participants in this group (0.1%) who were withdrawn from the study, and most were due to withdrawals by the participant.

The disposition of HIV-positive participants is included in this summary but summarized separately in safety analyses.

Disposition of all participants ≥16 years of age randomized was similar by age group (Supplemental Tables 14.15 and 14.16).

Table 5. Disposition of All Randomized Subjects – Phase 2/3 Subjects ≥16 Years of Age

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=22085) n[b] (%)	**Placebo (N[a]=22080) n[b] (%)**	**Total (N[a]=44165) n[b] (%)**
Randomized	22085 (100.0)	22080 (100.0)	44165 (100.0)
Not vaccinated	55 (0.2)	50 (0.2)	105 (0.2)
Original blinded placebo-controlled follow-up period			
Vaccinated	22030 (99.8)	22030 (99.8)	44060 (99.8)
Dose 1	22030 (99.8)	22030 (99.8)	44060 (99.8)
Dose 2	21675 (98.1)	21650 (98.1)	43325 (98.1)
Discontinued from original blinded placebo-controlled vaccination period[c]	352 (1.6)	528 (2.4)	880 (2.0)
Reason for discontinuation			
Lost to follow-up	151 (0.7)	153 (0.7)	304 (0.7)
Withdrawal by subject	109 (0.5)	181 (0.8)	290 (0.7)
No longer meets eligibility criteria	26 (0.1)	120 (0.5)	146 (0.3)
Adverse event	27 (0.1)	26 (0.1)	53 (0.1)

Table 5. Disposition of All Randomized Subjects – Phase 2/3 Subjects ≥16 Years of Age

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=22085) n[b] (%)	Placebo (N[a]=22080) n[b] (%)	Total (N[a]=44165) n[b] (%)
Physician decision	5 (0.0)	8 (0.0)	13 (0.0)
Pregnancy	6 (0.0)	6 (0.0)	12 (0.0)
Protocol deviation	3 (0.0)	8 (0.0)	11 (0.0)
Death	3 (0.0)	4 (0.0)	7 (0.0)
Medication error without associated adverse event	3 (0.0)	2 (0.0)	5 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	18 (0.1)	20 (0.1)	38 (0.1)
Unblinded before 1-month post–Dose 2 visit	253 (1.1)	240 (1.1)	493 (1.1)
Completed 1-month post–Dose 2 visit	21382 (96.8)	21293 (96.4)	42675 (96.6)
Withdrawn from the study	343 (1.6)	484 (2.2)	827 (1.9)
Withdrawn after Dose 1 and before Dose 2	176 (0.8)	211 (1.0)	387 (0.9)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	100 (0.5)	139 (0.6)	239 (0.5)
Withdrawn after 1-month post–Dose 2 visit	67 (0.3)	134 (0.6)	201 (0.5)
Reason for withdrawal from the study			
Lost to follow-up	174 (0.8)	191 (0.9)	365 (0.8)
Withdrawal by subject	122 (0.6)	226 (1.0)	348 (0.8)
Protocol deviation	11 (0.0)	24 (0.1)	35 (0.1)
Death	16 (0.1)	15 (0.1)	31 (0.1)
Adverse event	9 (0.0)	8 (0.0)	17 (0.0)
Physician decision	3 (0.0)	6 (0.0)	9 (0.0)
No longer meets eligibility criteria	1 (0.0)	4 (0.0)	5 (0.0)
Pregnancy	0	1 (0.0)	1 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	5 (0.0)	9 (0.0)	14 (0.0)
Open-label follow-up period			
Originally randomized to BNT162b2	20404 (92.4)		
Received Dose 2/unplanned dose	87 (0.4)		
Completed 1-month post–Dose 2 visit	210 (1.0)		
Completed 6-month post–Dose 2 visit	6414 (29.0)		
Withdrawn from the study	105 (0.5)		
Withdrawn before 6-month post–Dose 2 visit	103 (0.5)		
Withdrawn after 6-month post–Dose 2 visit	2 (0.0)		
Reason for withdrawal from the study			
Withdrawal by subject	56 (0.3)		

Table 5. Disposition of All Randomized Subjects – Phase 2/3 Subjects ≥16 Years of Age

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=22085) n^b (%)	Placebo (N^a=22080) n^b (%)	Total (N^a=44165) n^b (%)
Protocol deviation	35 (0.2)		
Lost to follow-up	4 (0.0)		
Death	3 (0.0)		
Physician decision	2 (0.0)		
Adverse event	1 (0.0)		
No longer meets eligibility criteria	1 (0.0)		
Other	3 (0.0)		
Originally randomized to placebo		20948 (94.9)	
Withdrawn from the study after unblinding and before Dose 3		497 (2.3)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		19612 (88.8)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		15986 (72.4)	
Discontinued from open-label vaccination period[d]		24 (0.1)	
Reason for discontinuation from open-label vaccination period			
Protocol deviation		6 (0.0)	
Adverse event		5 (0.0)	
Withdrawal by subject		5 (0.0)	
Pregnancy		4 (0.0)	
Death		2 (0.0)	
Lost to follow-up		2 (0.0)	
Completed 1-month post–Dose 4 visit		7209 (32.6)	
Withdrawn from the study		14 (0.1)	
Withdrawn after Dose 3 and before Dose 4		11 (0.0)	
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit		2 (0.0)	
Withdrawn after 1-month post–Dose 4 visit		1 (0.0)	
Reason for withdrawal from the study			
Withdrawal by subject		7 (0.0)	
Protocol deviation		3 (0.0)	
Death		2 (0.0)	
Adverse event		1 (0.0)	
Lost to follow-up		1 (0.0)	

Table 5. Disposition of All Randomized Subjects – Phase 2/3 Subjects ≥16 Years of Age

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=22085) n^b (%)	Placebo (N^a=22080) n^b (%)	Total (N^a=44165) n^b (%)

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, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 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.
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 is defined as the time period from Dose 1 to 1 month post–Dose 2.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).
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(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adds s002 all p3 rand

There were no clinically meaningful differences in disposition by age group, baseline SARS-CoV-2 status, ethnicity, race, or sex. These data are presented in the following tables:

Age Group: 16 to 55 Years	Supplemental Table 14.15
Age Group: >55 Years	Supplemental Table 14.16
Baseline SARS-CoV-2 Status: Positive	Supplemental Table 14.17
Baseline SARS-CoV-2 Status: Negative	Supplemental Table 14.18
Ethnicity: Hispanic/Latino	Supplemental Table 14.19
Ethnicity: Non-Hispanic/Non-Latino	Supplemental Table 14.20
Ethnicity: Not Reported	Supplemental Table 14.21
Race: White	Supplemental Table 14.22
Race: Black or African American	Supplemental Table 14.23
Race: All Others	Supplemental Table 14.24
Sex: Male	Supplemental Table 14.25
Sex: Female	Supplemental Table 14.26

10.2. 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 lists important PDs in all participants ≥16 years of age 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.

Details of important PDs with the potential to impact the statistical analysis populations or to impact the assessment of safety of the participants are discussed below:

10.3. Vaccine Administration and Timing

10.3.1. Phase 1

Refer to the final analysis interim C4591001 CSR dated 03 December 2020, Section 10.3.1 for details about vaccination administration and timing during Phase 1 of the study.

10.3.2. Phase 2/3 Participants ≥16 Years of Age

Almost all participants were administered study intervention as randomized; 99.7% received Dose 1 and 98.5% received Dose 2 of BNT162b2 in the BNT162b2 group, and 99.8% received Dose 1 and 98.0% received Dose 2 of placebo in the placebo group (Table 6).

For Dose 1, 4 participants randomized to the placebo group received BNT162b2, and 2 participants randomized to the BNT162b2 group received placebo. Two participants randomized to the BNT162b2 group and 1 participant randomized to the placebo group received an indeterminate vaccine for Dose 1.

For Dose 2, 5 participants randomized to the placebo group received BNT162b2, and 3 participants randomized to the BNT162b2 group received placebo.

After unblinding, 88.8% of original placebo participants received Dose 3 (first dose of BNT162b2 30 µg) and 72.4% received Dose 4 (second dose of BNT162b2 30 µg) at the time of the data cutoff date.

The majority of participants received Dose 2 between 21 to 27 days after Dose 1 in the BNT162b2 (62.6%) and placebo (62.7%) groups (Table 7). After unblinding, most original placebo participants received Dose 4 (second dose of BNT162b2 30 µg) between 14 to 20 (22.6%) and 21 to 27 (48.1%) days after Dose 3.

Table 6. Vaccine as Administered by Vaccine Group – Phase 2/3 Subjects ≥16 Years of Age – All Randomized Subjects

Vaccine (as Administered)	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=22085) n[b] (%)	Placebo (N[a]=22080) n[b] (%)
Vaccinated	22030 (99.8)	22030 (99.8)
Not vaccinated	55 (0.2)	50 (0.2)
Dose 1		
BNT162b2 (30 µg)	22026 (99.7)	4 (0.0)
Placebo	2 (0.0)	22025 (99.8)
Indeterminate vaccine[c]	2 (0.0)	1 (0.0)
Dose 2		
BNT162b2 (30 µg)	21756 (98.5)	5 (0.0)
Placebo	3 (0.0)	21645 (98.0)
Indeterminate vaccine[c]	0	0
Dose 3		
First dose BNT162b2 (30 µg)		19612 (88.8)
Indeterminate vaccine[c]		0
Dose 4		
Second dose BNT162b2 (30 µg)		15986 (72.4)
Indeterminate vaccine[c]		0

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. "Indeterminate vaccine" refers to subjects whose vaccine (as administered) could not be determined.
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(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
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Table 7. Vaccine Administration Timing – Phase 2/3 Subjects ≥16 Years of Age – All Randomized Subjects

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=22085) n[b] (%)	**Placebo (N[a]=22080) n[b] (%)**
Randomized	22085 (100.0)	22080 (100.0)
Not vaccinated	55 (0.2)	50 (0.2)
Dose 1	22030 (99.8)	22030 (99.8)
Dose 2[c]	21759 (98.5)	21650 (98.1)
<14 Days	0	2 (0.0)
14 to 20 Days	7374 (33.4)	7283 (33.0)
21 to 27 Days	13823 (62.6)	13850 (62.7)
28 to 34 Days	249 (1.1)	300 (1.4)
35 to 41 Days	96 (0.4)	90 (0.4)
42 to 48 Days	59 (0.3)	47 (0.2)
49 to 55 Days	43 (0.2)	38 (0.2)
>55 Days	115 (0.5)	40 (0.2)
Dose 3 (first dose of BNT162b2 [30 µg])		19612 (88.8)
Dose 4 (second dose of BNT162b2 [30 µg])[d]		15986 (72.4)
<14 Days		2 (0.0)
14 to 20 Days		4980 (22.6)
21 to 27 Days		10617 (48.1)
28 to 34 Days		247 (1.1)
35 to 41 Days		92 (0.4)
42 to 48 Days		34 (0.2)
49 to 55 Days		12 (0.1)
>55 Days		2 (0.0)

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. Days calculated since Dose 1.
d. Days calculated since Dose 3.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/advx_s002_time_p3_rand

10.4. Data Sets Analyzed

10.4.1. Phase 1

Refer to the final analysis interim C4591001 CSR dated 03 December 2020, Section 10.4.1 for details about the data sets analyzed during Phase 1 of the study, respectively.

The immunogenicity population for participants randomized to BNT162b2 30 µg or corresponding placebo are presented in Supplemental Table 14.2. In the younger age group, 1 (33.3%) participant in the placebo group was excluded from the Dose 1 and Dose 2 evaluable immunogenicity population because the participant was not eligible for the study at randomization (Appendix 16.2.3.2). This participant met exclusion criterion #19 (any screening hematology and/or blood chemistry laboratory value that meets the definition of ≥Grade 1 abnormality) but was included in the Dose 1 and Dose 2 all-available immunogenicity populations (Appendix 16.2.2).

One (8.3%) participant in the BNT162b2 30 µg group was excluded from the Dose 2 evaluable immunogenicity population because the participant did not have a blood sample collected within 6 to 8 days after Dose 2 (Appendix 16.2.3.2).

In the older age group, 1 (8.3%) participant in the BNT162b2 30 µg group was excluded from the Dose 1 and Dose 2 evaluable immunogenicity populations because of a protocol deviation (Appendix 16.2.3.2). This participant also met exclusion criterion #19 (any screening hematology and/or blood chemistry laboratory value that meets the definition of ≥Grade 1 abnormality) but was included in the Dose 1 and Dose 2 all-available immunogenicity populations (Appendix 16.2.2).

10.4.2. Phase 2/3

10.4.2.1. Safety Population – Phase 2/3 Participants ≥16 Years of Age

Refer to the final analysis interim C4591001 CSR dated 03 December 2020, Section 10.4.3 for details about the populations analyzed up to the data cutoff date of 14 November 2020 in Phase 2/3 of the study.

The safety population included a total of 44,050 participants: 22,026 participants in the BNT162b2 group and 22,021 participants in the placebo group (Table 8). Most of the total 115 (0.3%) participants excluded from the safety population were excluded because those participants did not receive study vaccine.

Table 8. Safety Population – Phase 2/3 Subjects ≥16 Years of Age

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
Randomized[b]			44165
Vaccinated	22032	22025	44060 (99.8)
Safety population	22026	22021	44050 (99.7)
HIV-positive	100	100	200 (0.5)
Indeterminate vaccine[c]			3 (0.0)
Excluded from safety population			115 (0.3)
Reason for exclusion			
Subject did not receive study vaccine			105 (0.2)
Unreliable data due to lack of PI oversight			10 (0.0)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
c. "Indeterminate vaccine" refers to subjects whose vaccine group (as administered) could not be determined. These subjects were not included in the safety analysis but their safety data is listed separately.
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There were no clinically meaningful differences in the safety population by age group, baseline SARS-CoV-2 status, ethnicity, race, or sex. These data are presented in the in the following tables:

Age Group	Supplemental Table 14.30
Baseline SARS-CoV-2 Status	Supplemental Table 14.31
Ethnicity	Supplemental Table 14.32
Race	Supplemental Table 14.33
Sex	Supplemental Table 14.34

During the blinded placebo-controlled follow-up period, 51.1% of participants in the BNT162b2 group and 51.4% of participants in the placebo group had follow-up time between ≥4 months to <6 months after Dose 2 (Table 9). From Dose 2 to the cutoff date, 54.5% of participants in the BNT162b2 group had a total follow-up time of ≥6 months.

In the younger age group, 48.5% of participants in the BNT162b2 group and 48.3% of participants in the placebo group had follow-up time between ≥4 months to <6 months after

Dose 2 during the blinded placebo-controlled follow-up period (Supplemental Table 14.27). From Dose 2 to the cutoff date, 51.0% of participants in the BNT162b2 group had a total follow-up time of ≥6 months.

In the older age group, 54.8% of participants in the BNT162b2 group and 55.9% of participants in the placebo group had follow-up time between ≥4 months to <6 months after Dose 2 during the blinded placebo-controlled follow-up period (Supplemental Table 14.28). From Dose 2 to the cutoff date, 59.6% of participants in the BNT162b2 group had a total follow-up time of ≥6 months.

During the open-label follow-up period, 47.5% of original placebo participants had follow-up time between ≥1 month to <2 months after Dose 1 of BNT162b2 (Supplemental Table 14.29).

Table 9. Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Placebo (N[a]=22021) n[b] (%)	Total (N[a]=44047) n[b] (%)
Subjects (%) with length of follow-up of:			
Original blinded placebo-controlled follow-up period			
<2 Months	1251 (5.7)	1331 (6.0)	2582 (5.9)
≥2 Months to <4 months	7744 (35.2)	8070 (36.6)	15814 (35.9)
≥4 Months to <6 months	11253 (51.1)	11316 (51.4)	22569 (51.2)
≥6 Months	1778 (8.1)	1304 (5.9)	3082 (7.0)
Total exposure from Dose 2 to cutoff date			
<2 Months	390 (1.8)		
≥2 Months to <4 months	679 (3.1)		
≥4 Months to <6 months	8951 (40.6)		
≥6 Months	12006 (54.5)		

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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adsl fu d2 p3 saf

10.4.2.2. Efficacy Populations – Updated Analysis

The proportions of participants included in the updated efficacy populations were similar in the BNT162b2 and placebo groups (Table 10).

Table 10. Efficacy Populations – Blinded Placebo-Controlled Follow-up Period

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	23219 (100.0)	23210 (100.0)	46429 (100.0)
Dose 1 all-available efficacy population	23140 (99.7)	23137 (99.7)	46277 (99.7)
Subjects without evidence of infection before Dose 1	22200 (95.6)	22191 (95.6)	44391 (95.6)
Subjects excluded from Dose 1 all-available efficacy population	79 (0.3)	73 (0.3)	152 (0.3)
Reason for exclusion[c]			
Did not receive at least 1 vaccination	58 (0.2)	51 (0.2)	109 (0.2)
Data considered potentially unreliable due to lack of PI oversight identified as significant quality event	21 (0.1)	22 (0.1)	43 (0.1)
Dose 2 all-available efficacy population	22771 (98.1)	22741 (98.0)	45512 (98.0)
Subjects without evidence of infection prior to 7 days after Dose 2	21544 (92.8)	21470 (92.5)	43014 (92.6)
Subjects excluded from Dose 2 all-available efficacy population	448 (1.9)	469 (2.0)	917 (2.0)
Reason for exclusion[c]			
Did not receive 2 vaccinations	384 (1.7)	443 (1.9)	827 (1.8)
Data considered potentially unreliable due to lack of PI oversight identified as significant quality event	21 (0.1)	22 (0.1)	43 (0.1)
Unblinded prior to 7 days after Dose 2	45 (0.2)	11 (0.0)	56 (0.1)
Evaluable efficacy (7 days) population	22255 (95.8)	22410 (96.6)	44665 (96.2)
Subjects without evidence of infection prior to 7 days after Dose 2	21069 (90.7)	21175 (91.2)	42244 (91.0)
Subjects excluded from evaluable efficacy (7 days) population	964 (4.2)	800 (3.4)	1764 (3.8)
Reason for exclusion[c]			
Randomized but did not meet all eligibility criteria	33 (0.1)	30 (0.1)	63 (0.1)
Data considered potentially unreliable due to lack of PI oversight identified as significant quality event	21 (0.1)	22 (0.1)	43 (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)	732 (3.2)	748 (3.2)	1480 (3.2)
Unblinded prior to 7 days after Dose 2	45 (0.2)	11 (0.0)	56 (0.1)
Had other important protocol deviations on or prior to 7 days after Dose 2	240 (1.0)	60 (0.3)	300 (0.6)

Table 10. Efficacy Populations – Blinded Placebo-Controlled Follow-up Period

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)

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. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (02:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adsl eff pop

Most participants who were excluded from the evaluable efficacy population had not received all vaccinations as randomized or did not receive Dose 2 within the predefined window (ie, 19 to 42 days after Dose 1). There were 240 participants in the BNT162b2 group and 60 participants in the placebo group excluded for having important protocol deviations on or prior to 7 days after Dose 2. In the BNT162b2 group, most of these deviations were related to improper administration of the investigational product (203 participants, as compared with 23 participants in the placebo group). Specifically, in the BNT162b2 group most PDs were due to dosing/administration errors (errors in dilution of the vaccine, 76 participants) or administration of investigational product that was deemed not suitable for use (temperature excursions in shipment or storage at the distributor, 110 participants) that would have not applied to placebo (Table 11).

Table 11. Subjects Excluded From Evaluable Efficacy Population Due to Important Protocol Deviations on or Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=240)	Placebo (N[a]=60)
	n[b] (%)	n[b] (%)
Concomitant Medications	3 (1.3)	7 (11.7)
Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	0 (0.0)	1 (1.7)
Subject received chronic systemic treatment with known immunosuppressant medication, or radiotherapy, within 60 days before enrollment through conclusion of the study.	1 (0.4)	1 (1.7)

Table 11. Subjects Excluded From Evaluable Efficacy Population Due to Important Protocol Deviations on or Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=240)	Placebo (N[a]=60)
	n[b] (%)	n[b] (%)
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.	2 (0.8)	5 (8.3)
Inclusion/Exclusion	16 (6.7)	15 (25.0)
Participant failed to meet inclusion criterion #01 (Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study phase).	1 (0.4)	0 (0.0)
Participant failed to meet inclusion criterion #03 (Healthy participants who are determined by medical history, physical examination and clinical judgement of the investigator to be eligible for inclusion in the study)	1 (0.4)	5 (8.3)
Participant met exclusion criterion #01 (participant having other medical or psychiatric condition)	0 (0.0)	2 (3.3)
Participant met exclusion criterion #02 (participant having known infection with HIV, HCV or HBV)	4 (1.7)	3 (5.0)
Participant met exclusion criterion #11 (women who are pregnant or breastfeeding)	4 (1.7)	3 (5.0)
Participant met exclusion criterion #13 (participant receiving treatment with immunosuppressive therapy as specified in protocol)	4 (1.7)	1 (1.7)
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 (0.0)	1 (1.7)
Participant met exclusion criterion #22 (investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members)	2 (0.8)	0 (0.0)
Investigational Product	203 (84.6)	23 (38.3)
Dosing/administration error, subject did not receive correct dose of vaccine	76 (31.7)	3 (5.0)
IP administered that was deemed not suitable for use by Almac	110 (45.8)	0 (0.0)
Incorrect IP assigned to subject due to IRT not being utilized	1 (0.4)	0 (0.0)
Incorrect vaccine allocation/assigned to subject	5 (2.1)	5 (8.3)
Other IP deviation	9 (3.8)	11 (18.3)
Subject was vaccinated despite being ineligible	1 (0.4)	2 (3.3)
Subject was vaccinated despite meeting temporary delay criterion #4 (receiving short-term (	2 (0.8)	2 (3.3)
Laboratory	2 (0.8)	1 (1.7)
Nasal swab can't be analyzed due to incorrect shipping procedure	2 (0.8)	1 (1.7)
Other	19 (7.9)	15 (25.0)
Efficacy data considered potentially unreliable due to lack of PI oversight identified as significant quality event	15 (6.3)	13 (21.7)
Safety and efficacy data considered potentially unreliable due to lack of PI oversight identified as significant quality event.	4 (1.7)	2 (3.3)

Table 11. Subjects Excluded From Evaluable Efficacy Population Due to Important Protocol Deviations on or Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=240)	Placebo (N[a]=60)
	n[b] (%)	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 excluded from evaluable efficacy population due to important protocol deviations in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific characteristic.
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(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
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10.5. Demographic and Other Baseline Characteristics

10.5.1. Phase 1

Refer to Section 10.5.1 of the final analysis interim C4591001 CSR dated 03 December 2020 for demographics and baseline characteristics of healthy participants in Phase 1.

10.5.2. Phase 2/3

10.5.2.1. Safety Population – Participants ≥16 Years of Age

10.5.2.1.1. Overall

Demographic characteristics for all Phase 2/3 participants ≥16 years of age were similar in the BNT162b2 and placebo groups (Table 12). Overall, most participants were White (82.0%), with 9.6% Black or African American participants and 4.3% Asian participants, and all other racial groups were ≤2.5%. There were 25.9% Hispanic/Latino participants. Median age was 51.0 years and 50.9% of participants were male. Obesity was reported in 34.4% of participants in this safety population.

Baseline SARS-CoV-2 status was positive (defined as a positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19) in 3.1% of participants in the BNT162b2 group and 3.3% of participants in the placebo group.

Demographic data including participants 12 through 15 years of age enrolled in this study are summarized in Section 10.5.2.2. These participants were included in the updated analysis of efficacy, and safety data for participants 12 through 15 years of age will be reported separately.

Table 12. Demographic Characteristics – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Placebo (N[a]=22021) n[b] (%)	Total (N[a]=44047) n[b] (%)
Sex			
Male	11322 (51.4)	11098 (50.4)	22420 (50.9)
Female	10704 (48.6)	10923 (49.6)	21627 (49.1)
Race			
White	18056 (82.0)	18064 (82.0)	36120 (82.0)
Black or African American	2098 (9.5)	2118 (9.6)	4216 (9.6)
American Indian or Alaska Native	221 (1.0)	217 (1.0)	438 (1.0)
Asian	952 (4.3)	942 (4.3)	1894 (4.3)
Native Hawaiian or other Pacific Islander	58 (0.3)	32 (0.1)	90 (0.2)
Multiracial	550 (2.5)	533 (2.4)	1083 (2.5)
Not reported	91 (0.4)	115 (0.5)	206 (0.5)
Racial designation			
Japanese	78 (0.4)	78 (0.4)	156 (0.4)
Ethnicity			
Hispanic/Latino	5704 (25.9)	5695 (25.9)	11399 (25.9)
Non-Hispanic/non-Latino	16211 (73.6)	16212 (73.6)	32423 (73.6)
Not reported	111 (0.5)	114 (0.5)	225 (0.5)
Country			
Argentina	2883 (13.1)	2881 (13.1)	5764 (13.1)
Brazil	1452 (6.6)	1448 (6.6)	2900 (6.6)
Germany	249 (1.1)	250 (1.1)	499 (1.1)
South Africa	401 (1.8)	399 (1.8)	800 (1.8)
Turkey	249 (1.1)	249 (1.1)	498 (1.1)
USA	16792 (76.2)	16794 (76.3)	33586 (76.3)
Age group (at vaccination)			
16-55 Years	13069 (59.3)	13095 (59.5)	26164 (59.4)
>55 Years	8957 (40.7)	8926 (40.5)	17883 (40.6)
Age at vaccination (years)			
Mean (SD)	49.7 (15.99)	49.6 (16.05)	49.7 (16.02)
Median	51.0	51.0	51.0
Min, max	(16, 89)	(16, 91)	(16, 91)
Baseline SARS-CoV-2 status			
Positive[c]	689 (3.1)	716 (3.3)	1405 (3.2)
Negative[d]	21185 (96.2)	21180 (96.2)	42365 (96.2)
Missing	152 (0.7)	125 (0.6)	277 (0.6)

Table 12. Demographic Characteristics – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Placebo (N[a]=22021) n[b] (%)	Total (N[a]=44047) n[b] (%)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	271 (1.2)	304 (1.4)	575 (1.3)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	6535 (29.7)	6524 (29.6)	13059 (29.6)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	7670 (34.8)	7558 (34.3)	15228 (34.6)
Obese (≥30.0 kg/m^2)	7543 (34.2)	7629 (34.6)	15172 (34.4)
Missing	7 (0.0)	6 (0.0)	13 (0.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
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Within each age group, most demographic characteristics were similar in the BNT162b2 group and the placebo group (Supplemental Tables 14.35 and 14.36, respectively). Overall, 4.0% of participants in the younger age group were SARS-CoV-2 baseline positive, and 1.9% of participants in the older age group were SARS-CoV-2 baseline positive, and the proportions were similar in the BNT162b2 and placebo groups. There was a lower proportion of non-Hispanic/non-Latino participants in the younger BNT162b2 and placebo groups (68.6% and 68.8%, respectively) than in the older BNT162b2 and placebo groups (80.9% and 80.7%, respectively).

Within each baseline SARS-CoV-2 status group, demographic characteristics were similar in the BNT162b2 group and the placebo group (Supplemental Tables 14.37 and 14.38, respectively). Most participants were White regardless of baseline status; however, there was a higher proportion of White participants among those with a negative baseline status (82.9%) than with a positive baseline status (57.7%). The median age was 43.0 years in participants with a positive baseline status and 51.0 years in participants with a negative baseline status. There were 41.4% and 34.2% of participants who were obese with positive and negative baseline status, respectively.

Demographic characteristics are presented by subgroup in the following tables:

Age Group: 16 to 55 Years	Supplemental Table 14.35
Age Group: >55 Years	Supplemental Table 14.36
Baseline SARS-CoV-2 Status: Positive	Supplemental Table 14.37
Baseline SARS-CoV-2 Status: Negative	Supplemental Table 14.38
Ethnicity: Hispanic/Latino	Supplemental Table 14.39
Ethnicity: Non-Hispanic/Non-Latino	Supplemental Table 14.40
Ethnicity: Not Reported	Supplemental Table 14.41
Race: White	Supplemental Table 14.42
Race: Black or African American	Supplemental Table 14.43
Race: All Others	Supplemental Table 14.44
Sex: Male	Supplemental Table 14.45
Sex: Female	Supplemental Table 14.46

Participants ≥16 years of age had a diverse medical history profile consistent with that of individuals in the general population in the same age group (Supplemental Table 14.47). In the BNT162b2 group, conditions in the surgical and medical procedures (8430 [38.3%]), metabolism and nutrition disorders (6587[29.9%]), and immune system disorders (5987 [27.2%]; of which 3303 [15.0%] were seasonal allergy) SOCs were most frequently reported.

Overall, 20.7% of participants had any comorbidity (per the Charlson comorbidity index) (Supplemental Table 14.48). The most frequently reported comorbidities were diabetes without chronic complications (7.7%), chronic pulmonary disease (8.1%), and any malignancy (3.6%), which were reported at similar frequencies in each vaccine group.

In the younger age group, 13.3% of participants had any comorbidity (Supplemental Table 14.49). The most frequently reported comorbidities were diabetes without chronic complications (3.7%) and chronic pulmonary disease (7.4%), which were reported at similar frequencies in each vaccine group.

In the older age group, 31.6% of participants had any comorbidity (Supplemental Table 14.50). The most frequently reported comorbidities were diabetes without chronic complications (13.6%) and chronic pulmonary disease (9.1%), which were reported at similar frequencies in each vaccine group.

10.5.2.1.1.1. Participants With Confirmed Stable HIV Disease

Demographic characteristics for participants with confirmed stable HIV disease were similar in the BNT162b2 and the placebo groups (Supplemental Table 14.51). Overall, 54.5% of participants were Black or African American, 40.5% of participants were White, and all other racial groups were ≤1.5%. There were 16.0% Hispanic/Latino participants. Median age was

49.5 years and 67.5% of participants were male. Obese participants made up 39.0% of this population.

10.5.2.1.2. Participants With At Least 6 Months Follow-Up Time – Original BNT162b2 Participants

Demographic characteristics for all original BNT162b2 Phase 2/3 participants ≥16 years of age and had at least 6 months of follow-up time after Dose 2 are presented in Table 13. Overall, most participants were White (86.4%), with 7.1% Black or African American participants and 3.8% Asian participants, and other racial groups were ≤1.6%. There were 27.8% Hispanic/Latino participants. Median age was 53.0 years and 50.3% of participants were male. Obese participants made up 34.2% of this safety population.

Table 13. Demographic Characteristics – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=12006) n[b] (%)
Sex	
Male	6040 (50.3)
Female	5966 (49.7)
Race	
White	10370 (86.4)
Black or African American	851 (7.1)
American Indian or Alaska Native	55 (0.5)
Asian	452 (3.8)
Native Hawaiian or other Pacific Islander	31 (0.3)
Multiracial	195 (1.6)
Not reported	52 (0.4)
Racial designation	
Japanese	44 (0.4)
Ethnicity	
Hispanic/Latino	3339 (27.8)
Non-Hispanic/non-Latino	8604 (71.7)
Not reported	63 (0.5)
Country	
Argentina	2118 (17.6)
Brazil	596 (5.0)
USA	9292 (77.4)

Table 13. Demographic Characteristics – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=12006) n[b] (%)
Age group (at vaccination)	
16-55 Years	6666 (55.5)
>55 Years	5340 (44.5)
Age at vaccination (years)	
Mean (SD)	51.4 (15.44)
Median	53.0
Min, max	(18, 85)
Baseline SARS-CoV-2 status	
Positive[c]	250 (2.1)
Negative[d]	11678 (97.3)
Missing	78 (0.6)
Body mass index (BMI)	
Underweight (<18.5 kg/m^2)	136 (1.1)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	3527 (29.4)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	4232 (35.2)
Obese (≥30.0 kg/m^2)	4107 (34.2)
Missing	4 (0.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
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. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
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10.5.2.1.3. Original Placebo Participants Who Then Received BNT162b2

Demographic characteristics for all original placebo Phase 2/3 participants who then received BNT162b2 later during the open-label follow-up period are presented in Table 14. Overall, most participants were White (83.1%), with 8.3% Black or African American participants and 4.3% Asian participants, and all other racial groups were ≤2.6%. There were

25.5% Hispanic/Latino participants. Median age was 51.0 years and 50.2% of participants were male. Obese participants made up 34.4% of this safety population.

Table 14. Demographic Characteristics – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=19611) n[b] (%)
Sex	
Male	9841 (50.2)
Female	9770 (49.8)
Race	
White	16299 (83.1)
Black or African American	1636 (8.3)
American Indian or Alaska Native	189 (1.0)
Asian	849 (4.3)
Native Hawaiian or other Pacific Islander	28 (0.1)
Multiracial	509 (2.6)
Not reported	101 (0.5)
Racial designation	
Japanese	77 (0.4)
Ethnicity	
Hispanic/Latino	5002 (25.5)
Non-Hispanic/non-Latino	14499 (73.9)
Not reported	110 (0.6)
Country	
Argentina	2612 (13.3)
Brazil	1428 (7.3)
Germany	241 (1.2)
South Africa	362 (1.8)
Turkey	242 (1.2)
USA	14726 (75.1)
Age group (at vaccination)	
16-55 Years	11404 (58.2)
>55 Years	8207 (41.8)
Age at vaccination (years)	
Mean (SD)	50.1 (15.91)

Table 14. Demographic Characteristics – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=19611) n[b] (%)
Median	51.0
Min, max	(16, 91)
Baseline SARS-CoV-2 status	
Positive[c]	590 (3.0)
Negative[d]	18909 (96.4)
Missing	112 (0.6)
Body mass index (BMI)	
Underweight (<18.5 kg/m^2)	258 (1.3)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	5805 (29.6)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	6790 (34.6)
Obese (≥30.0 kg/m^2)	6753 (34.4)
Missing	5 (0.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
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. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
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10.5.2.2. All Participants

Demographic characteristics for all participants (including adolescents) were similar in the BNT162b2 group and the placebo group (Supplemental Table 14.52).

10.5.2.3. Evaluable Efficacy (7 Days) Population – Blinded Placebo-Controlled Follow-Up Period

Demographics of participants in the updated evaluable efficacy population for participants without evidence of infection prior to 7 days after Dose 2 were similar in the BNT162b2 and placebo groups (Table 15). This analysis population had generally similar demographics compared to the safety population (refer to Section 10.5.2.1.1).

Table 15. Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=21069) n[b] (%)	Placebo (N[a]=21175) n[b] (%)	Total (N[a]=42244) n[b] (%)
Sex			
Male	10824 (51.4)	10689 (50.5)	21513 (50.9)
Female	10245 (48.6)	10486 (49.5)	20731 (49.1)
Race			
White	17458 (82.9)	17604 (83.1)	35062 (83.0)
Black or African American	1799 (8.5)	1812 (8.6)	3611 (8.5)
American Indian or Alaska Native	188 (0.9)	182 (0.9)	370 (0.9)
Asian	959 (4.6)	949 (4.5)	1908 (4.5)
Native Hawaiian or other Pacific Islander	55 (0.3)	31 (0.1)	86 (0.2)
Multiracial	522 (2.5)	489 (2.3)	1011 (2.4)
Not reported	88 (0.4)	108 (0.5)	196 (0.5)
All others[c]	1812 (8.6)	1759 (8.3)	3571 (8.5)
Racial Designation			
Japanese	78 (0.4)	74 (0.3)	152 (0.4)
Ethnicity			
Hispanic/Latino	5241 (24.9)	5217 (24.6)	10458 (24.8)
Non-Hispanic/non-Latino	15725 (74.6)	15846 (74.8)	31571 (74.7)
Not reported	103 (0.5)	112 (0.5)	215 (0.5)
Country			
Argentina	2624 (12.5)	2617 (12.4)	5241 (12.4)
Brazil	1326 (6.3)	1314 (6.2)	2640 (6.2)
Germany	238 (1.1)	242 (1.1)	480 (1.1)
South Africa	307 (1.5)	297 (1.4)	604 (1.4)
Turkey	231 (1.1)	226 (1.1)	457 (1.1)
USA	16343 (77.6)	16479 (77.8)	32822 (77.7)
Age group (years)			
12 to 15	1005 (4.8)	978 (4.6)	1983 (4.7)
16 to 55	11753 (55.8)	11824 (55.8)	23577 (55.8)
>55	8311 (39.4)	8373 (39.5)	16684 (39.5)
≥65	4245 (20.1)	4296 (20.3)	8541 (20.2)
16 to 17	344 (1.6)	334 (1.6)	678 (1.6)
16 to 25	1657 (7.9)	1668 (7.9)	3325 (7.9)
16 to 64	15819 (75.1)	15901 (75.1)	31720 (75.1)
18 to 64	15475 (73.4)	15567 (73.5)	31042 (73.5)

Table 15. Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=21069) n[b] (%)	**Placebo (N[a]=21175) n[b] (%)**	**Total (N[a]=42244) n[b] (%)**
55 to 64	4499 (21.4)	4493 (21.2)	8992 (21.3)
65 to 74	3392 (16.1)	3442 (16.3)	6834 (16.2)
≥75	853 (4.0)	854 (4.0)	1707 (4.0)
75 to 85	848 (4.0)	848 (4.0)	1696 (4.0)
>85	5 (0.0)	6 (0.0)	11 (0.0)
Comorbidities[d]			
Yes	9390 (44.6)	9411 (44.4)	18801 (44.5)
No	11679 (55.4)	11764 (55.6)	23443 (55.5)
Age at vaccination (years)			
Mean (SD)	48.3 (17.41)	48.2 (17.41)	48.3 (17.41)
Median	50.0	50.0	50.0
Min, max	(12, 89)	(12, 91)	(12, 91)

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, or the total sample. 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.
d. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2 (≥16 Years of age) or BMI ≥95th percentile (12-15 Years of age).
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Demographic characteristics for the Dose 1 all-available efficacy population and for participants with or without evidence of infection prior to 7 days after Dose 2 (evaluable efficacy [7 days] population) were similar to those in Table 15 (Supplemental Tables 14.53 and 14.54, respectively).

10.6. Participant Compliance

10.6.1. Immunogenicity Blood Samples

10.6.1.1. Phase 1

Refer to the final analysis interim C4591001 CSR dated 03 December 2020, Section 10.6.1.1 for details about immunogenicity blood samples taken during Phase 1 of the study, respectively.

Immunogenicity blood samples taken from participants randomized to BNT162b2 30 µg or corresponding placebo are presented in Supplemental Table 14.3. Most participants had immunogenicity blood samples taken within the protocol specified time frames.

10.6.1.2. Phase 2/3

Refer to the final analysis interim C4591001 CSR dated 03 December 2020, Section 10.6.1.2 for details about immunogenicity blood samples taken during Phase 2 of the study.

10.6.2. E-Diary

10.6.2.1. Phase 1 and Phase 2

Refer to the final analysis interim C4591001 CSR dated 03 December 2020, Sections 10.6.2.1 and 10.6.2.2 for details about transmission of e-diary data during Phase 1 and Phase 2 of the study, respectively.

10.6.2.2. Phase 2/3

Overall, transmission of e-diary data was ≥90.1% (range: 90.1% to 94.0%) for each day during the 7 days after Dose 1 of BNT162b2. After Dose 2 of BNT162b2, transmission of e-diary data was 76.5% on Day 1 and ranged from 83.8% to 85.6% for each day during Day 2 through Day 7 (Supplemental Table 14.55). Transmission rates were similar in the BNT162b2 group and the placebo group.

10.7. Prior and Concomitant Vaccines, Medications, and Procedures

10.7.1. Phase 1

Refer to the final analysis interim C4591001 CSR dated 03 December 2020, Section 10.7.1 for details about participants who received concomitant vaccines during Phase 1 of the study.

10.7.2. Phase 2/3 Participants ≥16 Years of Age

A small percentage of participants ≥16 years of age in either group (≤14.4%) received any concomitant vaccine after Dose 1, and most concomitant vaccines received were the influenza vaccine (Supplemental Table 14.56).

11. EFFICACY AND IMMUNOGENICITY EVALUATION

11.1. Efficacy Results

11.1.1. Interim Analysis 1 and Final Analysis of Efficacy

Efficacy results of the interim analysis (first primary efficacy objective only) based on an accrued 94 cases (data cutoff date: 04 November 2020), and the final analysis of efficacy based on an accrued 170 cases (data cutoff date: 14 November 2020) are presented in Section 11.1 of the C4591001 final analysis interim CSR dated 03 December 2020.

Results of efficacy analyses demonstrated that BNT162b2 at 30 µg provided protection against COVID-19 in participants who had no evidence of prior infection with SARS-CoV-2 and in participants regardless of prior infection status. Consistently high VE was observed across demographic subgroups, with severe cases observed predominantly in the placebo group.

11.1.2. Updated Analysis of Efficacy

Updated efficacy analyses were performed with all cases accrued during blinded placebo-controlled follow-up through the cut-off date of 13 March 2021. Updated efficacy analyses were conducted for the primary efficacy endpoints, including subgroup analyses, and for secondary efficacy endpoints of severe disease and CDC-defined severe disease.

11.1.2.1. Updated Analysis of Primary Endpoints

Overwhelming efficacy was declared at the first (and only) interim analysis and was confirmed at the final analysis. A descriptive update based on a total of 927 confirmed cases for the first primary endpoint accrued during blinded placebo-controlled follow-up, up to the data cutoff date of 13 March 2021, is summarized below.

11.1.2.1.1. Vaccine Efficacy Without Prior Evidence of SARS-CoV-2 Infection – 7 Days After Dose 2 – Updated Analysis

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 91.3%, with 77 COVID-19 cases in the BNT162b2 group compared to 850 cases in the placebo group (Table 16). The 2-sided 95% CI for vaccine efficacy was 89.0% to 93.2%. The posterior probability for the true VE being greater than 30%, given the available data, was >99.99%.

The vaccine efficacy of BNT162b2 for the same efficacy endpoint based on the Dose 2 all-available efficacy population was 91.4% (2-sided 95% CI: 89.1%, 93.3%), with 78 and 866 cases in the BNT162b2 and placebo group, respectively (Supplemental Table 14.57).

Table 16. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	77	6.247 (20712)	850	6.003 (20713)	91.3	(89.0, 93.2)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (01:59)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 wo eval

11.1.2.1.2. Vaccine Efficacy With or Without Prior Evidence of SARS-CoV-2 Infection – 7 Days After Dose 2 – Updated Analysis

Among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 91.1%, with 81 and 873 cases in the BNT162b2 and placebo groups, respectively (Table 17). The 2-sided 95% CI for vaccine efficacy was 88.8% to 93.0%. The posterior probability for the true VE being greater than 30%, given the available data, was >99.99%.

The vaccine efficacy of BNT162b2 for the same efficacy endpoint based on the Dose 2 all-available efficacy population was 91.2 % (2-sided 95% CI: 88.9%, 93.0%), with 82 and 889 cases in the BNT162b2 and placebo group, respectively (Supplemental Table 14.58).

Table 17. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	81	6.509 (21642)	873	6.274 (21689)	91.1	(88.8, 93.0)	>0.9999

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (01:59)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_cov_7pd2_eval

11.1.2.1.3. All Confirmed Cases of COVID-19 After Dose 1 – All-Available Efficacy Population

A number of confirmed cases of COVID-19 are not captured in the analyses of the primary endpoints for the evaluable efficacy population because they either occurred in participants who were excluded from the evaluable efficacy population, or occurred less than 7 days after Dose 2.

All reports of COVID-19 with onset at any time after Dose 1 are accounted for in Table 18, which provides a summary of confirmed cases for all participants in the Dose 1 all-available efficacy (modified intention-to-treat) population adjusted for exposure, regardless of evidence of infection before or during the vaccination regimen. Among these participants, 131 cases of COVID-19 occurred after Dose 1 in the BNT162b2 group compared to 1034 cases in the placebo group. The estimated VE against confirmed COVID-19 occurring after Dose 1 was 87.8% (2-sided 95% CI: 85.3%, 89.9%).

In this population, the estimated VE against all cases occurring ≥7 days after Dose 2 was 91.2%. The estimated VE was 91.7% from ≥11 days after Dose 1 to before Dose 2, 96.2% for cases occurring from ≥7 days after Dose 2 to <2 months after Dose 2, 90.1% for the period from ≥2 months to <4 months after Dose 2, and 83.7% for the period ≥4 months after Dose 2.

Table 18. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=23040)		Placebo (N[a]=23037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence after Dose 1	131	8.412 (22505)	1034	8.124 (22434)	87.8	(85.3, 89.9)
After Dose 1 to before Dose 2	46	1.339 (22505)	110	1.331 (22434)	58.4	(40.8, 71.2)
After Dose 1 to <11 days after Dose 1	41	0.677 (22505)	50	0.675 (22434)	18.2	(-26.1, 47.3)
≥11 Days after Dose 1 to before Dose 2	5	0.662 (22399)	60	0.656 (22369)	91.7	(79.6, 97.4)
Dose 2 to 7 days after Dose 2	3	0.424 (22163)	35	0.422 (22057)	91.5	(72.9, 98.3)
≥7 Days after Dose 2	82	6.649 (22132)	889	6.371 (22001)	91.2	(88.9, 93.0)
≥7 days after Dose 2 to <2 Months after Dose 2	12	2.923 (22132)	312	2.884 (22001)	96.2	(93.3, 98.1)
≥2 Months after Dose 2 to <4 Months after Dose 2	46	2.696 (20814)	449	2.593 (20344)	90.1	(86.6, 92.9)
≥4 Months after Dose 2	24	1.030 (12670)	128	0.895 (11802)	83.7	(74.7, 89.9)

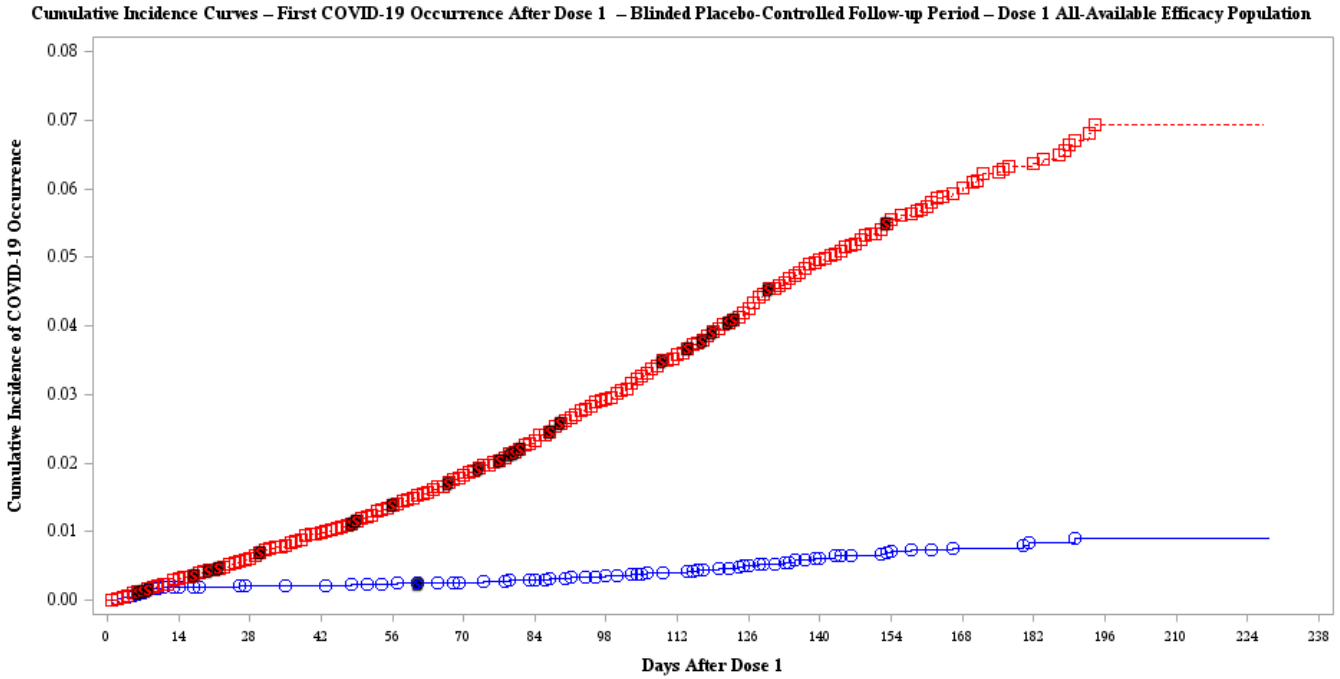
Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 19APR2021 (17:34)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve cov pd1 aai

The early onset of protection is readily apparent in Figure 2, which displays cumulative incidence for the first COVID-19 occurrence after Dose 1 among all vaccinated participants based on Dose 1 all-available efficacy (modified intention-to-treat) population. Disease onset appears to track together for BNT162b2 and placebo until approximately 11 days after Dose 1 (consistent with the data shown in Table 18), at which point the curves diverge, with cases steadily accumulating in the placebo group, while remaining virtually flat in the BNT162b2 group.

The darker-appearing symbols for both BNT162b2 (blue circles) and placebo (red squares) curves in Figure 2 have an "S" written inside the open symbol, which denotes severe cases.

Severe COVID-19 cases reported in the updated analysis are discussed further in Section 11.1.2.2.

Figure 2. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1– Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population



Note: "S" indicates subjects with severe COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adc19ef Table Generation: 27MAR2021 (11:38)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_f001_km_d1_aai

11.1.2.1.4. Vaccine Efficacy by Subgroup – Updated Analysis

11.1.2.1.4.1. Subgroups of Age, Sex, Race, Ethnicity, and Country

For both primary endpoints, VE was also evaluated for subgroups of participants by age, sex, race, ethnicity, and country. Overall, the results show high VE across the subgroups.

In the evaluable efficacy population, among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE was ≥90% in most subgroups, similar to the estimated 91.3% overall VE (Table 19). High VE was also observed across age groups, with an estimated VE of 100.0% in 12 to 15 year olds, 90.6% in 16 to 64 year olds, 94.5% in those ≥65 years, and 96.2% in those ≥75 years of age. Estimated VEs were 87.6% among Asian and 88.5% among Hispanic/Latino participants; the estimated VE was 92.6% in the United States, 86.5% in Argentina, 86.2% in Brazil, and 100.0% in South Africa, Germany, and Turkey.

Similar results were observed for subgroup analyses among participants with or without prior evidence of SARS-CoV-2 infection before and during the vaccination regimen (Supplemental Table 14.59). Additionally, in analyses for the Dose 1 all-available efficacy population, which included all confirmed cases occurring at any time after Dose 1, no clinically meaningful differences among the subgroups were identified (Supplemental Table 14.60).

Subgroup analyses included evaluation of VE by prior SARS-CoV-2 status at baseline. The number of participants with positive prior SARS-CoV-2 status at baseline was relatively small, and the 95% CIs for the estimated VEs in these subgroup analyses were very wide; therefore, the data must be interpreted with caution. However, the results may provide some information regarding the benefits of vaccination for individuals with prior SARS-CoV-2 infection.

Participants with positive prior SARS-CoV-2 status at baseline were defined as those with positive N-binding antibody or NAAT results at Visit 1 or a medical history of COVID-19. In the evaluable efficacy analysis for this subgroup, the estimated VE against cases occurrring ≥7 days after Dose 2 was 46.9% (3 cases BNT162b2; 6 cases placebo) (Supplemental Table 14.59), and in the all-available efficacy analysis the estimated VE against cases occurring at any time after Dose 1 was 19.2% (13 cases BNT162b2, 17 cases placebo) (Supplemental Table 14.60).

It is important to note that the subgroup defined above includes participants with both past infections (positive N-binding antibody) and current infections (NAAT positive). Since it is reasonable to expect that vaccination may be less effective in participants currently infected with SARS-CoV-2 at Visit 1, it may be relevant to examine VE specifically in participants who were positive for N-binding only (and were not NAAT-positive) at Visit 1. In the evaluable efficacy analysis for these participants, the estimated VE against cases occurrring ≥7 days after Dose 2 was 58.9% (2 cases BNT162b2; 5 cases placebo) (Supplemental Table 14.59), and in the all-available efficacy analysis the estimated VE against cases occurring at any time after Dose 1 was 70.5% (2 cases BNT162b2, 7 cases placebo) (Supplemental Table 14.60). Therefore, estimates of VE were considerably higher in

participants who were positive for N-binding antibody only, suggesting that vaccination provides a benefit for individuals with previous SARS-CoV-2 infection.

Table 19. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	77	6.247 (20712)	850	6.003 (20713)	91.3	(89.0, 93.2)
Age group (years)						
12 to 15	0	0.154 (1001)	16	0.147 (972)	100.0	(75.3, 100.0)
16 to 55	52	3.593 (11517)	568	3.439 (11533)	91.2	(88.3, 93.5)
>55	25	2.499 (8194)	266	2.417 (8208)	90.9	(86.3, 94.2)
≥65	7	1.233 (4192)	124	1.202 (4226)	94.5	(88.3, 97.8)
16 to 17	0	0.061 (342)	10	0.057 (331)	100.0	(58.2, 100.0)
16 to 25	8	0.482 (1629)	80	0.466 (1622)	90.3	(80.0, 96.0)
16 to 64	70	4.859 (15519)	710	4.654 (15515)	90.6	(87.9, 92.7)
18 to 64	70	4.798 (15177)	700	4.597 (15184)	90.4	(87.7, 92.6)
55 to 64	21	1.399 (4426)	157	1.334 (4388)	87.3	(79.8, 92.3)
65 to 74	6	0.994 (3350)	98	0.966 (3379)	94.1	(86.6, 97.9)
≥75	1	0.239 (842)	26	0.237 (847)	96.2	(76.9, 99.9)
75 to 85	1	0.238 (837)	25	0.235 (841)	96.0	(75.9, 99.9)
>85	0	0.001 (5)	1	0.001 (6)	100.0	(-4055.9, 100.0)
Sex						
Male	42	3.246 (10637)	399	3.047 (10433)	90.1	(86.4, 93.0)
Female	35	3.001 (10075)	451	2.956 (10280)	92.4	(89.2, 94.7)
Race						
White	67	5.208 (17186)	747	5.026 (17256)	91.3	(88.9, 93.4)
Black or African American	4	0.545 (1737)	48	0.527 (1737)	91.9	(78.0, 97.9)
American Indian or Alaska Native	0	0.041 (186)	3	0.037 (176)	100.0	(-119.0, 100.0)
Asian	3	0.260 (946)	23	0.248 (934)	87.6	(58.9, 97.6)

Table 19. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Native Hawaiian or other Pacific Islander	0	0.015 (54)	1	0.008 (30)	100.0	(-1961.2, 100.0)
Multiracial	3	0.151 (518)	22	0.128 (476)	88.5	(61.6, 97.8)
Not reported	0	0.026 (85)	6	0.030 (104)	100.0	(2.8, 100.0)
All others[f]	6	0.494 (1789)	55	0.451 (1720)	90.0	(76.9, 96.5)
Ethnicity						
Hispanic/Latino	29	1.786 (5161)	241	1.711 (5120)	88.5	(83.0, 92.4)
Non-Hispanic/non-Latino	47	4.429 (15449)	609	4.259 (15484)	92.6	(90.0, 94.6)
Not reported	1	0.032 (102)	0	0.033 (109)	-∞	(NA, NA)
Country						
Argentina	15	1.012 (2600)	108	0.986 (2586)	86.5	(76.7, 92.7)
Brazil	12	0.406 (1311)	80	0.374 (1293)	86.2	(74.5, 93.1)
Germany	0	0.047 (236)	1	0.048 (242)	100.0	(-3874.2, 100.0)
South Africa	0	0.080 (291)	9	0.074 (276)	100.0	(53.5, 100.0)
Turkey	0	0.027 (228)	5	0.025 (222)	100.0	(-0.1, 100.0)
USA	50	4.674 (16046)	647	4.497 (16094)	92.6	(90.1, 94.5)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
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(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_cov_7pd2_wo_sg_eval

11.1.2.1.4.2. Subgroup Analyses by Risk Status

Analyses of efficacy by risk status were performed. For these analyses, at-risk participants were defined as those who had at least one Charlson Comorbidity Index condition or who were obese (defined as BMI ≥30 kg/m^2). For a summary of Charlson comorbidities among all participants at study entry, see Supplemental Table 14.48.

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE was similar for participants at risk (91.6%) and for participants not at risk (91.0%) (Table 20). The estimated VE for participants ≥65 years of age and at risk was 91.8%, as compared with 98.1% for those ≥65 years of age and not at risk. The estimated VE was similar in obese (91.6%) and non-obese (91.1%) participants. Results were similar among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen (Table 21).

Table 20. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	77	6.247 (20712)	850	6.003 (20713)	91.3	(89.0, 93.2)
At risk[f]						
Yes	35	2.797 (9167)	401	2.681 (9136)	91.6	(88.2, 94.3)
No	42	3.450 (11545)	449	3.322 (11577)	91.0	(87.6, 93.6)
Age group (years) and at risk						
12-15 and not at risk	0	0.121 (788)	11	0.116 (769)	100.0	(61.9, 100.0)
12-15 and at risk	0	0.034 (213)	5	0.032 (203)	100.0	(-2.0, 100.0)
16-64 and not at risk	41	2.776 (8887)	385	2.661 (8886)	89.8	(85.9, 92.8)
16-64 and at risk	29	2.083 (6632)	325	1.993 (6629)	91.5	(87.5, 94.4)
≥65 and not at risk	1	0.553 (1870)	53	0.546 (1922)	98.1	(89.2, 100.0)
≥65 and at risk	6	0.680 (2322)	71	0.656 (2304)	91.8	(81.4, 97.1)
Obese[g]						
Yes	27	2.103 (6796)	314	2.050 (6875)	91.6	(87.6, 94.6)
No	50	4.143 (13911)	536	3.952 (13833)	91.1	(88.1, 93.5)

Table 20. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Age group (years) and obese						
12-15 and not obese	0	0.135 (878)	13	0.131 (867)	100.0	(68.3, 100.0)
12-15 and obese	0	0.019 (123)	3	0.016 (105)	100.0	(-104.8, 100.0)
16-64 and not obese	46	3.178 (10212)	444	3.028 (10166)	90.1	(86.6, 92.9)
16-64 and obese	24	1.680 (5303)	266	1.624 (5344)	91.3	(86.7, 94.5)
≥65 and not obese	4	0.829 (2821)	79	0.793 (2800)	95.2	(87.1, 98.7)
≥65 and obese	3	0.404 (1370)	45	0.410 (1426)	93.2	(78.9, 98.7)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Includes subjects who had at least one of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥30 kg/m^2 [≥16 Years of age] or BMI ≥95th percentile [12-15 Years of age]).
g. Subjects (≥16 Years of age) who had BMI ≥30 kg/m^2. For 12 through 15 years age group, obesity is defined as a BMI at or above the 95th percentile. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev htm.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 30MAR2021 (22:35)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 wo rg eval

Table 21. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	81	6.509 (21642)	873	6.274 (21689)	91.1	(88.8, 93.0)
At risk[f]						
Yes	36	2.925 (9601)	410	2.807 (9570)	91.6	(88.1, 94.2)
No	45	3.584 (12041)	463	3.466 (12119)	90.6	(87.2, 93.2)
Age group (years) and at risk						
12-15 and not at risk	0	0.132 (867)	11	0.129 (864)	100.0	(61.1, 100.0)
12-15 and at risk	0	0.038 (242)	7	0.035 (230)	100.0	(36.2, 100.0)
16-64 and not at risk	44	2.887 (9254)	397	2.779 (9289)	89.3	(85.4, 92.4)
16-64 and at risk	30	2.186 (6964)	330	2.100 (6980)	91.3	(87.3, 94.2)
≥65 and not at risk	1	0.566 (1920)	55	0.559 (1966)	98.2	(89.6, 100.0)
≥65 and at risk	6	0.701 (2395)	73	0.672 (2360)	92.1	(82.0, 97.2)
Obese[g]						
Yes	28	2.207 (7139)	319	2.158 (7235)	91.4	(87.4, 94.4)
No	53	4.301 (14497)	554	4.114 (14448)	90.8	(87.9, 93.2)
Age group (years) and obese						
12-15 and not obese	0	0.148 (969)	14	0.145 (970)	100.0	(70.5, 100.0)
12-15 and obese	0	0.022 (140)	4	0.019 (124)	100.0	(-31.1, 100.0)
16-64 and not obese	49	3.303 (10629)	458	3.158 (10614)	89.8	(86.2, 92.5)
16-64 and obese	25	1.768 (5584)	269	1.719 (5649)	91.0	(86.4, 94.3)
≥65 and not obese	4	0.850 (2899)	82	0.811 (2864)	95.3	(87.6, 98.8)
≥65 and obese	3	0.417 (1415)	46	0.420 (1462)	93.4	(79.5, 98.7)

Table 21. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Includes subjects who had at least one of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥30 kg/m^2 [≥16 Years of age] or BMI ≥95th percentile [12-15 Years of age]).
g. Subjects (≥16 Years of age) who had BMI ≥30 kg/m^2. For 12 through 15 years age group, obesity is defined as a BMI at or above the 95th percentile. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev htm.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 30MAR2021 (22:35)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 rg eval

11.1.2.1.4.3. Subgroup Analyses by Comorbidity Status

Among participants without prior evidence of SARS-CoV-2 infection before and during vaccination regimen,estimated VE was similar for participants with any comorbidity (91.6% with 2-sided 95% CI of 88.2% to 94.3%) and for those with no comorbidity (91.0% with 2-sided 95% CI of 87.6% to 93.6%) (Table 22). When evaluated by type of comorbidity, the estimated VE was >85% for participants with each comorbidity evaluated, including any malignancy, cardiovascular disease, chronic pulmonary disease, diabetes, obesity, and hypertension. Results were similar for participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen (Table 23).

Table 22. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	77	6.247 (20712)	850	6.003 (20713)	91.3	(89.0, 93.2)
Comorbidity						
No comorbidity	42	3.450 (11545)	449	3.322 (11577)	91.0	(87.6, 93.6)
Any comorbidity[f]	35	2.797 (9167)	401	2.681 (9136)	91.6	(88.2, 94.3)
Any malignancy	3	0.228 (770)	27	0.214 (748)	89.6	(66.2, 98.0)
Cardiovascular	3	0.172 (584)	23	0.159 (555)	88.0	(60.2, 97.7)
Chronic pulmonary disease	8	0.490 (1684)	69	0.460 (1671)	89.1	(77.3, 95.5)
Diabetes	9	0.465 (1529)	61	0.444 (1517)	85.9	(71.4, 93.8)
Obese (≥30.0 kg/m^2 [≥16 Years of age])	27	2.083 (6673)	311	2.034 (6770)	91.5	(87.4, 94.5)
Obese (≥95th percentile [12-15 Years of age])	0	0.019 (123)	3	0.016 (105)	100.0	(-104.8, 100.0)
Hypertension	15	1.481 (4900)	191	1.427 (4896)	92.4	(87.2, 95.8)
Diabetes (including gestational diabetes)	9	0.468 (1538)	63	0.447 (1531)	86.3	(72.4, 94.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Subject who had 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2 (≥16 Years of age) or BMI ≥95th percentile (12-15 Years of age).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 30MAR2021 (22:39)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 wo cg eval

Table 23. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	81	6.509 (21642)	873	6.274 (21689)	91.1	(88.8, 93.0)
Comorbidity						
No comorbidity	45	3.584 (12041)	463	3.466 (12119)	90.6	(87.2, 93.2)
Any comorbidity[f]	36	2.925 (9601)	410	2.807 (9570)	91.6	(88.1, 94.2)
Any malignancy	3	0.234 (792)	27	0.217 (762)	89.7	(66.5, 98.0)
Cardiovascular	3	0.180 (607)	23	0.163 (569)	88.2	(60.9, 97.7)
Chronic pulmonary disease	8	0.512 (1764)	72	0.480 (1750)	89.6	(78.4, 95.7)
Diabetes	9	0.485 (1597)	62	0.463 (1582)	86.1	(71.9, 93.9)
Obese (≥30.0 kg/m^2 [≥16 Years of age])	28	2.185 (6999)	315	2.139 (7111)	91.3	(87.2, 94.3)
Obese (≥95th percentile [12-15 Years of age])	0	0.022 (140)	4	0.019 (124)	100.0	(-31.1, 100.0)
Hypertension	15	1.535 (5078)	193	1.479 (5077)	92.5	(87.3, 95.9)
Diabetes (including gestational diabetes)	9	0.488 (1606)	64	0.466 (1596)	86.5	(72.8, 94.1)

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Subject who had 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2 (≥16 Years of age) or BMI ≥95th percentile (12-15 Years of age).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 30MAR2021 (22:39)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_cov_7pd2_cg_eval

11.1.2.2. Updated Analysis of Secondary Endpoints

11.1.2.2.1. Efficacy for Severe COVID-19 Cases – Updated Analysis

11.1.2.2.1.1. Participants Without Evidence of Infection Before and During Vaccination Regimen

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against severe COVID-19 as defined by FDA occurring at least 7 days after Dose 2 was 95.3% (2-sided 95% CI: 71.0%, 99.9%), with 1 and 21 cases in the BNT162b2 and placebo groups, respectively (Table 24). The posterior probability for the true vaccine efficacy being greater than 30%, given the available data, was >99.99%.

Table 24. Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First severe COVID-19 occurrence from 7 days after Dose 2	1	6.257 (20712)	21	6.120 (20713)	95.3	(71.0, 99.9)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (02:26)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve sev cov 7pd2 wo eval

11.1.2.2.1.2. Participants With or Without Evidence of Infection Before and During Vaccination Regimen

Among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, estimated VE against severe COVID-19 as defined by FDA occurring at least 7 days after Dose 2 was 95.3% (2-sided 95% CI: 70.9%, 99.9%), with 1 and 21 cases in the BNT162b2 and placebo groups, respectively (Table 25). The posterior probability for the true vaccine efficacy being greater than 30%, given the available data, was >99.99%.

Table 25. Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First severe COVID-19 occurrence from 7 days after Dose 2	1	6.522 (21649)	21	6.404 (21730)	95.3	(70.9, 99.9)	>0.9999

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (02:26)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_sev_cov_7pd2_eval

11.1.2.2.1.3. All Confirmed Cases of Severe COVID-19 After Dose 1 – All-Available Population

Among participants in the Dose 1 all-available efficacy (modified intention-to-treat) population, 1 case of severe COVID-19 as defined by FDA occurred after Dose 1 in the BNT162b2 group compared to 30 cases in the placebo group (Table 26). The estimated VE against severe COVID-19 occurring after Dose 1 was 96.7% (2-sided 95% CI: 80.3%, 99.9%).

Table 26. Vaccine Efficacy – First Severe COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=23040)		Placebo (N[a]=23037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First severe COVID-19 occurrence after Dose 1	1	8.439 (22505)	30	8.288 (22435)	96.7	(80.3, 99.9)
After Dose 1 to before Dose 2	0	1.351 (22505)	6	1.360 (22435)	100.0	(14.5, 100.0)
Dose 2 to 7 days after Dose 2	0	0.425 (22170)	1	0.423 (22070)	100.0	(-3783.5, 100.0)
≥7 Days after Dose 2	1	6.663 (22142)	23	6.505 (22048)	95.8	(73.9, 99.9)

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 19APR2021 (18:26)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_sev_cov_pd1_aai

11.1.2.2.1.4. Vaccine Efficacy for Severe COVID-19 Cases per CDC Definition – Updated Analysis

In addition, a supportive analysis was conducted for efficacy against severe cases of COVID-19 using the CDC definition of severe COVID-19 (hospitalization, admission to the intensive care unit (ICU), intubation or mechanical ventilation, or death).[2]

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against CDC-defined severe COVID-19 occurring at least 7 days after Dose 2 was 100.0% (2-sided 95% CI: 88.1%, 100.0%), with 0 and 32 cases in the BNT162b2 and placebo groups, respectively (Table 27).

Table 27. Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First severe COVID-19 occurrence based on CDC-definition from 7 days after Dose 2	0	6.250 (20688)	32	6.108 (20680)	100.0	(88.1, 100.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (02:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_sev_7pd2_cdc_wo_eval

Among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against CDC-defined severe COVID-19 occurring at least 7 days after Dose 2 was 100.0% (2-sided 95% CI: 88.0%, 100.0%), with 0 and 32 cases in the BNT162b2 and placebo groups, respectively (Table 28).

Among participants in the Dose 1 all-available efficacy population, 1 case of CDC-defined severe COVID-19 occurred after Dose 1 in the BNT162b2 group (but before Dose 2) compared to 45 cases in the placebo group (Supplemental Table 14.61). The estimated VE against severe CDC-defined COVID-19 occurring after Dose 1 was 97.8% (2-sided 95% CI: 87.2%, 99.9%).

Table 28. Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First severe COVID-19 occurrence based on CDC-definition from 7 days after Dose 2	0	6.514 (21620)	32	6.391 (21693)	100.0	(88.0, 100.0)

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (02:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve sev 7pd2 cdc eval

11.1.2.2.1.5. COVID-19 Narratives – Updated Analysis

Narratives of severe and/or multiple COVID-19 cases are provided in Section 14 COVID-19 Case (Severe and/or Multiple).

11.1.2.3. Signs and Symptoms of COVID-19

The criteria for COVID-19 case determination are described in Appendix 16.1.1, Protocol Section 8.1.

The signs and symptoms reported for cases contributing to the analysis for the first primary efficacy endpoint (77 cases in the BNT162b2 group and 850 cases in the placebo group) are summarized in Supplemental Table 14.62. These include cases occurring at least 7 days after the second vaccination among participants in the evaluable efficacy population who had no evidence of SARS-CoV-2 infection before or during the vaccination regimen. In this analysis, 36.4% of cases in the BNT162b2 group reported only 1 symptom, compared with 20.9% of cases in the placebo group; and 15.6% of the cases in the BNT162b2 group reported 4 or more symptoms, compared with 30.8% of cases in the placebo group. Most cases reported new or increased cough (63.9% of symptomatic cases overall), and other symptoms reported most frequently were new or increased muscle pain (45.2%), sore throat (38.6%), new loss of taste or smell (36.0%), and fever (35.9%). Similar results were reported for the evaluable efficacy population with or without evidence of SARS-CoV-2 infection before or during the vaccination regimen (Supplemental Table 14.63).

Supplemental Table 14.64 summarizes the signs and symptoms for all cases of COVID-19 occurring at any time after Dose 1 (131 cases in the BNT162b2 group and 1034 cases in the placebo group). These include cases occurring among participants in the Dose 1 all-available efficacy population, regardless of evidence of SARS-CoV-2 infection before or during the vaccination regimen. The proportions of cases reporting 4 or more symptoms were 19.1% in the BNT162b2 group compared with 30.0% of cases in the placebo group. The most frequently reported symptoms were similar to those for the analysis of the first primary efficacy endpoint.

In the evaluable efficacy population, signs and symptoms for FDA-defined severe cases of COVID-19 occurring at least 7 days after the second vaccination were reported for 1 participant in the BNT162b2 group and 21 participants in the placebo group, both among participants without (Supplemental Table 14.65) and with or without (Supplemental Table 14.66) evidence of SARS-CoV-2 infection before or during the vaccination regimen. The participant in the BNT162b2 group had 1 symptom of severe disease, SpO_2 ≤93%. In the placebo group, 57.1% (12/21) of the severe cases had clinical signs at rest indicative of severe systemic illness (defined as RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO_2 ≤93% on room air at sea level, or PaO_2/FiO_2 <300 mm Hg); 42.9% (9/21) had respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO), and 28.6% (6/21) were admitted to an ICU.

The signs and symptoms reported for all FDA-defined confirmed cases of severe COVID-19 reported at any time after Dose 1 (in the all-available population) (1 case in the BNT162b2 group and 30 cases in the placebo group) are summarized in Supplemental Table 14.67. The participant who was diagnosed with severe COVID-19 after receiving BNT162b2 had one symptom, SpO_2 ≤93% (Appendix 16.2.8.3). Among the 30 severe cases in the placebo group, 63.3% had clinical signs at rest indicative of severe systemic illness; 46.7% had respiratory failure; and 26.7% were admitted to an ICU.

11.1.2.4. Efficacy Conclusions – Updated Analysis

Updated Analysis – Efficacy Against Confirmed COVID-19

- In the updated descriptive efficacy analysis (cut-off date 13 March 2021), among participants in the evaluable efficacy population without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 91.3% (2-sided 95% CI: 89.0%, 93.2%), with 77 cases in the BNT162b2 group and 850 cases in the placebo group. Among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 91.1% (2-sided 95% CI: 88.8%, 93.0%), with 81 and 873 cases in the BNT162b2 and placebo groups, respectively.

- All cases of confirmed COVID-19 are accounted for in the analyses of VE in the all-available (modified intention-to-treat) population (regardless of evidence of infection before or during the vaccination regimen). In this analysis, the estimated VE against all

cases occurring at any time after Dose 1 was 87.8% (2-sided 95% CI: 85.3%, 89.9%), with 131 cases in the BNT162b2 group and 1034 cases in the placebo group.

- In this same all-available (modified intention-to-treat) population, the estimated VE against all cases occurring ≥7 days after Dose 2 was 91.2%. The estimated VE was 91.7% from ≥11 days after Dose 1 to before Dose 2, 96.2% for cases occurring from ≥7 days after Dose 2 to <2 months after Dose 2, 90.1% for the period from ≥2 months to <4 months after Dose 2, and 83.7% for the period ≥4 months after Dose 2.

Efficacy in Demographic and Risk Subgroups

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen (efficacy evaluable population), VE against COVID-19 occurring at least 7 days after Dose 2 was evaluated for demographic and risk subgroups, with results as follows:

- Estimated VE was ≥90% in most demographic subgroups, similar to the estimated 91.3% overall VE.

- High VE was observed across age subgroups, with an estimated VE of 100.0% in 12 to 15 year olds, 90.6% in 16 to 64 year olds, 94.5% in those ≥65 years, and 96.2% in those ≥75 years of age.

- The estimated VE was 86.5% in Argentina, 86.2% in Brazil, 92.6% in the United States, and 100.0% in South Africa, Germany, and Turkey.

- The estimated VE was similar for participants at risk (91.6%) and participants not at risk (91.0%). The estimated VE for participants ≥65 years of age and at risk was 91.8%, as compared with 98.1% for those ≥65 years of age and not at risk. The estimated VE was similar in obese (91.6%) and non-obese (91.1%) participants. When evaluated by type of comorbidity, the estimated VE was >85% for participants with each comorbidity evaluated, including any malignancy, cardiovascular disease, chronic pulmonary disease, diabetes, obesity, and hypertension.

Efficacy Against Severe Cases of COVID-19

- Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen (evaluable efficacy population), the estimated VE against FDA defined severe COVID-19 (protocol definition) occurring at least 7 days after Dose 2 was 95.3% (2-sided 95% CI: 71.0%, 99.9%), with 1 and 21 cases in the BNT162b2 and placebo groups, respectively. Similarly, the estimated VE was also 95.3% (2-sided 95% CI: 70.9%, 99.9%) among participants with or without evidence of SARS-CoV-2 infection, also with 1 and 21 cases in the BNT162b2 and placebo groups, respectively.
- Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen (evaluable efficacy population), the estimated VE against CDC-defined severe COVID-19 occurring at least 7 days after Dose 2 was 100.0% (2-sided 95% CI: 88.1%, 100.0%), with 0 and 32 cases in the BNT162b2 and placebo

groups, respectively. Similarly, the estimated VE was also 100.0% (2-sided 95% CI: 88.0%, 100.0%) among participants with or without evidence of SARS-CoV-2 infection, also with 0 and 32 cases in the BNT162b2 and placebo groups, respectively.

- Among participants in the Dose 1 all-available (modified intention-to-treat) population (regardless of evidence of infection before or during the vaccination regimen), the estimated VE against FDA-defined severe cases of COVID-19 occurring at any time after Dose 1 was 96.7% (2-sided 95% CI: 80.3%, 99.9%), with 1 case of severe COVID-19 in the BNT162b2 group compared to 30 cases in the placebo group.

11.2. Immunogenicity Results

11.2.1. Phase 1

Phase 1 immunogenicity results up to 1 month after Dose 2 in participants who received BNT162b1 and BNT162b2 vaccine candidates at the 10-µg, 20-µg, and 30-µg dose levels, and up to 7 weeks after Dose 1 of BNT162b1 at the 100-µg dose level (younger age group only) or placebo are presented in Section 11.2.1 of the final analysis interim C4591001 CSR dated 03 December 2020. BNT162b1 and BNT162b2 elicited robust SARS-CoV-2 neutralizing antibody response 7 days after Dose 2 in younger and older adults, based on GMTs, GMFRs, proportions of participants achieving a ≥4-fold rise in neutralizing titers, and RCDCs. Neutralizing antibody response was maintained through 1 month after Dose 2 and was similar for the candidates within the corresponding age and dose groups.

The persistence of SARS-CoV-2 serum 50% neutralizing activity and S1-binding IgG at 6 months after Dose 2 was evaluated for participants who received the 30 µg dose level of BNT162b2 (and corresponding placebo). Blood samples from some earlier time points for these participants were re-analyzed with the 6-month post Dose 2 samples to assure assay comparability between time points.

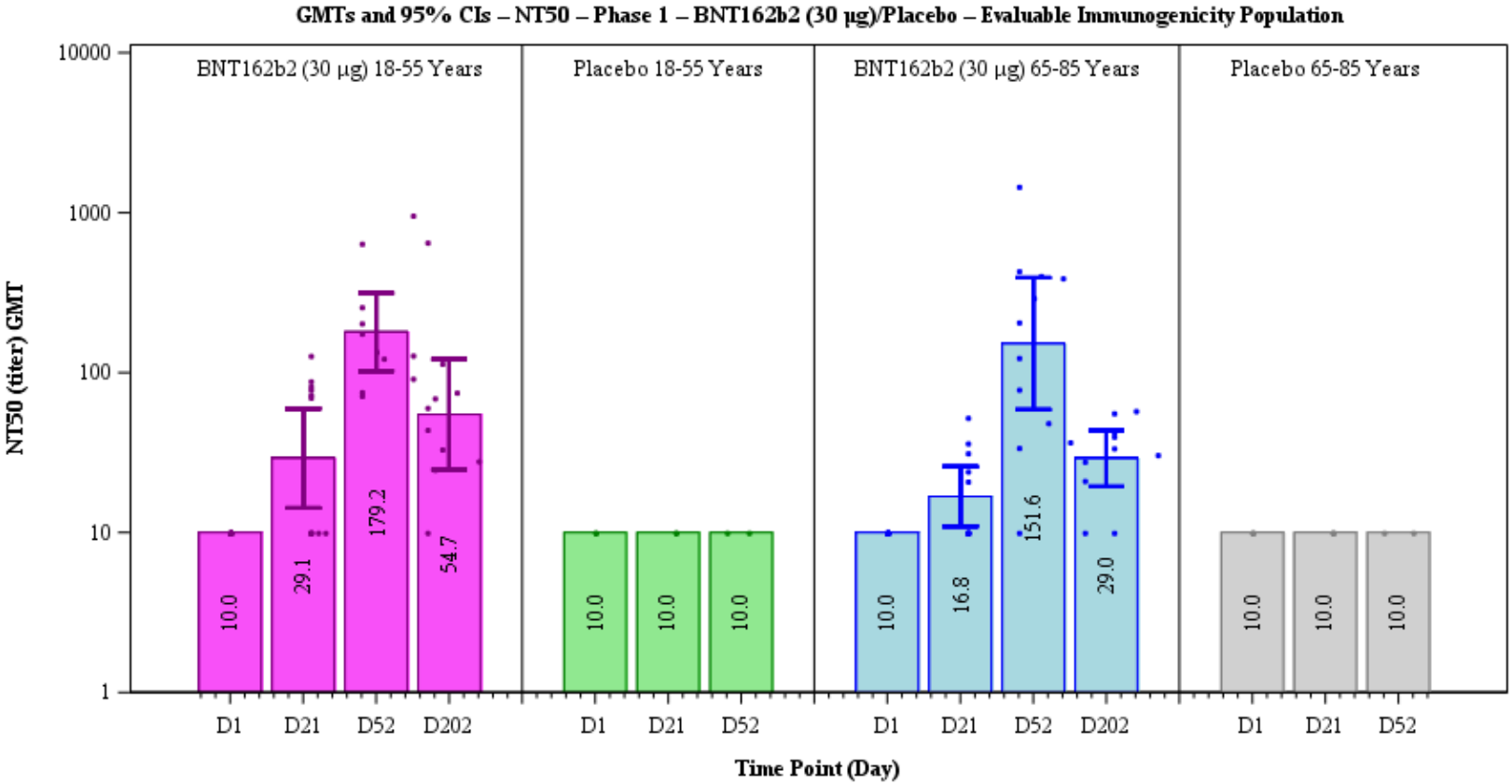
11.2.1.1. GMTs and GMCs

Among participants who received the 30 µg dose level of BNT162b2, in both age groups, the observed SARS-CoV-2 serum 50% neutralizing GMTs declined from 1 month after Dose 2 (Day 52) to 6 months after Dose 2 (Day 202). In the younger age group, GMTs were 179.2 at 1 month after Dose 2 and 54.7 at 6 months after Dose 2; in the older age group GMTs declined from 151.6 to 29.0 (Figure 3; Supplemental Table 14.4). Observed S1-binding IgG GMCs demonstrated similar declines (Figure 4; Supplemental Table 14.4).

In both age groups, results for the all-available immunogenicity population were similar to those observed for the evaluable immunogenicity population (Supplemental Table 14.5).

RCDCs of SARS-CoV-2 50% neutralizing titers and S1-binding IgG concentrations are presented in Supplemental Figures 14.1 through 14.4.

Figure 3. Geometric Mean Titers and 95% CIs: SARS-CoV-2 Neutralization Assay – NT50 – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population



Abbreviations: D = day; GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.

Note: Dots represent individual antibody levels.

Note: Number within each bar denotes geometric mean titer.

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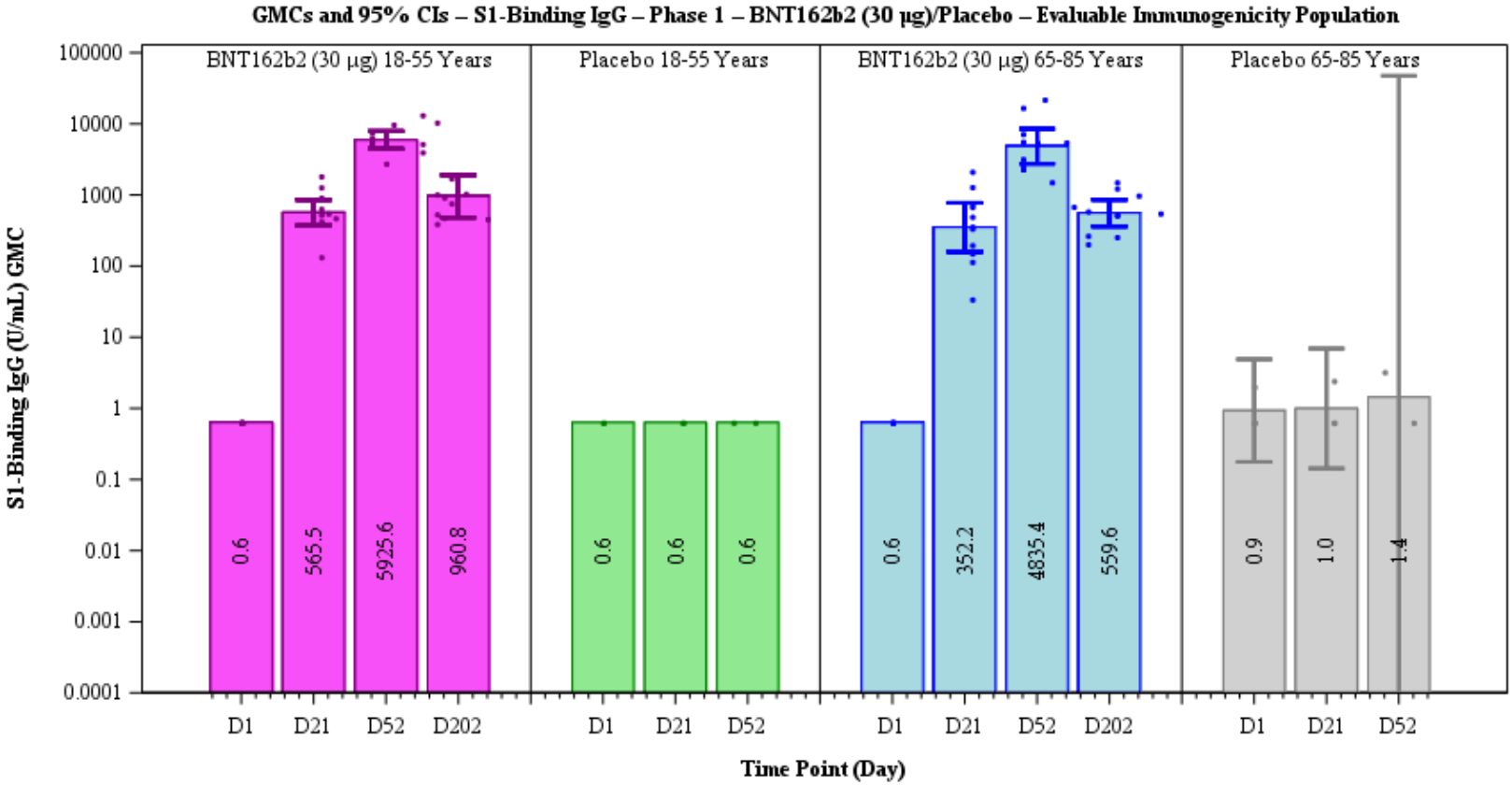
Figure 4. Geometric Mean Concentrations and 95% CIs: S1-Binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population



Abbreviations: D = day; GMC = geometric mean concentration; IgG = immunoglobulin G; S1 = spike protein S1 subunit.

Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.

Note: Dots represent individual antibody levels.

Note: Number within each bar denotes geometric mean titer.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 01APR2021 (02:19) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA1/adva_f002_s1_b2_p1

11.2.1.2. GMFRs

In the younger and older age groups, respectively, GMFRs of SARS-CoV-2 serum 50% neutralizing titers from before vaccination with BNT162b2 30 µg to each subsequent time point were 2.9 and 1.7 at Day 21 (before Dose 2); 17.9 and 15.2 at 1 month after Dose 2; 5.5 and 2.9 at 6 months after Dose 2. Results for GMFRs of S1-binding IgG concentrations reflected similar trends (Supplemental Table 14.6).

In both age groups, results for the all-available immunogenicity population were similar to those observed for the evaluable immunogenicity population (Supplemental Table 14.7).

11.2.1.3. GMRs

At 6 months after Dose 2 of BNT162b2 30 µg, GMRs of SARS-CoV-2 50% neutralizing titers to S1-binding IgG levels were 0.057 in the younger age group and 0.052 in the older age group. These values are similar to those observed at Day 21 (Supplemental Table 14.8).

In both age groups, results for the all-available immunogenicity population were similar to those observed for the evaluable immunogenicity population (Supplemental Table 14.9).

11.2.1.4. Number (%) of Participants Achieving a ≥4-Fold Rise from Baseline

In the younger age group, the proportions of participants achieving a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers from before vaccination to each time point were: 50.0% (6/12) at Day 21; 100.0% (11/11) at 1 month after Dose 2; and 60.0% (6/10) at 6 months after Dose 2 of BNT162b2 30 µg. In the older age group, these proportions were 9.1% (1/11) at Day 21; 81.8% (9/11) at 1 month after Dose 2; and 27.3% (3/11) at 6 months after Dose 2 of BNT162b2 30 µg (Supplemental Table 14.10).

With respect to S1-binding IgG concentrations, 100% of participants in both age groups had a ≥4-fold increase from baseline at each of these time points.

In both age groups, results for the all-available immunogenicity population were similar to those observed for the evaluable immunogenicity population (Supplemental Table 14.11).

11.2.1.5. Phase 1 Immunogenicity Conclusions

For Phase 1 participants who received BNT162b2 30 µg, at 6 months after Dose 2, SARS-CoV-2 serum neutralizing titers and serum S1-binding IgG concentrations had decreased relative to those observed at 1 month after Dose 2, but remained higher than values observed at prevaccination and compared with the placebo group.

11.2.2. Phase 2/3

Phase 2 immunogenicity results from the first 360 participants up to 1 month after Dose 2 in participants who received BNT162b2 30 µg or placebo are presented in Section 11.2.4 of the final analysis interim C4591001 CSR dated 03 December 2020. BNT162b2 at 30 µg elicited robust SARS-CoV-2 neutralization and S1-binding IgG antibody responses at 1 month after Dose 2, similar to those previously observed in Phase 1 of the study.

Immunogenicity data for Phase 2/3 will be reported separately.

12. SAFETY EVALUATION

Refer to the final analysis interim C4591001 CSR dated 03 December 2020, Section 12.1, 12.2, and 12.3 for details about the safety evaluation during Phase 1, Phase 2, and Phase 2/3 of the study, respectively.

In this interim CSR, the reactogenicity subset comprised of 9839 participants in Phase 2/3 (360 participants from Phase 2 included) who used an e-diary for reporting local reactions and systemic events.

12.1. Phase 1

Full details of Phase 1 safety up to 1 month after Dose 2 (data cutoff date: 24 August 2020) are presented in Section 12.1 of the final analysis interim C4591001 CSR dated 03 December 2020.

All doses tested for BNT162b1 and BNT162b2 (10 µg, 20 µg, and 30 µg) were safe and well tolerated except for BNT162b1 at 100 µg, which was discontinued after the first dose due to the reactogenicity profile.

BNT162b2 at 30 µg was selected to proceed into the Phase 2/3 portion of the study because this dose and construct provided the optimum combination of a favorable reactogenicity profile and a robust immune response.

12.1.1. Local Reactions and Systemic Events – Phase 1

Full details of local reactions and systemic events are presented in Sections 12.1.1 and 12.1.2 of the final analysis interim C4591001 CSR dated 03 December 2020.

The majority of reactogenicity events were mild or moderate in severity. Local and systemic reactogenicity events after each dose for both BNT162b1 and BNT162b2 in older adults were milder and less frequent than those observed in younger adults. Reactogenicity was generally higher after Dose 2 than Dose 1.

12.1.2. Adverse Events – Phase 1

In Phase 1, AEs reported up to 1 month after Dose 2 (data cutoff 24 August 2020) for BNT162b1 and BNT162b2 (all dose levels) and long-term follow-up (approximately 4 months after Dose 2 [data cutoff date: 14 November 2020]) for BNT162b2 30-µg are presented in Section 12.1.3 of the final analysis interim C4591001 CSR dated 03 December 2020. Most AEs were mild or moderate. There were no discontinuations because of AEs, and there was 1 severe SAE (neuritis; unrelated to vaccination) reported in a younger participant in the BNT162b2 30 µg group.

Phase 1 follow-up of safety is presented from Dose 1 to the unblinding date (data cutoff date: 13 March 2021) for the BNT162b2 30-µg group only in participants ≥18 through 55 and 65 through 85 years of age.

12.1.2.1. Summary of Adverse Events – Phase 1

From Dose 1 of BNT162b2 30 µg to the unblinding date, 6 (50.0%) participants in the younger age group and 3 (25.0%) participants in the older age group reported at least 1 AE (Supplemental Table 14.12). Two (16.7%) participants in the BNT162b2 30 µg younger age group and 1 (8.3%) participant in the BNT162b2 30 µg older age group reported at least 1 severe AE. In the BNT162b2 30 µg younger age group, 3 (25.0%) participants reported at least 1 related AE and 1 (8.3%) participant reported 1 severe SAE.

No AEs were reported in either the younger or older participants in the placebo group (Supplemental Table 14.12). No SAEs or related AEs were reported in the BNT162b2 30 µg older age group. No AEs leading to withdrawal, life-threatening AEs, or deaths were reported in either the younger or older participants in the BNT162b2 30 µg group.

12.1.2.2. Analysis of Adverse Events – Phase 1

From Dose 1 of BNT162b2 30 µg to the unblinding date, AEs were most commonly reported in the SOC of nervous system disorders (3 [25.0%] participants in the younger age group and 1 [8.3%] participant in the older age group), followed by musculoskeletal and connective tissue disorders (1 [8.3%] participant in each age group) (Supplemental Table 14.13). All AEs by PT were reported by no more than 1 participant.

12.1.3. Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events – Phase 1

12.1.3.1. Deaths – Phase 1

There were no Phase 1 participants randomized to BNT162b2 30 µg or corresponding placebo who died through the data cutoff date of 13 March 2021 (Supplemental Table 14.12).

12.1.3.2. Serious Adverse Events – Phase 1

From Dose 1 to the unblinding date, 1 participant in the BNT162b2 30 µg younger age group reported a severe SAE (neuritis) that was assessed by the investigator as not related to study intervention (Supplemental Tables 14.12 and 14.14).

12.1.3.3. Safety-Related Participant Withdrawals – Phase 1

No Phase 1 participants randomized to BNT162b2 30 µg or corresponding placebo reported any AEs leading to withdrawal from the study from Dose 1 to the unblinding date (Supplemental Table 14.12).

12.1.3.4. Other Significant Adverse Events – Phase 1

AEs of special interest were not defined for Phase 1 of this study.

12.1.3.5. Other Safety Assessments – Phase 1

12.1.3.5.1. Pregnancy – Phase 1

Pregnancy was not reported in any Phase 1 participants from Dose 1 to the unblinding date (data cutoff date: 13 March 2021) (Supplemental Table 14.13).

12.1.3.6. Analysis and Discussion of Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events – Phase 1

During the period covered in this interim CSR, 1 SAE was reported in the younger age group and no AEs leading to withdrawals and no deaths were reported in either age group.

12.1.4. Clinical Laboratory Evaluation – Phase 1

Clinical laboratory evaluations showed a transient decrease in lymphocytes that was observed in all age and dose groups after Dose 1, which resolved within a few days, were not associated with any other clinical sequelae, and were not considered clinically relevant.

Refer to Section 12.1.5 of the final analysis interim C4591001 CSR dated 03 December 2020 for details of clinical laboratory evaluations.

12.1.5. Physical Examination Findings – Phase 1

Overall, there were fewer abnormalities noted during physical examinations after BNT162b2 than after BNT162b1 in both age groups.

Full details of physical examinations are presented in Section 12.1.6 of the final analysis interim C4591001 CSR dated 03 December 2020.

12.1.6. Phase 1 Safety Conclusions

BNT162b2 30 µg was safe and well tolerated at up to 6 months after Dose 2.

12.2. Phase 2/3

12.2.1. Local Reactions – Phase 2/3 Participants ≥16 Years of Age

In the BNT162b2 group, pain at the injection site was reported more frequently in the younger age group (N=2899 post Dose 1; N=2682 post Dose 2) than in the older age group (N=2008 post Dose 1; N=1860 post Dose 2), and frequency was similar after Dose 1 compared with Dose 2 of BNT162b2 in the younger age group (83.7% vs 78.3%) and in the older age group (70.1% vs 66.1%) (Figure 5 and Figure 6, respectively, and Supplemental Table 14.68). In the placebo group, pain at the injection site after Doses 1 and 2 was reported at slightly higher frequencies in the younger age group (14.2% and 11.6%, respectively) than in the older age group (9.3% and 7.8%, respectively).

In the BNT162b2 group, frequencies of redness and swelling were similar in the younger and older age group after Doses 1 and 2 (Supplemental Table 14.68). Frequencies of redness were similar after Dose 1 compared with Dose 2 of BNT162b2 in the younger age group (5.4% vs 5.6%) and in the older age group (5.3% vs 7.2%). Frequencies of swelling were similar after Dose 1 compared with Dose 2 of BNT162b2 in the younger age group (6.3% vs 6.8%, respectively) and in the older age group (7.0% vs 7.8%). In the placebo group, redness and swelling were reported infrequently in the younger (≤1.0%) and older (≤1.2%) groups after Doses 1 and 2.

Overall, across age groups, pain at the injection site did not increase after Dose 2, and redness and swelling were generally similar in frequency after Dose 1 and Dose 2. Severe

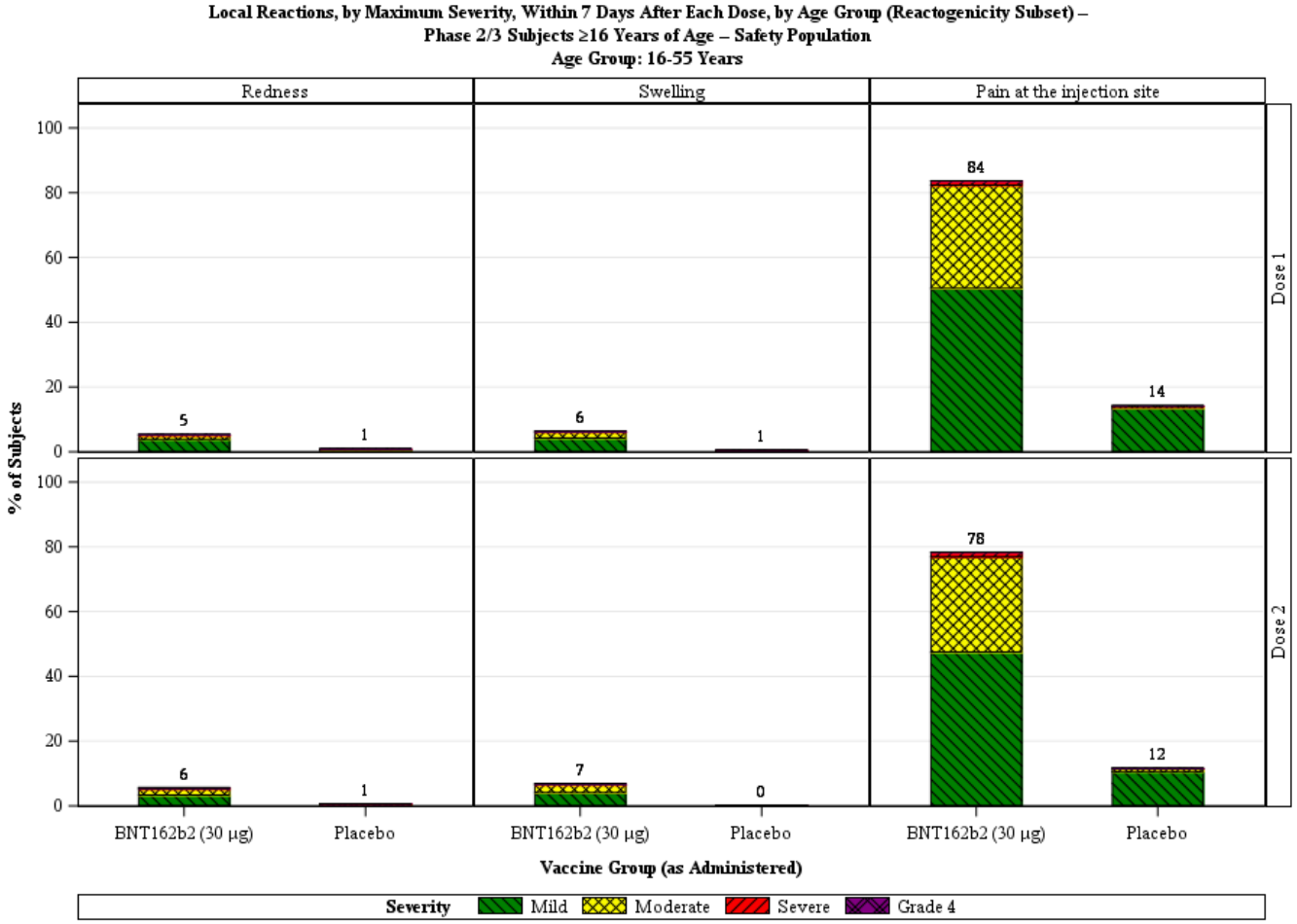
redness and swelling were reported infrequently and were similar between the younger and older age groups (≤0.7%) after any dose. Severe pain at the injection site occurred more frequently in the younger age group compared to the older age group (2.5% vs 0.7%) (Supplemental Table 14.68). After the first and second dose and in both age groups, the majority of local reactions were mild or moderate in severity, and no Grade 4 local reactions were reported.

The median onset for local reactions after either dose of BNT162b2 was between Day 1.0 and Day 2.0 (Day 1.0 was the day of vaccination) in the younger age group and between Day 1.0 and Day 3.0 in the older age group (Supplemental Table 14.69). Local reactions resolved with median durations between 1.0 and 2.0 days in both age groups (Supplemental Table 14.70).

Subgroup Analyses

There were 177 BNT162b2 and 187 placebo participants with baseline positive SARS-CoV-2 status, and 4701 BNT162b2 and 4690 placebo participants with baseline negative SARS-CoV-2 status (Supplemental Table 14.71). For local reactions the frequency of redness, swelling, and pain at the injection site after any dose of BNT162b2 was 8.5%, 10.2%, and 80.2% compared with 9.9%, 11.1%, and 84.5% for those positive and negative at baseline, respectively. While the frequency of local reactions was numerically higher in those negative at baseline, these differences are not clinically meaningful.

Figure 5. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population
Age Group: 16 Through 55 Years of Age



Note: Number above each bar denotes percentage of subjects reporting the reaction with any severity.
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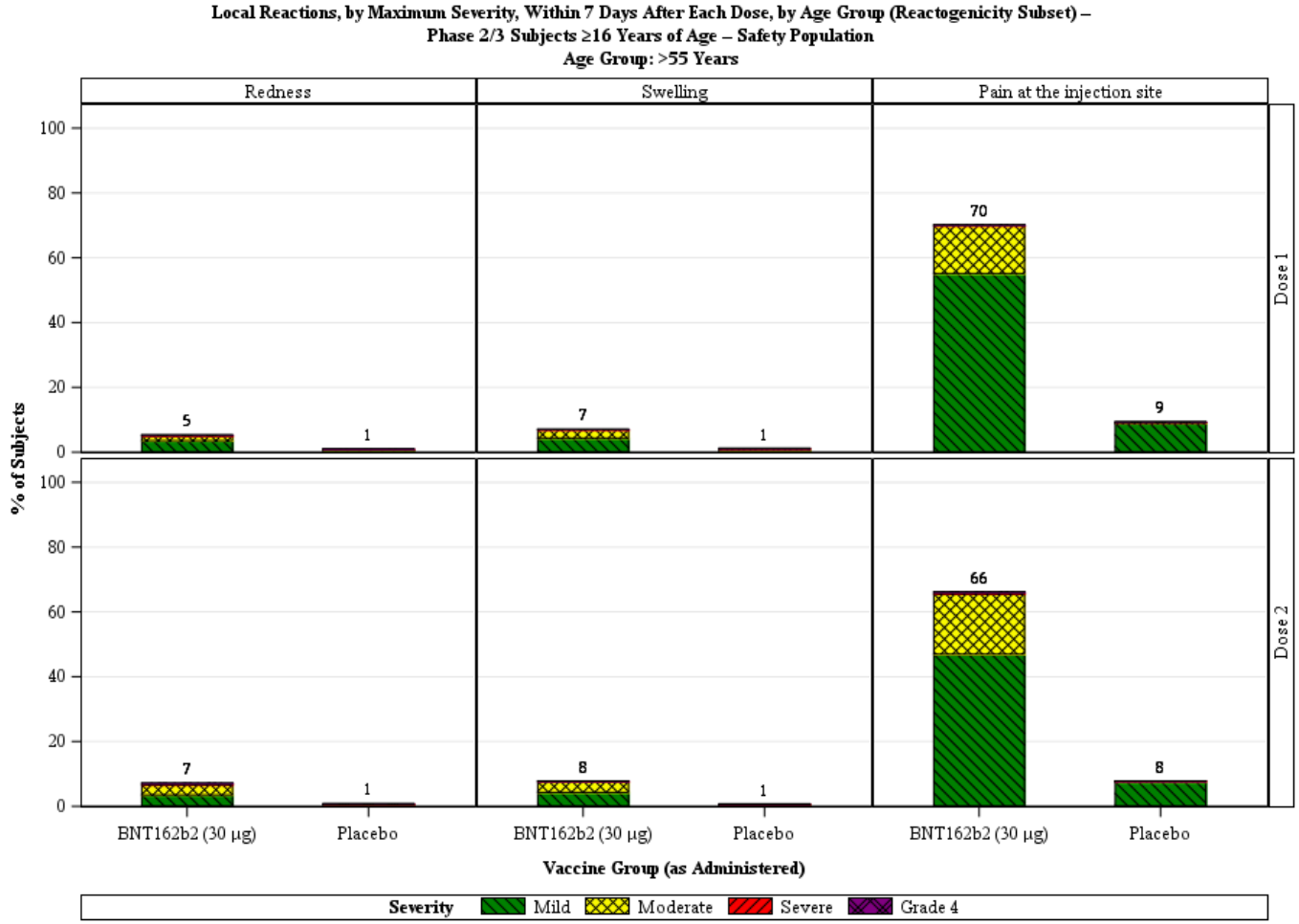
Figure 6. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population
Age Group: >55 Years of Age

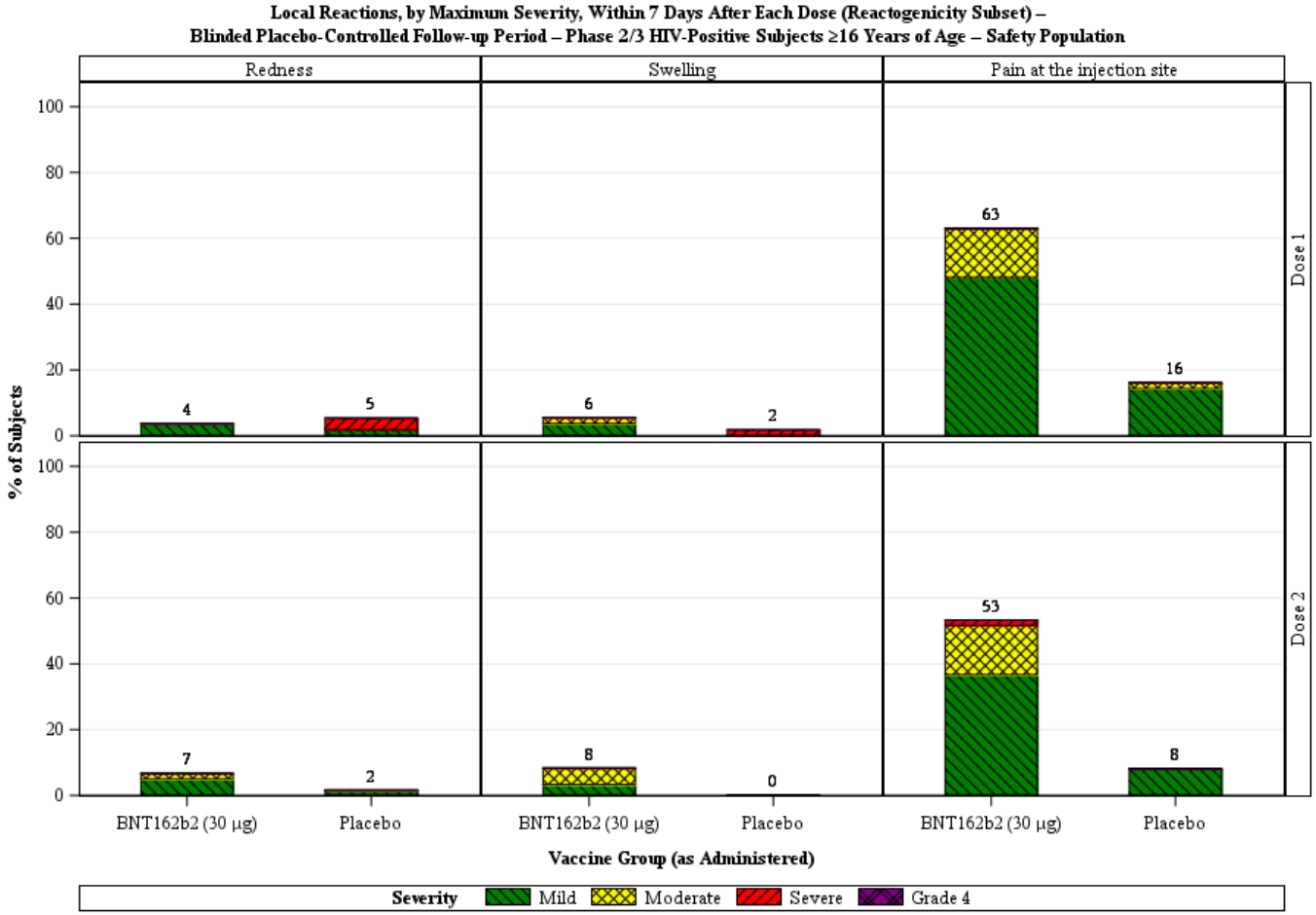


Note: Number above each bar denotes percentage of subjects reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_f001_lr_max_age_p3

12.2.1.1. Participants with Confirmed Stable HIV Disease

Local reactions in participants with confirmed stable HIV disease were similar to those observed for all participants ≥16 years of age by severity, onset day, and median duration (Supplemental Tables 14.72, 14.73, and 14.74 , respectively, and Figure 7). The frequency of pain at the injection site was similar after Dose 1 compared with Dose 2 of BNT162b2 (63.0% vs 53.3%) (Supplemental Table 14.72). The frequency of redness and swelling was similar after Dose 1 compared with Dose 2 of BNT162b2 (redness: 3.7% vs 6.7%; swelling: 5.6% vs 8.3%, respectively). There was 1 (1.7%) severe reaction (pain at the injection site) reported after Dose 2 of BNT162b2 and no Grade 4 reactions were reported.

Figure 7. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population



Abbreviation: HIV = human immunodeficiency virus.
Note: Number above each bar denotes percentage of subjects reporting the reaction with any severity.
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(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_f001_lr_max_hiv_p3

12.2.2. Systemic Events – Phase 2/3 Participants ≥16 Years of Age

Systemic events were generally increased in frequency and severity in the younger group (Figure 8) compared with the older group (Figure 9), with frequencies and severity increasing with number of doses (Dose 1 vs Dose 2). Vomiting and diarrhea were exceptions, which were reported similarly infrequently in both age groups and at similar incidences after each dose.

Systemic events in the younger group compared with the older group, with frequencies increasing with number of doses (Dose 1 vs Dose 2) (Supplemental Table 14.75), were:

- fatigue: younger group (49.4% vs 61.5%) compared to older group (33.7% vs 51.0%)
- headache: younger group (43.5% vs 54.0%) compared to older group (25.0% vs 39.4%)
- muscle pain: younger group (22.9% vs 39.3%) compared to older group (13.6% vs 28.9%)
- chills: younger group (16.5% vs 37.8%) compared to older group (6.5% vs 23.4%)
- joint pain: younger group (11.8% vs 23.8%) compared to older group (8.7% vs 19.0%)
- fever: younger group (4.1% vs 16.4%) compared to older group (1.3% vs 11.8%)
- vomiting: younger group (1.2% vs 2.2%) compared to the older group (0.5% vs 0.7%)
- diarrhea: younger group (10.7% vs 10.0%) compared to the older group (8.4% vs 8.2%).

Systemic events were generally reported less frequently in the placebo group than in the BNT162b2 group, for both age groups and doses, with some exceptions. In the younger age group, vomiting and diarrhea (after Dose 1 and Dose 2) were reported at similar frequencies in the placebo group and the BNT162b2 group (Figure 8). In the older age group, vomiting and diarrhea (after Dose 1 and Dose 2) were reported at similar frequencies in the placebo group and the BNT162b2 group (Figure 9).

Following both Dose 1 and Dose 2, use of antipyretic/pain medication was slightly less frequent in the older age group (19.0% vs 37.0%) than in the younger age group (27.8% vs 45.2%) after both doses, and medication use increased in both age groups after Dose 2 as compared with after Dose 1 (Supplemental Table 14.75). Use of antipyretic/pain medication was less frequent in the placebo group than in the BNT162b2 group and was similar after Dose 1 and Dose 2 in the younger and older placebo groups (ranging from 9.3% to 13.7%).

Severe fever (>38.9°C to 40.0°C) increased in frequency with the number of doses (Dose 1 versus Dose 2) in younger (0.3% vs 1.5%) and older (0.0% vs 0.4%) participants who received BNT162b2 and was reported in 0.1% of participants who received placebo in both age group after both doses. One participant in the younger BNT162b2 group reported fever of 41.2°C only on Day 2 after Dose 2 and was nonfebrile for all other days of the reporting

period (Supplemental Table 14.75 and Appendix 16.2.7.3.1). Grade 4 fever was not reported in the older BNT162b2 group or in any placebo participants.

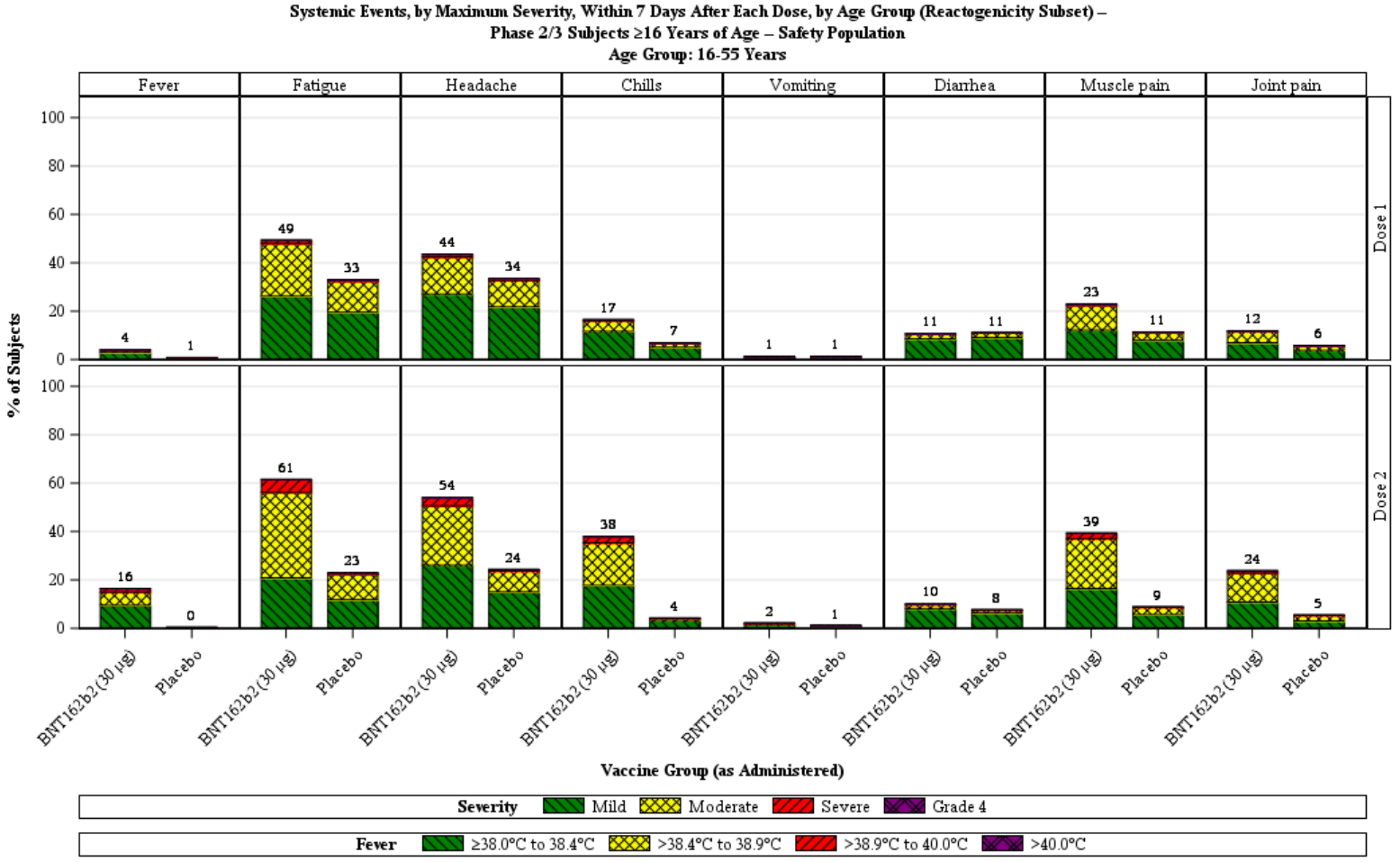
After the first and second dose and in both age groups, the majority of systemic events were mild or moderate in severity.

Systemic events in the younger and older age groups after either dose of BNT162b2 had a median onset day between Day 2.0 and Day 4.0 (Day 1.0 was the day of vaccination) (Supplemental Table 14.76) and resolved with a median duration of 1 day in both age groups (Supplemental Table 14.77).

Subgroup Analyses

There were 177 BNT162b2 and 187 placebo participants with baseline positive SARS-CoV-2 status, and 4701 BNT162b2 and 4690 placebo participants with baseline negative SARS-CoV-2 status. For any fever after either dose there were 31 (17.5%) compared to 714 (15.1%) in those positive and negative for SARS-CoV-2 at baseline, respectively. Severe fever (>38.9°C to 40.0°C) was reported in 1 (0.6%) participant and 49 (1.0%) participants in those positive and negative for SARS-CoV-2 at baseline, respectively. The frequency for other systemic events after any dose of BNT162b2 was numerically lower for those positive at baseline: fatigue, headache and chills the frequency was 54.2%, 49.7% and 32.8% compared with 65%, 57.4%, 34.7% for those positive and negative for SARS-CoV-2 at baseline, respectively. Joint pain was another exception where 27.1% compared to 25.0% were reported between those positive and negative for SARS-CoV-2 at baseline (Supplemental Table 14.78). Note that the baseline SARS-CoV-2 positive subgroup included far fewer participants the negative subgroup, so their results should be interpreted with caution.

Figure 8. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population
Age Group: 16 Through 55 Years



Note: Number above each bar denotes percentage of subjects reporting the event with any severity.
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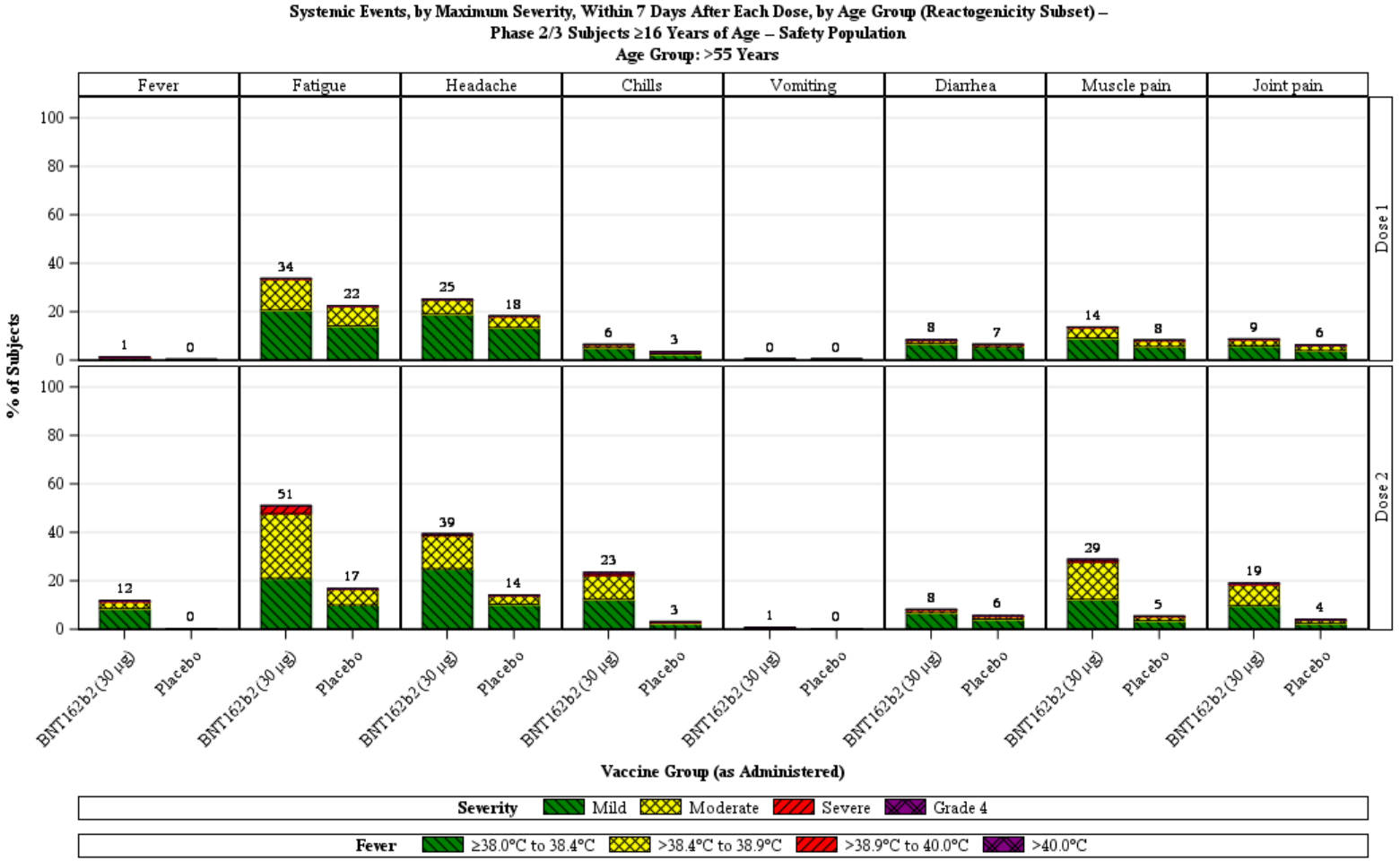
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_f001_se_max_age_p3

Figure 9. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population
Age Group: >55 Years

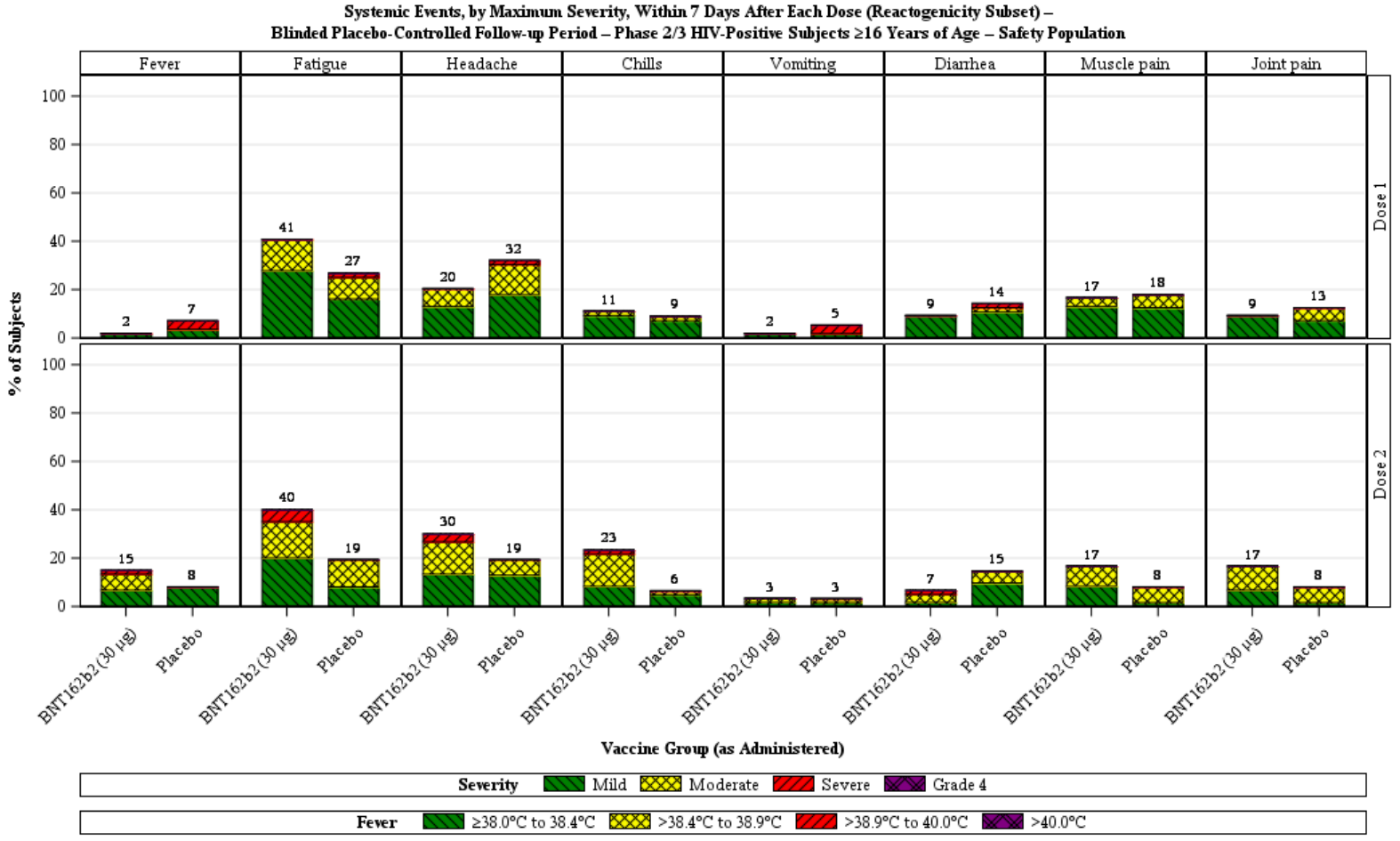


Note: Number above each bar denotes percentage of subjects reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_f001_se_max_age_p3

12.2.2.1. Participants with Confirmed Stable HIV Disease

Systemic events from participants with confirmed stable HIV disease were similar to those observed for all participants ≥16 years of age by severity, onset day, and duration (Supplemental Tables 14.79, 14.80, and 14.81, respectively, and Figure 10). Fever, headache, chills, and joint pain increased in frequency from Dose 1 to Dose 2 while fatigue, vomiting, diarrhea, and muscle pain were similar after each dose. There were no severe systemic events after Dose 1 of BNT162b2 but after Dose 2, there was 1 (1.7%) severe fever (>38.9°C to 40.0°C), 3 (5.0%) participants with severe fatigue, 2 (3.3%) participants with severe headache, 1 (1.7%) participant with severe chills, and 1 (1.7%) participant with severe diarrhea. There were no grade 4 systemic events reported after either dose.

Figure 10. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population



Abbreviation: HIV = human immunodeficiency virus.
Note: Number above each bar denotes percentage of subjects reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_f001_se_max_hiv_p3

12.2.3. Adverse Events – Phase 2/3 Participants ≥16 Years of Age

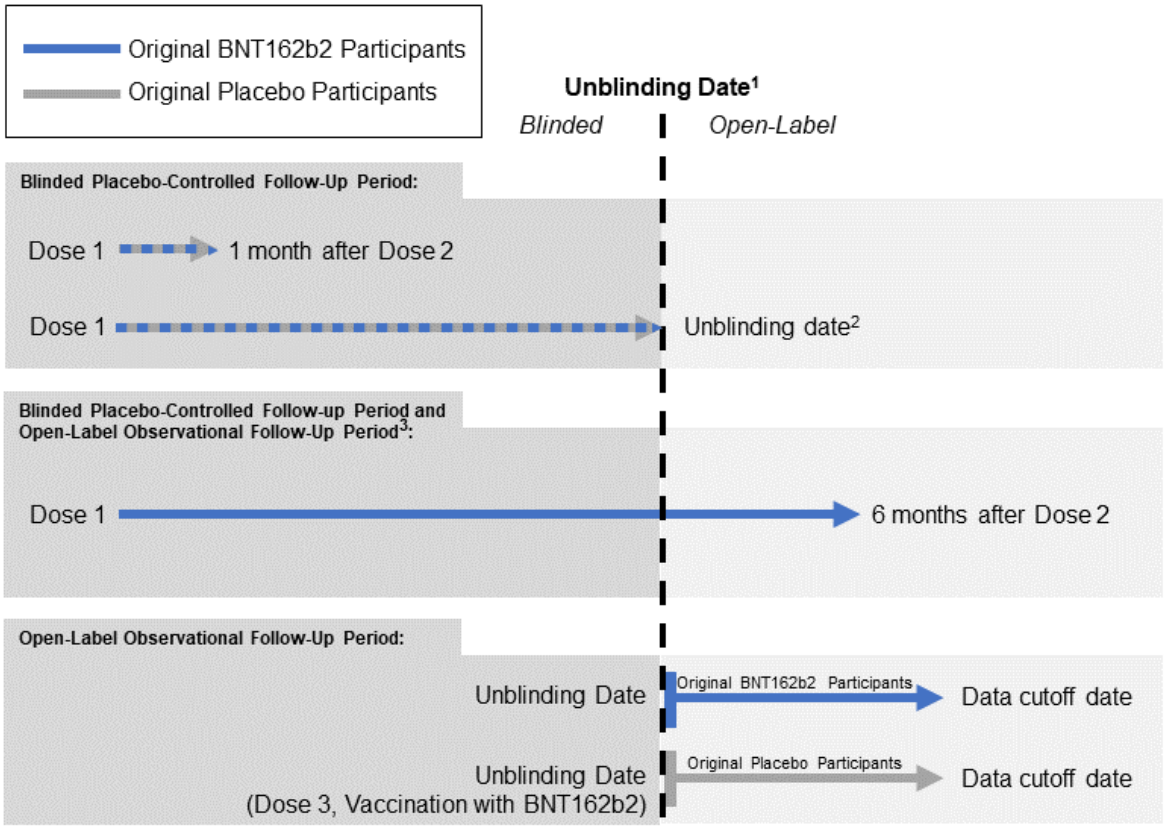
AE safety data are from either the blinded placebo-controlled follow-up period, the open-label observational follow-up period, or both. The time periods and safety analysis groups are presented below and in Figure 11.

- Blinded placebo-controlled follow-up period from Dose 1 to 1 month after Dose 2 (frequencies) (Section 12.2.3.1)
- Blinded placebo-controlled follow-up period from Dose 1 to the unblinding date (IRs) (Section 12.2.3.2)
- Open-label follow-up period – original BNT162b2 participants (IRs) (Section 12.2.3.3)
- Blinded placebo-controlled and open-label follow-up periods from Dose 1 to 6 months after Dose 2 – original BNT162b2 participants (frequencies) (Section 12.2.3.4)
- Open-label follow-up period – original placebo participants who then received BNT162b2 (IRs) (Section 12.2.3.5)

For AE analyses beyond 1 month after Dose 2, and for AEs after unblinding, IRs per 100 Person-Years are reported (as opposed to frequencies) to account for the variable exposure since unblinding began for individual participants.

In this ongoing study, tables summarizing participant withdrawals may include some participants who were reported as withdrawn but remain in the study and are continuing to be evaluated. These participants are documented in the Errata.

Figure 11 Phase 2/3 Safety Analyses: Time Periods and Analysis Groups



[1] Will vary by participant. Adverse event data analyzed from Dose 1 to unblinding date (on or after 14 December 2020), or from unblinding date to data cutoff date, are reported as incidence rates adjusted for exposure time.
[2] Up to ~6 months after Dose 2.
[3] Cumulative BNT162b2 follow-up to at least 6 months after Dose 2.

12.2.3.1. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2

12.2.3.1.1. Summary of Adverse Events – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2

An overview of AEs from Dose 1 to 1 month after Dose 2 for the 43,847 participants during the blinded placebo-controlled follow-up period (including those analyzed in Phase 2) is presented in Table 29. The numbers of overall participants who reported at least 1 AE and at least 1 related AE were higher in the BNT162b2 group (30.2% and 23.9%, respectively) as compared with the placebo group (13.9% and 6.0%, respectively). The higher frequencies in the BNT162b2 was due to terms consistent with reactogenicity reported at greater frequency in the BNT162b2 group vs the placebo group. This pattern is further described in Section 12.2.3.1.2.1. Severe AEs were reported by 1.2% and 0.7% in in the BNT162b2 and placebo groups respectively, and life-threatening AEs were similar (0.1% in both groups).

SAEs and AEs leading to withdrawal were reported by ≤0.6% and ≤0.2%, respectively, in both groups. Discontinuations due to related AEs were reported in 13 participants in the BNT162b2 group and 11 participants in the placebo group (0.1% in both groups).

From Dose 1 to 1 month after Dose 2, there were 3 deaths in the BNT162b2 group and 5 deaths in the placebo group during the blinded follow-up period.

In the younger age group, the number of participants who reported at least 1 AE from Dose 1 to 1 month after Dose 2 was 4233 (32.6%) and 1871 (14.4%) in the BNT162b2 and placebo groups, respectively (Supplemental Table 14.82). In the older age group, the number of participants who reported at least 1 AE from Dose 1 to 1 month after Dose 2 was 2384 (26.7%) and 1177 (13.2%) in the BNT162b2 and placebo groups, respectively (Supplemental Table 14.83).

Table 29. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
Adverse Event	**BNT162b2 (30 µg) (N[a]=21926) n[b] (%)**	**Placebo (N[a]=21921) n[b] (%)**
Any event	6617 (30.2)	3048 (13.9)
Related[c]	5241 (23.9)	1311 (6.0)
Severe	262 (1.2)	150 (0.7)
Life-threatening	21 (0.1)	26 (0.1)
Any serious adverse event	127 (0.6)	116 (0.5)
Related[c]	3 (0.0)	0
Severe	71 (0.3)	66 (0.3)
Life-threatening	21 (0.1)	26 (0.1)
Any adverse event leading to withdrawal	32 (0.1)	36 (0.2)
Related[c]	13 (0.1)	11 (0.1)
Severe	10 (0.0)	10 (0.0)
Life-threatening	3 (0.0)	7 (0.0)
Death	3 (0.0)	5 (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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s091_all_pd2_p3_saf1

12.2.3.1.1.1. Participants with Confirmed Stable HIV Disease – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2

From Dose 1 to 1 month after Dose 2, the subset of 200 HIV-positive participants during the blinded placebo-controlled follow-up period showed generally similar trends as the overall population (likewise attributed to reactogenicity reported in the BNT162b2 group). The numbers of HIV-positive participants who reported at least 1 AE and at least 1 related AE were higher in the BNT162b2 group (26.0% and 19.0%, respectively) as compared with the placebo group (13.0% and 3.0%, respectively) (Supplemental Table 14.84). In this group, there was 1 severe AE and 1 AE leading to withdrawal (both were in the BNT162b2 group), and there were no SAEs or deaths.

12.2.3.1.2. Analysis of Adverse Events – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2

12.2.3.1.2.1. Adverse Events by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2

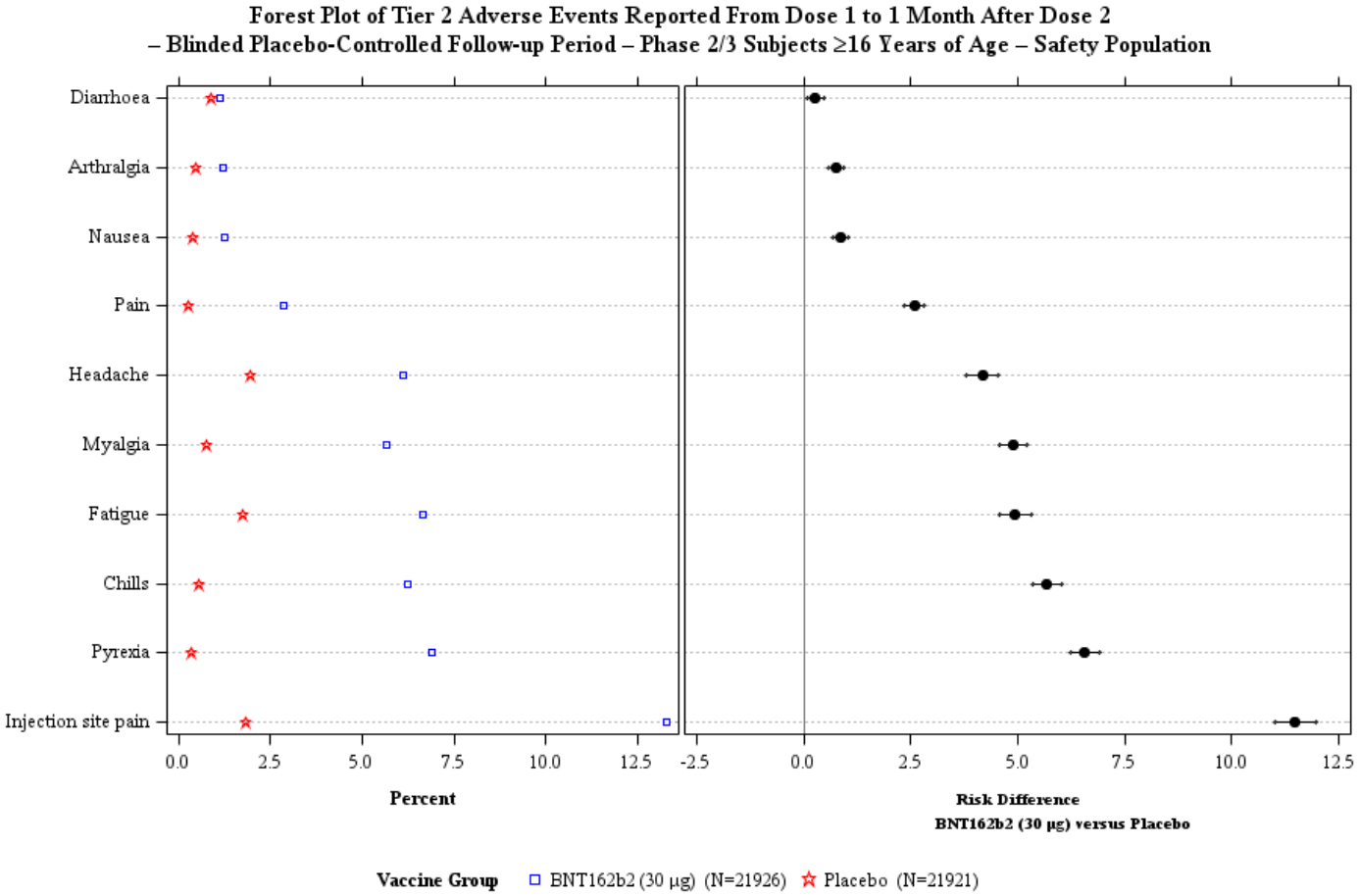
There are no Tier 1 AEs identified for this program.

Tier 2 AEs (defined as an event rate ≥1.0% in any vaccine group [PT level]) reported from Dose 1 to 1 month after Dose 2 are presented in Figure 12 and Supplemental Table 14.85.

Most Tier 2 AEs were reactogenicity events and all were reported in 4 SOCs: general disorders and administration site conditions, musculoskeletal and connective tissue disorders, nervous system disorders, and gastrointestinal disorders. The proportions of participants reporting Tier 2 AEs were generally higher in the BNT162b2 group (N=21,926; ranging from 1.1% to 13.3%) than in the placebo group (N=21,921; ranging from 0.3% to 1.9%). Most of the PTs were in the SOC of general disorders and administration site conditions:

- injection site pain (2915 [13.3%] BNT162b2 vs 397 [1.8%] placebo)
- pyrexia (1517 [6.9%] BNT162b2 vs 77 [0.4%] placebo)
- fatigue (1463 [6.7%] BNT162b2 vs 379 [1.7%] placebo)
- chills (1365 [6.2%] BNT162b2 vs 120 [0.5%] placebo)
- pain (628 [2.9%] BNT162b2 vs 61 [0.3%] placebo).

Figure 12. Forest Plot of Tier 2 Adverse Events Reported From Dose 1 to 1 Month After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population



Note: MedDRA (v23.1) coding dictionary applied.
Note: A MedDRA preferred term is defined as a Tier 2 event if there are at least 1% subjects with the AE term in at least 1 vaccine group.
Note: 2-Sided CI based on the Miettinen and Numinen method for the difference in proportions (BNT162b2 (30 µg) - placebo) expressed as a percentage. They are not adjusted for multiplicity and should be used for screening purposes only.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (17:59)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_f001_t2_p3

From Dose 1 to 1 month after Dose 2 during the blinded placebo-controlled follow-up period, 6617 (30.2%) BNT162b2 participants and 3048 (13.9%) placebo participants reported at least 1 AE. Most reported AEs were in SOCs with reactogenicity events. (Table 30):

- general disorders and administration site conditions (4725 [21.5%] BNT162b2 vs 993 [4.5%] placebo)
- musculoskeletal and connective tissue disorders (1804 [8.2%] BNT162b2 vs 527 [2.4%] placebo)
- nervous system disorders (1565 [7.1%] BNT162b2 vs 600 [2.7%] placebo)
- gastrointestinal disorders (699 [3.2%] BNT162b2 vs 464 [2.1%] placebo)

The number of BNT162b2 participants who reported at least 1 AE from Dose 1 to 1 month after Dose 2 was 4233 (32.6%) and 2384 (26.7%) in the younger and older groups (Supplemental Tables 14.86 and 14.87, respectively). In the younger versus older BNT162b2 age groups, AE frequencies in above SOCs were:

- general disorders and administration site conditions (3161 [24.3%] vs 1564 [17.5%])
- musculoskeletal and connective tissue disorders (1201 [9.2%] vs 603 [6.8%])
- nervous system disorders (1067 [8.2%] vs 498 [5.6%])
- gastrointestinal disorders (440 [3.4%] vs 259 [2.9%]).

As shown in Table 30, the most frequently reported AEs in the BNT162b2 group by PT overall were injection site pain (2915 [13.3%]), pyrexia (1517 [6.9%]), fatigue (1463 [6.7%]), chills (1365 [6.2%]), headache (1339 [6.1%]), and myalgia (1239 [5.7%]). During this time period from Dose 1 to 1 month after Dose 2, most of these AEs were reported during the e-diary 7-day reporting period (Supplemental Tables 14.88 and 14.89).

The frequency of AEs in the SOC of investigations was higher in the BNT162b2 group (0.8%) as compared with the placebo group (0.2%) mainly due to the higher frequency of the PT Body temperature increased (120 in the BNT162b2 group and 12 in the placebo group).

In the skin and subcutaneous tissue disorders SOC, there were 17 participants who reported night sweats in the BNT162b2 group (compared to 3 in the placebo group), and all but 1 of these participants reported the AE within the first 7 days after Dose 1 or 2, respectively (Supplemental Tables 14.88 and 14.89), and there were 31 participants who reported hyperhidrosis in the BNT162b2 group (compared to 9 in the placebo group), and all but 3 of these participants reported the AE within the first 7 days after Dose 1 or 2 (Supplemental Tables 14.88 and 14.89).

Nineteen study participants reported events in the Hepatobiliary Disorders SOC (14 BNT162b2 recipients and 5 placebo recipients) (Table 30). Of the 19 total participants, 3 participants had hepatic events (Appendix 16.2.7.4.1):

- One participant in the placebo group reported hepatic cirrhosis

- One participant in the placebo group reported nonalcoholic fatty liver disease
- One participant in the BNT162b2 group reported alcoholic cirrhosis

The remaining 16 participants reported biliary events (cholecystitis/cholecystitis acute, biliary colic, bile duct stone, and biliary dyskinesia): 13 participants in the BNT162b2 group and 3 participants in the placebo group.

- In the BNT162b2 group, 8 participants reported cholelithiasis (1 reported an event each of cholelithiasis and cholecystitis), 1 participant reported cholecystitis acute, 2 participants reported biliary colic, and 1 participant each reported bile duct stone/biliary dyskinesia.
- In the placebo group, there were 3 participants who reported the following: 1 participant reported an event each of cholecystitis acute and cholelithiasis, 1 participant reported cholecystitis acute, and 1 participant reported cholelithiasis.

In the nervous systems disorder SOC, there were 3 participants who reported facial paralysis in the BNT162b2 group (compared to none in the placebo group). More details are presented in Section 12.2.3.2.2.

For lymphadenopathy the frequency in the BNT162b2 group was 0.4% compared to the frequency of 0.0% on the placebo group. Most AEs of lymphadenopathy in the BNT162b2 group were judged by the investigator as related to study intervention (further discussed in Section 12.2.3.2.2.

Other events of clinical interest that were evaluated by the sponsor related to cardiac disorders, appendicitis, optic neuritis, and hypersensitivity/anaphylaxis are discussed in Section 12.2.4.4.

Beyond the 9839 participants in the Phase 2/3 reactogenicity subset, events related to reactogenicity are no longer reported using an e-diary but are instead reported as AEs. As previously described in the final analysis interim CSR dated 03 December 2020, an analysis was conducted to evaluate if the imbalance in AEs observed from Dose 1 to 1 month after Dose 2 was attributed to reactogenicity events. The analysis examined the AEs reported within 7 days after each dose, which represented the reactogenicity reporting period. The time period was chosen because many AEs were reported in the SOCs of general disorders and administration site conditions, musculoskeletal and connective tissue disorders, and nervous system disorders, which includes AEs consistent with reactogenicity events (Section 9.5.2.2), and could only be attributed to reactogenicity if they occurred during this time period as opposed to occurring up to 1 month from each dose.

PTs reported from Dose 1 to 7 days after Dose 1 and from Dose 2 to 7 days after Dose 2 in the SOCs of general disorders and administration site conditions (injection site pain, chills, fatigue, and pyrexia), musculoskeletal and connective tissue disorders (myalgia), and nervous system disorders (headache) represented the majority of PTs reported in those SOCs (Supplemental Tables 14.88 and 14.89). AEs reported from Dose 1 to 7 days after Dose 1

and from Dose 2 to 7 days after Dose 2 were largely attributable to reactogenicity events. This observation provides a reasonable explanation for the greater rates of AEs observed overall in the BNT162b2 group compared with the placebo group, consistent with results previously described in the final analysis interim CSR dated 03 December 2020.

In addition to analysis of AEs corresponding to e-diary terms that were reported within 7 days after Dose 1 or Dose 2 that are attributable to reactogenicity, additional consideration was given to AE terms that are reported at higher frequency in the BNT162b2 group compared to placebo. The following additional AEs were identified: pain in extremity, decreased appetite, lethargy, asthenia, malaise, night sweats, and hyperhidrosis. Careful examination of these terms after either dose of BNT162b2 shows that these events are clustered within the 7-day period when reactogenicity events are known to occur. Since the majority of the participants did not have an e-diary and reported reactogenicity as AEs, there is considerable leeway in how symptoms are described by participants from multiple countries, interpreted by investigators and reported as AEs. As these events are occurring when reactogenicity is being reported, these events are considered to be attributable to the experience of reactogenicity events and are plausibly associated with local reactions and systemic events.

PTs were reported more frequently in the younger age group (Supplemental Tables 14.90 and 14.92 for 16 through 55, and Supplemental Tables 14.91 and 14.93 for >55 years of age).

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	6617 (30.2)	(29.6, 30.8)	3048 (13.9)	(13.4, 14.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	105 (0.5)	(0.4, 0.6)	19 (0.1)	(0.1, 0.1)
Lymphadenopathy	83 (0.4)	(0.3, 0.5)	7 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anaemia	4 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Lymph node pain	7 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Blood loss anaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Thrombocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypochromic anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Leukopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy mediastinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Splenomegaly	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	56 (0.3)	(0.2, 0.3)	50 (0.2)	(0.2, 0.3)
Palpitations	6 (0.0)	(0.0, 0.1)	14 (0.1)	(0.0, 0.1)
Tachycardia	13 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Atrial fibrillation	7 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Coronary artery disease	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Acute myocardial infarction	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Cardiac failure congestive	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Left ventricular hypertrophy	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mitral valve incompetence	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arrhythmia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arteriospasm coronary	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cardiac arrest	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mitral valve prolapse	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial ischaemia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tricuspid valve incompetence	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular extrasystoles	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Atrioventricular block complete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block left	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiovascular disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Junctional ectopic tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left atrial enlargement	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tachyarrhythmia	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)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Congenital bladder neck obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Type V hyperlipidaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	65 (0.3)	(0.2, 0.4)	43 (0.2)	(0.1, 0.3)
Vertigo	25 (0.1)	(0.1, 0.2)	20 (0.1)	(0.1, 0.1)
Ear pain	11 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Tinnitus	9 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Vertigo positional	8 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Deafness unilateral	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear discomfort	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerumen impaction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Meniere's disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic otitis media	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness neurosensory	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eustachian tube dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sudden hearing loss	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	13 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Hypothyroidism	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Hypogonadism	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid mass	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Autoimmune thyroiditis	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)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	60 (0.3)	(0.2, 0.4)	50 (0.2)	(0.2, 0.3)
Cataract	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Eye pain	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Eye irritation	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Vision blurred	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Chalazion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vitreous detachment	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blepharitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Conjunctivitis allergic	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Keratitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Ocular hyperaemia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Glaucoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lacrimation increased	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal detachment	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Asthenopia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blepharospasm	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diplopia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amaurosis fugax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Conjunctival hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dacryostenosis acquired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetic retinopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Episcleritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye inflammation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Iritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scleral discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulcerative keratitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual acuity reduced	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	699 (3.2)	(3.0, 3.4)	464 (2.1)	(1.9, 2.3)
Diarrhoea	248 (1.1)	(1.0, 1.3)	188 (0.9)	(0.7, 1.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Nausea	274 (1.2)	(1.1, 1.4)	87 (0.4)	(0.3, 0.5)
Vomiting	66 (0.3)	(0.2, 0.4)	32 (0.1)	(0.1, 0.2)
Toothache	24 (0.1)	(0.1, 0.2)	27 (0.1)	(0.1, 0.2)
Abdominal pain upper	25 (0.1)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)
Abdominal pain	19 (0.1)	(0.1, 0.1)	19 (0.1)	(0.1, 0.1)
Gastrooesophageal reflux disease	12 (0.1)	(0.0, 0.1)	16 (0.1)	(0.0, 0.1)
Dyspepsia	12 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Odynophagia	13 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Constipation	7 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Dental caries	8 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Gastritis	3 (0.0)	(0.0, 0.0)	10 (0.0)	(0.0, 0.1)
Haemorrhoids	3 (0.0)	(0.0, 0.0)	10 (0.0)	(0.0, 0.1)
Aphthous ulcer	8 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Abdominal discomfort	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Abdominal distension	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Flatulence	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Irritable bowel syndrome	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Dry mouth	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Large intestine polyp	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Abdominal pain lower	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Dysphagia	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Stomatitis	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Diverticulum	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal disorder	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hiatus hernia	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Retching	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cheilitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Food poisoning	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival pain	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lip swelling	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rectal haemorrhage	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swollen tongue	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Colitis microscopic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Eructation	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossodynia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematochezia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Noninfective gingivitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abnormal faeces	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute abdomen	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anal pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angular cheilitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Appendix disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic gastritis	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)
Colitis ulcerative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal haemorrhagic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Femoral hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Frequent bowel movements	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gastric polyps	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal mucosa hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia teeth	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 obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal varices haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophagitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral lichenoid reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peptic ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Proctalgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland mucocoele	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Teething	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varices oesophageal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Volvulus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4725 (21.5)	(21.0, 22.1)	993 (4.5)	(4.3, 4.8)
Injection site pain	2915 (13.3)	(12.8, 13.8)	397 (1.8)	(1.6, 2.0)
Fatigue	1463 (6.7)	(6.3, 7.0)	379 (1.7)	(1.6, 1.9)
Pyrexia	1517 (6.9)	(6.6, 7.3)	77 (0.4)	(0.3, 0.4)
Chills	1365 (6.2)	(5.9, 6.6)	120 (0.5)	(0.5, 0.7)
Pain	628 (2.9)	(2.6, 3.1)	61 (0.3)	(0.2, 0.4)
Injection site erythema	185 (0.8)	(0.7, 1.0)	28 (0.1)	(0.1, 0.2)
Injection site swelling	140 (0.6)	(0.5, 0.8)	23 (0.1)	(0.1, 0.2)
Malaise	130 (0.6)	(0.5, 0.7)	22 (0.1)	(0.1, 0.2)
Asthenia	76 (0.3)	(0.3, 0.4)	25 (0.1)	(0.1, 0.2)
Injection site pruritus	38 (0.2)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Injection site bruising	13 (0.1)	(0.0, 0.1)	18 (0.1)	(0.0, 0.1)
Influenza like illness	23 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.0)
Chest pain	12 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Injection site warmth	14 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Axillary pain	14 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site induration	10 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Injection site oedema	12 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Non-cardiac chest pain	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Oedema peripheral	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Peripheral swelling	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Chest discomfort	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Feeling hot	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site discomfort	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Swelling face	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Injection site haematoma	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site haemorrhage	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Injection site reaction	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site mass	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Swelling	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cyst	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Feeling abnormal	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site nodule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site rash	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sensation of foreign body	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Face oedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Medical device pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thirst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site bruise	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Capsular contracture associated with breast implant	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gait disturbance	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device site granuloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mucosal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Therapeutic response unexpected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site swelling	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)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	14 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Cholelithiasis	8 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Cholecystitis acute	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Biliary colic	2 (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 dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nonalcoholic fatty liver disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
IMMUNE SYSTEM DISORDERS	22 (0.1)	(0.1, 0.2)	25 (0.1)	(0.1, 0.2)
Seasonal allergy	8 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Drug hypersensitivity	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Food allergy	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Hypersensitivity	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Allergy to arthropod bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Milk allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	337 (1.5)	(1.4, 1.7)	365 (1.7)	(1.5, 1.8)
Urinary tract infection	58 (0.3)	(0.2, 0.3)	52 (0.2)	(0.2, 0.3)
Tooth infection	24 (0.1)	(0.1, 0.2)	29 (0.1)	(0.1, 0.2)
Sinusitis	18 (0.1)	(0.0, 0.1)	27 (0.1)	(0.1, 0.2)
Cellulitis	12 (0.1)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Herpes zoster	12 (0.1)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Ear infection	9 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Conjunctivitis	9 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Hordeolum	8 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Cystitis	6 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Gastroenteritis	5 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Rhinitis	5 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Tooth abscess	9 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	9 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Diverticulitis	8 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Otitis externa	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Otitis media	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	5 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Appendicitis	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Gingivitis	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Oral herpes	4 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Acute sinusitis	1 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Pneumonia	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Skin infection	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Vaginal infection	0	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Onychomycosis	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Periodontitis	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pyelonephritis	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Folliculitis	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Furuncle	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Localised infection	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Nasopharyngitis	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Otitis media acute	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Paronychia	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Genital herpes	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Herpes simplex	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Influenza	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Postoperative wound infection	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tinea versicolour	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bacterial vulvovaginitis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bronchitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Chronic sinusitis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Gingival abscess	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impetigo	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Infected bite	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parotitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pustule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Acarodermatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Anal abscess	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial vaginosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctivitis bacterial	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Erysipelas	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Kidney infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Labyrinthitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Laryngitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ophthalmic herpes zoster	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral candidiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Papilloma viral infection	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash pustular	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sialoadenitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinusitis bacterial	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Trichomoniasis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess jaw	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal fistula infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial blepharitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Balanitis candida	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bartholin's abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bartholinitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blister infected	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bone abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Campylobacter infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Carbuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cellulitis orbital	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, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coxsackie viral infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis infected	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)
Eye infection bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Genital herpes simplex	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gonorrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Groin abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Helicobacter infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis A	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis C	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lyme disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nail infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Orchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parasitic gastroenteritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic inflammatory disease	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)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pilonidal cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary tuberculosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Puncture site infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	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)
Sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shigella sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Soft tissue infection	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)
Subacute endocarditis	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)
Syphilis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varicella	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	215 (1.0)	(0.9, 1.1)	269 (1.2)	(1.1, 1.4)
Fall	48 (0.2)	(0.2, 0.3)	51 (0.2)	(0.2, 0.3)
Ligament sprain	19 (0.1)	(0.1, 0.1)	22 (0.1)	(0.1, 0.2)
Skin laceration	14 (0.1)	(0.0, 0.1)	22 (0.1)	(0.1, 0.2)
Contusion	12 (0.1)	(0.0, 0.1)	19 (0.1)	(0.1, 0.1)
Exposure during pregnancy	10 (0.0)	(0.0, 0.1)	19 (0.1)	(0.1, 0.1)
Muscle strain	14 (0.1)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Road traffic accident	9 (0.0)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Skin abrasion	8 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Arthropod bite	12 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Limb injury	7 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Foot fracture	5 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Joint injury	5 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tooth fracture	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Procedural pain	8 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Meniscus injury	4 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Animal bite	2 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Arthropod sting	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Facial bones fracture	4 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Joint dislocation	7 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Rib fracture	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Ankle fracture	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Concussion	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Muscle rupture	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Wound	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Chest injury	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Corneal abrasion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ligament rupture	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Thermal burn	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Vaccination complication	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epicondylitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Fibula fracture	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hand fracture	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head injury	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Overdose	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Radius fracture	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Wrist fracture	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bone contusion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle injury	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Spinal compression fracture	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ulna fracture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Administration related reaction	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns second degree	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cervical vertebral fracture	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ligament injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Procedural dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Skin injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Stress fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tendon injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper limb fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaemia postoperative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns first 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)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental restoration failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear canal abrasion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exposure to communicable disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye contusion	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)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foreign body	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Foreign body aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foreign body in eye	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	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during breast feeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngeal perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post concussion syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural swelling	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)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory fume inhalation disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scapula fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Scar	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Soft tissue injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal column injury	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)
Spinal fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stab wound	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stoma site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subdural haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sunburn	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tibia fracture	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)
Traumatic haemothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Venom poisoning	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	172 (0.8)	(0.7, 0.9)	37 (0.2)	(0.1, 0.2)
Body temperature increased	120 (0.5)	(0.5, 0.7)	12 (0.1)	(0.0, 0.1)
Blood pressure increased	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Blood glucose increased	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Heart rate increased	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blood cholesterol increased	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood thyroid stimulating hormone increased	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight decreased	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
High density lipoprotein increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Mammogram abnormal	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostatic specific antigen increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alanine aminotransferase increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood chloride decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood creatinine increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure diastolic increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood pressure systolic increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood sodium decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood triglycerides increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis C antibody positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex test positive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intraocular pressure increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Mean cell volume decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Monocyte count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Platelet count increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SARS-CoV-2 antibody test positive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid function test abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Troponin increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urine ketone body present	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
White blood cell count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
White blood cells urine positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	100 (0.5)	(0.4, 0.6)	73 (0.3)	(0.3, 0.4)
Decreased appetite	39 (0.2)	(0.1, 0.2)	9 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	8 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Vitamin D deficiency	9 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	4 (0.0)	(0.0, 0.0)	9 (0.0)	(0.0, 0.1)
Hyperlipidaemia	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Hypokalaemia	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dyslipidaemia	4 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Gout	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Dehydration	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Hyperglycaemia	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Vitamin B12 deficiency	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypoglycaemia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Insulin resistance	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertriglyceridaemia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obesity	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Polydipsia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Folate deficiency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperkalaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypernatraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperuricaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypomagnesaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyponatraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypovolaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lactic acidosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1804 (8.2)	(7.9, 8.6)	527 (2.4)	(2.2, 2.6)
Myalgia	1239 (5.7)	(5.3, 6.0)	168 (0.8)	(0.7, 0.9)
Arthralgia	268 (1.2)	(1.1, 1.4)	102 (0.5)	(0.4, 0.6)
Pain in extremity	185 (0.8)	(0.7, 1.0)	44 (0.2)	(0.1, 0.3)
Back pain	97 (0.4)	(0.4, 0.5)	85 (0.4)	(0.3, 0.5)
Neck pain	29 (0.1)	(0.1, 0.2)	33 (0.2)	(0.1, 0.2)
Muscle spasms	27 (0.1)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)
Osteoarthritis	11 (0.1)	(0.0, 0.1)	16 (0.1)	(0.0, 0.1)
Musculoskeletal stiffness	12 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Tendonitis	10 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	8 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Bursitis	10 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Muscular weakness	10 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	10 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Muscle contracture	4 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	3 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Plantar fasciitis	4 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Arthritis	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Exostosis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Flank pain	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Joint swelling	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Joint stiffness	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Costochondritis	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle twitching	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Musculoskeletal pain	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Limb discomfort	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain in jaw	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovial cyst	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bone pain	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Tendon disorder	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Torticollis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arthropathy	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Axillary mass	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coccydynia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fibromyalgia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint effusion	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metatarsalgia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Mobility decreased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spondylitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Trigger finger	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arthritis reactive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dupuytren's contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint instability	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondrosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rheumatoid arthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scoliosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Systemic lupus erythematosus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	32 (0.1)	(0.1, 0.2)	36 (0.2)	(0.1, 0.2)
Basal cell carcinoma	3 (0.0)	(0.0, 0.0)	8 (0.0)	(0.0, 0.1)
Lipoma	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Uterine leiomyoma	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Colon adenoma	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Malignant melanoma	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Prostate cancer	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acrochordon	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Fibroadenoma of breast	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Squamous cell carcinoma of skin	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)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenoma benign	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)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Benign pancreatic neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Infected naevus	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 ductal breast carcinoma	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)
Lymphoproliferative disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malignant melanoma of eyelid	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)
Metastases to liver	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian germ cell teratoma benign	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatic carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile squamous cell carcinoma	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)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma	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)
NERVOUS SYSTEM DISORDERS	1565 (7.1)	(6.8, 7.5)	600 (2.7)	(2.5, 3.0)
Headache	1339 (6.1)	(5.8, 6.4)	424 (1.9)	(1.8, 2.1)
Dizziness	78 (0.4)	(0.3, 0.4)	60 (0.3)	(0.2, 0.4)
Paraesthesia	22 (0.1)	(0.1, 0.2)	23 (0.1)	(0.1, 0.2)
Migraine	24 (0.1)	(0.1, 0.2)	11 (0.1)	(0.0, 0.1)
Lethargy	25 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Syncope	11 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Sciatica	11 (0.1)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Dysgeusia	12 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Somnolence	9 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tension headache	8 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Presyncope	8 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Hypoaesthesia	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Tremor	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Burning sensation	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Parosmia	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Cervical radiculopathy	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Disturbance in attention	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperaesthesia	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuropathy peripheral	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Sinus headache	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness postural	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial paralysis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine without aura	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nerve compression	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Radiculopathy	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amnesia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post herpetic neuralgia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restless legs syndrome	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transient ischaemic attack	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amyotrophic lateral sclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Balance disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerebellar infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cerebral atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral capillary telangiectasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervicogenic headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depressed level of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug withdrawal headache	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial paresis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Generalised tonic-clonic seizure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypersomnia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myoclonus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nystagmus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Piriformis syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sciatic nerve neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord compression	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)
VIth nerve paralysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abortion spontaneous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device breakage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device connection issue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	97 (0.4)	(0.4, 0.5)	75 (0.3)	(0.3, 0.4)
Anxiety	21 (0.1)	(0.1, 0.1)	24 (0.1)	(0.1, 0.2)
Insomnia	25 (0.1)	(0.1, 0.2)	8 (0.0)	(0.0, 0.1)
Depression	17 (0.1)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Attention deficit hyperactivity disorder	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Irritability	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Panic attack	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Anxiety disorder	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Disorientation	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep disorder	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abnormal dreams	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Depressed mood	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Alcohol withdrawal syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bruxism	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental status changes	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nightmare	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Confusional state	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Libido decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Libido increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Listless	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Panic disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranoia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Schizophrenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Substance abuse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	34 (0.2)	(0.1, 0.2)	34 (0.2)	(0.1, 0.2)
Nephrolithiasis	6 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Dysuria	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Haematuria	4 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Acute kidney injury	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Pollakiuria	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Renal colic	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary retention	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bladder spasm	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hydronephrosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive nephropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oedematous kidney	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Perinephric oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal cyst haemorrhage	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)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary tract obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	45 (0.2)	(0.1, 0.3)	39 (0.2)	(0.1, 0.2)
Dysmenorrhoea	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Erectile dysfunction	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Ovarian cyst	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic pain	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Amenorrhoea	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast pain	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast mass	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Prostatitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Genital erythema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhagic ovarian cyst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Menstruation irregular	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metrorrhagia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Testicular pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine haemorrhage	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adenomyosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast calcifications	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)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical polyp	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysfunctional uterine bleeding	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)
Haematospermia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mammary duct ectasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menometrorrhagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nipple pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Polycystic ovaries	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatomegaly	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Scrotal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uterine inflammation	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)
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	194 (0.9)	(0.8, 1.0)	168 (0.8)	(0.7, 0.9)
Oropharyngeal pain	36 (0.2)	(0.1, 0.2)	31 (0.1)	(0.1, 0.2)
Nasal congestion	25 (0.1)	(0.1, 0.2)	32 (0.1)	(0.1, 0.2)
Cough	23 (0.1)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)
Rhinorrhoea	20 (0.1)	(0.1, 0.1)	13 (0.1)	(0.0, 0.1)
Rhinitis allergic	12 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Asthma	12 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Dyspnoea	6 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Throat irritation	6 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Epistaxis	5 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Sinus congestion	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	4 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Pulmonary embolism	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Sneezing	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphonia	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Upper respiratory tract congestion	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bronchospasm	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Productive cough	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Respiratory tract congestion	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Sleep apnoea syndrome	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wheezing	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthma exercise induced	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dry throat	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Allergic sinusitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Asthmatic crisis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oropharyngeal discomfort	1 (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)
Reflux laryngitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atelectasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Emphysema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemoptysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hiccups	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lung infiltration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal polyps	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)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleuritic pain	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)
Pneumothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinitis perennial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	224 (1.0)	(0.9, 1.2)	158 (0.7)	(0.6, 0.8)
Rash	54 (0.2)	(0.2, 0.3)	41 (0.2)	(0.1, 0.3)
Pruritus	23 (0.1)	(0.1, 0.2)	18 (0.1)	(0.0, 0.1)
Hyperhidrosis	31 (0.1)	(0.1, 0.2)	9 (0.0)	(0.0, 0.1)
Dermatitis contact	14 (0.1)	(0.0, 0.1)	19 (0.1)	(0.1, 0.1)
Urticaria	15 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Night sweats	17 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Rash pruritic	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Erythema	9 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Alopecia	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Eczema	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Skin lesion	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Rash maculo-papular	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Dermatitis	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Dermatitis allergic	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Angioedema	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dermal cyst	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash erythematous	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Actinic keratosis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Blister	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Papule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rash papular	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acne	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cold sweat	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diabetic foot	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug eruption	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pityriasis rosea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rosacea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seborrhoeic dermatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Skin mass	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis acneiform	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis bullous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyshidrotic eczema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fixed eruption	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hidradenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Onychomadesis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pseudofolliculitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stasis dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria papular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menopause	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
High risk sexual behaviour	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	28 (0.1)	(0.1, 0.2)	19 (0.1)	(0.1, 0.1)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tooth extraction	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Dental implantation	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Wisdom teeth removal	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dental care	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Endodontic procedure	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abortion induced	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Apicectomy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Botulinum toxin injection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac pacemaker replacement	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cataract operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug titration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facet joint block	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lens extraction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device implantation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Open reduction of fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin neoplasm excision	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toe operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vasectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound drainage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	83 (0.4)	(0.3, 0.5)	82 (0.4)	(0.3, 0.5)
Hypertension	42 (0.2)	(0.1, 0.3)	46 (0.2)	(0.2, 0.3)
Hot flush	7 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Flushing	11 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Deep vein thrombosis	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Haematoma	4 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Hypotension	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)

Table 30. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Orthostatic hypotension	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Varicose vein	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive crisis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic dilatation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aortic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diastolic hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pallor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Phlebolith	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Raynaud's phenomenon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_all_pd2_p3_saf

12.2.3.1.2.1.1. Participants with Confirmed Stable HIV Disease – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2

From Dose 1 to 1 month after Dose 2, and similar to the overall population, most AEs reported for the subset of 200 HIV-positive participants from Dose 1 to 1 month after Dose 2 were in SOCs with reactogenicity events (Supplemental Table 14.94). There were few AEs reported: 26 (26%) in the BNT162b2 group and 13 (13%) in the placebo group.

- general disorders and administration site conditions (19.0% BNT162b2 vs 2.0% placebo)
- musculoskeletal and connective tissue disorders (6.0% BNT162b2 vs 3.0% placebo)
- nervous system disorders (5.0% BNT162b2 vs 0.0% placebo)
- gastrointestinal disorders (3.0% BNT162b2 vs 4.0% placebo)
- infections and infestations (2.0% BNT162b2 vs 2.0% placebo)

12.2.3.1.2.2. Related Adverse Events by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2

From Dose 1 to 1 month after Dose 2, AEs assessed as related by the investigator during the blinded placebo-controlled follow-up period were reported by 23.9% of participants in the BNT162b2 group and 6.0% of participants in the placebo group (Table 29). Most related AEs were reactogenicity events and in the SOC of general disorders and administration site conditions, reported by 4650 (21.2%) BNT162b2 recipients and 883 (4.0%) placebo recipients (Supplemental Table 14.95). Among the BNT162b2 participants who had AEs of lymphadenopathy, 62 of 83 participants had events assessed by the investigator as related to study intervention (Supplemental Table 14.95 and Table 30, respectively); the majority of lymphadenopathy events occurred in the arm and neck region and were reported within 1 to 4 days after vaccination (Appendix 16.2.7.4.1; see Section 12.2.4.4.1.3 for more details).

Related AEs from Dose 1 to 1 month after Dose 2 are presented by age group in Supplemental Tables 14.96 and 14.97.

12.2.3.1.2.3. Immediate Adverse Events – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2

After Dose 1, participants with immediate AEs were low in frequency (≤0.5%). Most immediate AEs after Dose 1 were in the SOC of general disorders and administration site conditions, primarily injection site reactions in the BNT162b2 versus placebo groups, with injection site pain (0.3% vs 0.2%) most frequently reported (Supplemental Table 14.98).

After Dose 2, participants with immediate AEs were low in frequency (0.3%). Most immediate AEs after Dose 2 were in the SOC of general disorders and administration site conditions, primarily injection site reactions in the BNT162b2 versus placebo groups, with injection site pain (0.2% vs 0.1%) most frequently reported (Supplemental Table 14.99).

No immediate anaphylactic reactions occurred after either dose.

12.2.3.1.2.4. Severe or Life-Threatening Adverse Events – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2

From Dose 1 to 1 month after Dose 2, severe AEs reported during the blinded follow-up period were low in frequency, reported in 1.2% of BNT162b2 recipients and 0.7% of placebo recipients (Supplemental Table 14.100). Severe events were concentrated in the SOCs of general disorders and administration site conditions, generally reflecting terms consistent with reactogenicity, in the BNT162b2 versus placebo groups (0.4% vs 0.0%).

There were 21 participants (0.1%) in the BNT162b2 group and 26 participants (0.1%) in the placebo group who had at least 1 life-threatening AE from Dose 1 to 1 month after Dose 2 (Supplemental Table 14.101). None of the life-threatening AEs were assessed by the investigator as related to study intervention (Appendix 16.2.7.4.1).

No clinically meaningful differences were observed for severe or life-threatening AEs by age group in the following tables:

Severe by Age Group: 16-55 Years	Supplemental Table 14.102
Severe by Age Group: >55 Years	Supplemental Table 14.103
Life-Threatening by Age Group: 16-55 Years	Supplemental Table 14.104
Life-Threatening by Age Group: >55 Years	Supplemental Table 14.105

12.2.3.2. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date

12.2.3.2.1. Summary of Adverse Events – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date

An overview of AE IRs adjusted for exposure time from Dose 1 to the unblinding date for 43,847 participants during the blinded placebo-controlled follow-up (including those analyzed in Phase 2) is presented in Table 31. The IRs/100 PY for participants who reported at least 1 AE were 83.2 in the BNT162b2 group and 43.4 in the placebo group, and IRs for related AEs were 62.9 in the BNT162b2 group and 16.0 in the placebo group.

IRs of severe AEs, SAEs, and AEs leading to withdrawal were ≤4.3, ≤3.3, and ≤0.6 per 100 PY, respectively, in both groups. IRs for discontinuations because of related AEs were 0.2 per 100 PY in the BNT162b2 group and 0.1 per 100 PY in the placebo group.

From Dose 1 to the unblinding date, there were 15 (0.2 per 100 PY) deaths in the BNT162b2 group and 14 (0.2 per 100 PY) deaths in the placebo group (Section 12.2.4.1).

In the younger age group, the IRs for participants who reported at least 1 AE from Dose 1 to the unblinding date were 88.4 per 100 PY and 43.5 per 100 PY in the BNT162b2 and placebo groups, respectively (Supplemental Table 14.106). In the older age group, the IRs for participants who reported at least 1 AE from Dose 1 to the unblinding date were 75.7 per 100 PY and 43.3 per 100 PY in the BNT162b2 and placebo groups, respectively (Supplemental Table 14.107).

Table 31. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	6947	83.2	(81.3, 85.2)	3568	43.4	(42.0, 44.9)
Related[f]	5246	62.9	(61.2, 64.6)	1313	16.0	(15.1, 16.9)
Severe	356	4.3	(3.8, 4.7)	256	3.1	(2.7, 3.5)
Life-threatening	48	0.6	(0.4, 0.8)	54	0.7	(0.5, 0.9)
Any serious adverse event	268	3.2	(2.8, 3.6)	268	3.3	(2.9, 3.7)
Related[f]	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Severe	148	1.8	(1.5, 2.1)	156	1.9	(1.6, 2.2)
Life-threatening	48	0.6	(0.4, 0.8)	54	0.7	(0.5, 0.9)
Any adverse event leading to withdrawal	45	0.5	(0.4, 0.7)	51	0.6	(0.5, 0.8)
Related[f]	13	0.2	(0.1, 0.3)	12	0.1	(0.1, 0.3)
Severe	10	0.1	(0.1, 0.2)	12	0.1	(0.1, 0.3)
Life-threatening	15	0.2	(0.1, 0.3)	16	0.2	(0.1, 0.3)
Death	15	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.3)

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s092_all_unb_p3_saf

Subgroup Analyses

In the BNT162b2 group, there were 674 baseline SARS-CoV-2 positive and 21102 baseline SARS-CoV-2 negative participants, and there were 705 baseline SARS-COV-2 positive and 21092 SARS-CoV-2 negative participants in the placebo group (Supplemental Tables 14.108 and 14.109, respectively). Similar to what was observed in the overall AE analysis irrespective of baseline status (Table 31), IRs of at least 1 AE in the baseline SARS-CoV-2 positive subgroup were 70.7 per 100 PY in the BNT162b2 group and 31.9 per 100 PY in the placebo group (Supplemental Table 14.108), and IRs of at least 1 AE in the baseline SARS-CoV-2 negative subgroup were 83.6 per 100 PY in the BNT162b2 group and 43.8 per 100 PY in the placebo group (Supplemental Table 14.109). IRs of related AEs in the

BNT162b2 group were 51.8 per 100 PY (baseline positive) and 63.2 per 100 PY (baseline negative). The IRs of SAEs, related SAEs, severe SAEs, and life threatening SAEs were similar in the BNT162b2 and placebo groups, which support these events are not increased in baseline positive participants. Given the differences in exposure (2.5 vs 80.4) by baseline SARS-CoV-2 positive and negative status, respectively, direct comparisons should be interpreted with caution (Supplemental Tables 14.108 and 14.109). See Section 12.2.3.2.2 for subgroup analyses of SOCs by baseline status, which supports that there is no evidence that individuals who are positive at baseline report AEs at a higher rate than those who are negative at baseline.

The IR of any AEs and related AEs were similar in those positive and negative at baseline, with the IR for any AE of 70.7 per 100 PY (95% CI: 60.7, 81.9) and 83.6 per 100 PY (95% CI: 81.7, 85.7) and for related AE of 51.8 per 100 PY (95% CI: 43.3, 61.4) and 63.2 per 100 PY (95% CI:61.5, 65.0), respectively (Supplemental Tables 14.108 and 14.109, respectively). The IR for SAEs was 4.0 per 100 PY (95% CI: 1.9, 7.3) (baseline positive) and 3.2 per 100 PY (95% CI: 2.8, 3.6) (baseline negative), however none of the SAEs in the positive baseline group were related to BNT162b2, as assessed by the investigator. The death rate was also similar: 0.8 per 100 PY (95% CI: 0.1, 2.9) (baseline positive) and 0.2 per 100 PY (95% CI: 0.1, 0.3) (baseline negative).

IRs of at least 1 AE in the BNT162b2 group were 78.4 per 100 PY (95% CI: 74.9, 82.0; n=5684) in Hispanic/Latino and 85.4 per 100 PY (95% CI: 83.1, 87.8; n=16131) in Non-Hispanic/Non-Latino participants (Supplemental Tables 14.110 and 14.111, respectively). The IRs of SAEs, AEs leading to withdrawal, and death were similar in the Hispanic/Latino and Non-Hispanic/Non-Latino groups. None of the SAEs were considered related to BNT162b2 in the Hispanic/Latino group. IRs for participants with ethnicity Not reported are presented in Supplemental Table 14.112.

IRs of at least 1 AE in the BNT162b2 group were lower in Black or African American participants (53.5 per 100 PY) compared with White (83.1 per 100 PY) or All Others (120.1 per 100 PY) (Supplemental Tables 14.113 through 14.115). Other IRs were similar in the groups.

IRs of at least 1 AE in the BNT162b2 group were greater in females (91.0 per 100 PY [95% CI: 88.1, 94.0]) than males (76.0 per 100 PY [95% CI: 73.4, 78.6]); that cannot be accounted for by the rates in placebo for females (46.8 [95% CI: 44.7, 49.0]) and males (40.1 [95% CI: 38.2, 42.1]) (Supplemental Tables 14.117 and 14.116, respectively). IRs for related and severe AEs were also greater in females (68.6 per 100 PY [95% CI: 66.1, 71.2] and 4.9 per 100 PY [95% CI: 4.2, 5.6], respectively) than in males (57.5 per 100 PY [95% CI: 55.3, 59.8] and 3.7 per 100 PY [95% CI: 3.2, 4.3], respectively). However, life threatening AEs, SAEs, related SAEs, severe SAEs, life threatening SAEs and death IR were similar in males and females.

12.2.3.2.1.1. Participants with Confirmed Stable HIV Disease – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date

The subset of 200 HIV-positive participants during the blinded placebo-controlled follow-up period showed generally similar trends as the overall population. The IRs for HIV-positive participants who reported at least 1 AE and at least 1 related AE were 95.8 per 100 PY and 62.8 per 100 PY, respectively, for the BNT162b2 group and 52.0 per 100 PY and 10.4 per 100 PY, respectively, for the placebo group (Supplemental Table 14.118). There were 2 SAEs in the BNT162b2 group (1 severe and 1 life-threatening) and 2 SAEs in the placebo group (1 life-threatening). There were 2 AEs leading to withdrawal in the BNT162b2 group (1 life-threatening) and 1 AE (life-threatening) leading to withdrawal in the placebo group. There were 2 deaths, 1 each in the BNT162b2 and placebo groups; neither were assessed by the investigator as related to study intervention (see Section 12.2.4.1).

12.2.3.2.2. Analysis of Adverse Events – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date

12.2.3.2.2.1. Adverse Events by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date

IRs of AEs from Dose 1 to the unblinding date during the blinded placebo-controlled follow-up period are presented in (Supplemental Table 14.119). Results were similar to the Dose 1 to 1 month after Dose 2 follow-up period.

From Dose 1 to the unblinding date, the most common AEs by IRs were reactogenicity events and were reported at higher IRs in the BNT162b2 group than in the placebo group:

- general disorders and administration site conditions (56.9 per 100 PY BNT162b2 vs 12.3 per 100 PY placebo)
- musculoskeletal and connective tissue disorders (22.3 per 100 PY BNT162b2 vs 7.6 per 100 PY placebo)
- nervous system disorders (19.2 per 100 PY BNT162b2 vs 7.7 per 100 PY placebo)
- gastrointestinal disorders (9.0 per 100 PY BNT162b2 vs 6.2 per 100 PY placebo)

In the younger versus older BNT162b2 age groups (Supplemental Tables 14.120 and 14.121, respectively), AE IRs in these SOCs were:

- general disorders and administration site conditions (63.7 per 100 PY vs 46.9 per 100 PY)
- musculoskeletal and connective tissue disorders (24.6 per 100 PY vs 18.8 per 100 PY)
- nervous system disorders (21.8 per 100 PY vs 15.3 per 100 PY)
- gastrointestinal disorders (9.5 per 100 PY vs 8.2 per 100 PY)

The higher rates of AEs in these SOC is consistent with the reactogenicity analysis showing higher rates of reactogenicity in the younger age group. AEs with the highest IRs in the BNT162b2 group by PT overall were injection site pain (35.0 per 100 PY), pyrexia (18.2 per

100 PY), fatigue (17.6 per 100 PY), chills (16.4 per 100 PY), headache (16.2 per 100 PY), and myalgia (14.9 per 100 PY) (Supplemental Table 14.119).

The IR of AEs in the SOC of investigations was higher in the BNT162b2 group (2.2 per 100 PY) than in the placebo group (0.6 per 100 PY) mainly due to the higher IR of body temperature increased in the BNT162b2 group (IR of 1.5 per 100 PY vs 0.2 per 100 PY for the placebo group).

Cases of night sweats and hyperhidrosis are discussed in Section 12.2.3.1.2.1 (most were reported within 7 days after Dose 1 or 2).

In the nervous systems disorder SOC, there were 4 participants who reported facial paralysis in the BNT162b2 group (compared to 1 in the placebo group) (Supplemental Table 14.119). There is an additional case of facial paresis in the placebo group. Hence there are 4 cases of facial paralysis/paresis in the in the BNT162b2 group and 2 in the placebo group. See Section 12.2.4.4.1.2 for a full analysis.

There was 1 case of COVID-19 pneumonia (reported in the BNT162b2 group) which led to death (see Table 38). This participant was diagnosed based on a local COVID-19 test that was not protocol-approved and was not confirmed by a test result from the central laboratory. Therefore, this participant was not included in efficacy analyses.

Among the AEs of lymphadenopathy in the BNT162b2 group, the majority (62 of 87 participants; [0.7 per 100 PY]) were assessed by the investigator as related to study intervention (Supplemental Table 14.133). Most cases occurred in the arm and neck region and were reported within 1 to 4 days after vaccination (Appendix 16.2.7.4.1). See Section 12.2.4.4.1.3 for additional details.

The IRs for hepatobiliary disorders was 0.3 per 100 PY and 0.2 per 100 PY in the BNT162b2 and placebo group, respectively (Supplemental Table 14.119). There were 24 participants in the BNT162b2 group who had AEs in the SOC of hepatobiliary disorders compared to 16 participants in the placebo group (Supplemental Table 14.119). Narratives for these cases are located in Section 14.

A total of 11 cases of reported PTs associated with deafness in the blinded placebo-controlled follow-up period through the unblinding date included: Deafness, Deafness unilateral, Deafness neurosensory, Hypoacusis, and Sudden hearing loss. Six participants were randomized to the BNT162b2 group (age range 43 to 65 years of age), and 5 participants were randomized to placebo (age range 36 to 74 years of age) (Supplemental Table 14.119 and Appendix 16.2.7.4.1). For 1 participant in each group, onset was 19 days after Dose 1. Onset ranged from 1 to 55 days after Dose 2 for 5 participants in the BNT162b2 and ranged from 2 to 94 days after Dose 2 for 4 participants in the placebo group. The duration ranged from 9 to 155 days after AE onset with 4 events still ongoing at the time of data cutoff (13 March 2021). The toxicity grades were mostly mild (4 in the BNT162b2 group, and 2 in placebo) or moderate (1 in the BNT162b2 group, and 3 in placebo), with one being severe (BNT162b2 group). In the BNT162b2 group, 2 events were deemed related to study vaccine by the investigator. None of the reported events were SAEs.

Other events of clinical interest that were identified by the sponsor and/or from the CDC list of AESIs are discussed in Section 12.2.4.4.

Subgroup Analyses

In the baseline SARS-CoV-2 positive subgroup, differences in IRs in the BNT162b2 (70.7 per 100 PY) and placebo (31.9 per 100 PY) groups were due to reactogenicity events (chills, fatigue, injection site pain, pyrexia, myalgia, and headache) (Supplemental Table 14.122).

In the baseline SARS-CoV-2 negative subgroup, differences in IRs in the BNT162b2 (83.6 per 100 PY) and placebo (43.8 per 100 PY) groups were due to reactogenicity events (diarrhea, vomiting, chill, fatigue, injection site reactions [pain, erythema, swelling], pyrexia, arthralgia, myalgia, and headache) as well as other AEs (lymphadenopathy, nausea, asthenia, malaise, pain, body temperature increase, and pain in extremity) (Supplemental Table 14.123).

Given the differences in exposure (2.5 vs 80.4) by baseline SARS-CoV-2 positive and negative status, respectively, direct comparisons should be interpreted with caution (Supplemental Tables 14.122 and 14.123). The overall rate of AEs is 70.7 per 100 PY (95% CI: 60.7, 81.9) (baseline positive) compared with 83.6 per 100 PY (95% CI: 81.7, 85.7) (baseline negative). For other SOCs, the IR were either numerically lower or similar for the baseline positive group compared to the baseline negative group. Overall, there is no evidence that individuals who are positive at baseline report AEs at a higher frequency than those who are negative at baseline.

In the BNT162b2 group, overall IRs for participants reporting at least 1 AE were highest for participants of all other races (120.1 per 100 PY) compared to White participants (83.1 per 100 PY), with Black or African American participants having the lowest IR (53.5 per 100 PY) (Supplemental Tables 14.129, 14.127, and 14.128, respectively). The IR for nausea in the BNT162b2 group was higher in participants of all other races (4.7 per 100 PY BNT162b2 vs 1.6 per 100 PY placebo) and White participants (3.4 per 100 PY BNT162b2 vs 1.0 per 100 PY placebo) than in Black or African American participants where the IR was similar in both vaccine groups (1.3 per 100 PY BNT162b2 vs 1.2 per 100 PY placebo).

In the BNT162b2 group, the IR for participants reporting at least 1 AE was higher in non-Hispanic/non-Latino participants (85.4 per 100 PY BNT162b2 and 41.6 per 100 PY placebo) and Hispanic/Latino participants (78.4 per 100 PY BNT162b2 and 47.9 per 100 PY placebo) and lowest in the group where ethnicity was not reported (49.4 per 100 PY BNT162b2 and 43.3 per 100 PY placebo) (Supplemental Tables 14.125, 14.124, and 14.126, respectively). IRs were higher for mainly reactogenicity events (chills, fatigue, myalgia, diarrhea, injection site reactions [pain, erythema, and swelling], pain, pyrexia, and headache) as well as lymphadenopathy, nausea, influenza like illness, malaise, increased body temperature, and pain in extremity.

Overall, females reported a higher IR of AEs (91.0 per 100 PY BNT162b2, 46.8 per 100 PY placebo) than males (76.0 per 100 PY BNT162b2, 40.1 per 100 PY placebo), with a greater

difference in the BNT162b2 groups than in the placebo groups (Supplemental Tables 14.131 and 14.130, respectively). The higher IRs in females were due to reactogenicity AEs (vomiting, chills, fatigue, pyrexia, myalgia, and headache) as well as other AEs (lymphadenopathy, nausea, pain, increased body temperature, and pain in extremity). There were sex appropriate differences as well, such as higher IRs in the SOC of cardiac disorders in males (1.2 per 100 PY) versus females (0.9 per 100 PY) and lower IRs in the SOC of reproductive system and breast disorders in males (0.3 per 100 PY) versus females (0.9 per 100 PY).

12.2.3.2.2.1.1. Participants with Confirmed Stable HIV Disease – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date

From Dose 1 to the unblinding date, and similar to the overall population, most AEs reported for the subset of 200 HIV-positive participants from Dose 1 to the unblinding date were in SOCs with reactogenicity events (Supplemental Table 14.132):

- general disorders and administration site conditions (66.1 per 100 PY BNT162b2 vs 6.9 per 100 PY placebo)
- musculoskeletal and connective tissue disorders (19.8 per 100 PY BNT162b2 vs 10.4 per 100 PY placebo)
- nervous system disorders (16.5 per 100 PY BNT162b2 vs 0.0 per 100 PY placebo)
- gastrointestinal disorders (9.9 per 100 PY BNT162b2 vs 13.9 per 100 PY placebo)

12.2.3.2.2.2. Related Adverse Events by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date

From Dose 1 to the unblinding date, IRs of AEs assessed as related by the investigator during the blinded follow-up period were 62.9 per 100 PY and 16.0 per 100 PY in the BNT162b2 group and in the placebo group, respectively (Table 31). The IRs of related AEs were highest for reactogenicity events and in the SOC of general disorders and administration site conditions, IRs were 55.7 per 100 PY and 10.8 per 100 PY for BNT162b2 and placebo recipients, respectively (Supplemental Table 14.133). Additional terms identified as either synonymous with or otherwise plausibly associated with reactogenicity events (ie, secondary to reactogenicity events) occurring within 7 days after each dose were also considered related (pain in extremity, decreased appetite, lethargy, asthenia, malaise, night sweats, and hyperhidrosis) (Section 12.2.3.1.2.1).

Lymphadenopathy is discussed in Section 12.2.4.4.1.3. IRs of related AEs in the younger and older age groups were 70.0 per 100 PY and 52.3 per 100 PY, respectively for the BNT162b2 group and 18.0 per 100 PY and 13.0 per 100 PY, respectively, for the placebo group (Supplemental Tables 14.134 and 14.135).

12.2.3.2.2.3. Severe or Life-Threatening Adverse Events – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date

From Dose 1 to the unblinding date, severe AE IRs during the blinded follow-up period were 4.3 per 100 PY (95% CI: 3.8, 4.7) and 3.1 per 100 PY (95% CI: 2.7, 3.5) in BNT162b2 and placebo recipients, respectively (Supplemental Table 14.136). Severe events in the general

disorders and administration site conditions were generally reflecting terms consistent with reactogenicity, in the BNT162b2 versus placebo groups (1.2 per 100 PY vs 0.1 per 100 PY) as well as the Musculoskeletal SOC (0.6 per 100 PY vs 0.3 per 100 PY). The IR in all other SOCs were similar in the BNT162b2 and placebo groups.

The IRs for participants who had at least 1 life-threatening AE from Dose 1 to the unblinding date were similar: 0.6 per 100 PY (95% CI: 0.4, 0.8) in the BNT162b2 group and 0.7 per 100 PY (95% CI: 0.5, 0.9) in the placebo group (Supplemental Table 14.137). All of the IRs for the SOCs were similar in the BNT162b2 and placebo groups.

IRs of severe or life-threatening AEs in the younger and older age groups are presented in the following tables:

Severe by Age Group: 16-55 Years	Supplemental Table 14.138
Severe by Age Group: >55 Years	Supplemental Table 14.139
Life-Threatening by Age Group: 16-55 Years	Supplemental Table 14.140
Life-Threatening by Age Group: >55 Years	Supplemental Table 14.141

12.2.3.3. Open-Label Follow-Up Period – Original BNT162b2 Participants

12.2.3.3.1. Summary of Adverse Events – Open-Label Follow-Up Period – Original BNT162b2 Participants

Per protocol, AEs are reported through 1 month after the Dose 2 and within 48 hours after a blood draw. SAEs are reported to approximately 6 months after the last dose of study intervention. An overview of IRs of AEs from the unblinding date to the data cutoff date for participants originally randomized to BNT162b2 during the open-label follow-up is presented in Table 32. The IRs for any AE, at least 1 related AE, and severe AE were 8.8 per 100 PY, 0.7 per 100 PY, and 1.6 per 100 PY, respectively, which is markedly reduced relative to those from Dose 1 to the unblinding date (83.2, 62.9, 4.3 respectively [Table 31]). The IR of life-threatening AEs is 0.4 per 100 PY (95% CI: 0.2, 0.8), which is similar to the IR from Dose 1 to the unblinding date, 0.6 per 100 PY (95% CI: 0.4, 0.8).

The IR of SAEs during the open-label follow-up period (Table 32), 2.0 per 100 PY (95% CI: 1.5, 2.6) were lower than the IR from Dose 1 to the unblinding date, 3.2 per 100 PY (95% CI: 2.8, 3.6) (Table 31). There was a single related SAE (myocardial infarction) for an individual in the open label follow-up period (see Section 12.2.4.2.3). The IR of AEs leading to withdrawal also decreased (0.1 per 100 PY [95% CI: 0.0, 0.4]) in the open-label follow-up period compared with the blinded placebo-controlled period (0.5 per 100 PY [95% CI: 0.4, 0.7]) but the IR of deaths were similar (0.1 per 100 PY vs 0.2 per 100 PY in the open-label and blinded placebo-controlled follow-up periods, respectively).

Table 32. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021) – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	243	8.8	(7.7, 9.9)
Related[f]	20	0.7	(0.4, 1.1)
Severe	43	1.6	(1.1, 2.1)
Life-threatening	12	0.4	(0.2, 0.8)
Any serious adverse event	55	2.0	(1.5, 2.6)
Related[f]	1	0.0	(0.0, 0.2)
Severe	30	1.1	(0.7, 1.5)
Life-threatening	12	0.4	(0.2, 0.8)
Any adverse event leading to withdrawal	4	0.1	(0.0, 0.4)
Related[f]	0	0.0	(0.0, 0.1)
Severe	0	0.0	(0.0, 0.1)
Life-threatening	4	0.1	(0.0, 0.4)
Death	3	0.1	(0.0, 0.3)

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from the unblinding date to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s092_unb_cut_p3_saf

12.2.3.3.2. Analysis of Adverse Events – Open-Label Follow-Up Period – Original BNT162b2 Participants

12.2.3.3.2.1. Adverse Events by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Original BNT162b2 Participants

From the unblinding date to the data cutoff date for participants originally randomized to BNT162b2 during the open-label follow-up period, the IR for participants who reported at least 1 AE was 8.8 per 100 PY (Supplemental Table 14.142) compared to 83.2 per 100 PY from Dose 1 to the unblinding date (Table 31).

Overall, the rates in all SOCs after the unblinding date decreased or remained similar to those in the blinded placebo-controlled period.

The IR for the SOC of injury, poisoning and procedural complications was 1.4 per 100 PY, with the PT fall having the highest IR (0.4 per 100 PY) (Supplemental Table 14.142). The IR for the SOC of vascular disorders was 0.8 per 100 PY, with the PT hypertension having the highest IR (0.6 per 100 PY).

12.2.3.3.2.2. Related Adverse Events by System Organ Class and Preferred Term – Original BNT162b2 Participants

From the unblinding date to the data cutoff date for participants originally randomized to BNT162b2, the IR of AEs assessed as related by the investigator during the open-label follow-up period was 0.7 per 100 PY (Table 32). The IRs of related AEs were highest for reactogenicity events and in the SOC of general disorders and administration site conditions (0.5 per 100 PY) reflecting AEs from their initial vaccinations (Supplemental Table 14.143).

One younger participant had a life-threatening SAE of myocardial infarction 71 days after Dose 2 that was assessed by the investigator as related to study intervention, which lasted 1 day and resolved the same day (Appendix 16.2.7.5) (see Section 12.2.4.2.3).

12.2.3.4. Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Participants

12.2.3.4.1. Summary of Adverse Events – Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Participants

There were 12,006 participants who had at least 6 months of follow-up (Table 33). There were 3454 (28.8%) participants who reported at least 1 AE, and 2245 (18.7%) participants reported at least 1 related AE. Severe AEs and SAEs were reported by 2.1% and 1.6%, respectively. One participant discontinued because of an AE (not related). There were no deaths during the blinded and open-label follow-up periods in the group of original BNT162b2 participants with at least 6 months of follow-up after Dose 2.

When frequencies of AEs for participants with at least 6 months of follow-up time are examined by time since the second dose, the frequency of AEs and related AEs is 25.8% and 18.6% through 1 month after Dose 2 compared with 4.8% and 0.1% from 1 month after Dose 2 to 6 months after Dose 2 (Table 34). In the first month after vaccination 0.5% reported SAEs (1 related) and from 1 month to 6 months after Dose 2, the frequency of SAEs increased to 1.1% with 1 related SAE.

In the younger age group, the number of participants who reported at least 1 AE and 1 related AE from Dose 1 to 6 months after Dose 2 was 2013 (30.2%) and 1386 (20.8%), respectively (Supplemental Table 14.144). In the older age group, the number of participants who reported at least 1 AE and 1 related AE from Dose 1 to 6 months after Dose 2 was 1441 (27.0%) and 859 (16.1%), respectively (Supplemental Table 14.145).

Table 33. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2 – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=12006)
Adverse Event	n[b] (%)
Any event	3454 (28.8)
Related[c]	2245 (18.7)
Severe	248 (2.1)
Life-threatening	23 (0.2)
Any serious adverse event	190 (1.6)
Related[c]	2 (0.0)
Severe	116 (1.0)
Life-threatening	23 (0.2)
Any adverse event leading to withdrawal	1 (0.0)
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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (14:48)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
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Table 34. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)	After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)
Adverse Event	**n[b] (%)**	**n[b] (%)**
Any event	3092 (25.8)	572 (4.8)
Related[c]	2239 (18.6)	12 (0.1)
Severe	143 (1.2)	110 (0.9)
Life-threatening	8 (0.1)	15 (0.1)
Any serious adverse event	58 (0.5)	133 (1.1)
Related[c]	1 (0.0)	1 (0.0)
Severe	34 (0.3)	82 (0.7)
Life-threatening	8 (0.1)	15 (0.1)
Any adverse event leading to withdrawal	0	1 (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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 14APR2021 (08:45)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA_RR/adae_s091_all_pd2_p3_tp_saf2

12.2.3.4.2. Analysis of Adverse Events – Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Participants

12.2.3.4.2.1. Adverse Events by System Organ Class and Preferred Term – Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Participants

From Dose 1 to 6 months after Dose 2 during the blinded and open-label follow-up period, 3454 (28.8%) original BNT162b2 participants reported at least 1 AE (Table 35). The most frequently reported AEs were reactogenicity events.

- general disorders and administration site conditions (2016 [16.8%])
- musculoskeletal and connective tissue disorders (905 [7.5%])
- nervous system disorders (726 [6.0%])
- gastrointestinal disorders (407 [3.4%])

The number of original BNT162b2 participants who reported at least 1 AE from Dose 1 to 6 months after Dose 2 was 2013 (30.2%) and 1441 (27.0%) in the younger and older groups, respectively (Supplemental Tables 14.146 and 14.147, respectively).

In the younger versus older BNT162b2 age groups (Supplemental Tables 14.146 and 14.147, respectively), AE frequencies in above SOCs were:

- general disorders and administration site conditions (1246 [18.7%] vs 770 [14.4%])
- musculoskeletal and connective tissue disorders (539 [8.1%] vs 366 [6.9%])
- nervous system disorders (449 [6.7%] vs 277 [5.2%])
- gastrointestinal disorders (231 [3.5%] vs 176 [3.3%])

As shown in Table 35, the most frequently reported AEs in the BNT162b2 group were injection site pain (1191 [9.9%]), pyrexia (633 [5.3%]), chills (606 [5.0%]), fatigue (598 [5.0%]), headache (572 [4.8%]), and myalgia (549 [4.6%]).

When AEs are compared from 1 month after Dose 2 and from 1 month after Dose 2 to 6 months after Dose 2, the frequencies of AEs by most SOCs have decreased or remain the same with the additional follow-up time. The overall frequency of any AE for participants from 1 month after Dose 2 to 6 months after Dose 2 (4.8%) was decreased from the frequency during 1 month follow up time after Dose 2 (25.8%) (Supplemental Table 14.148).

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	3454 (28.8)	(28.0, 29.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	70 (0.6)	(0.5, 0.7)
Lymphadenopathy	50 (0.4)	(0.3, 0.5)
Anaemia	7 (0.1)	(0.0, 0.1)
Iron deficiency anaemia	5 (0.0)	(0.0, 0.1)
Lymph node pain	3 (0.0)	(0.0, 0.1)
Leukopenia	2 (0.0)	(0.0, 0.1)
Blood loss anaemia	1 (0.0)	(0.0, 0.0)
Coagulopathy	1 (0.0)	(0.0, 0.0)
Lymphadenopathy mediastinal	1 (0.0)	(0.0, 0.0)
Lymphocytosis	1 (0.0)	(0.0, 0.0)
Lymphopenia	1 (0.0)	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)
Pancytopenia	1 (0.0)	(0.0, 0.0)
Splenic infarction	1 (0.0)	(0.0, 0.0)
Splenomegaly	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	59 (0.5)	(0.4, 0.6)
Atrial fibrillation	9 (0.1)	(0.0, 0.1)
Tachycardia	9 (0.1)	(0.0, 0.1)
Palpitations	7 (0.1)	(0.0, 0.1)
Coronary artery disease	6 (0.0)	(0.0, 0.1)
Acute myocardial infarction	4 (0.0)	(0.0, 0.1)
Angina pectoris	4 (0.0)	(0.0, 0.1)
Myocardial infarction	4 (0.0)	(0.0, 0.1)
Cardiac failure congestive	3 (0.0)	(0.0, 0.1)
Angina unstable	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)
Arrhythmia	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)
Atrial flutter	1 (0.0)	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Bundle branch block right	1 (0.0)	(0.0, 0.0)
Cardiac arrest	1 (0.0)	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)
Cardiomegaly	1 (0.0)	(0.0, 0.0)
Coronary artery occlusion	1 (0.0)	(0.0, 0.0)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.0)
Mitral valve prolapse	1 (0.0)	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	3 (0.0)	(0.0, 0.1)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.0)
Gastrointestinal arteriovenous malformation	1 (0.0)	(0.0, 0.0)
Protein S deficiency	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	49 (0.4)	(0.3, 0.5)
Vertigo	21 (0.2)	(0.1, 0.3)
Ear pain	8 (0.1)	(0.0, 0.1)
Tinnitus	6 (0.0)	(0.0, 0.1)
Vertigo positional	4 (0.0)	(0.0, 0.1)
Cerumen impaction	3 (0.0)	(0.0, 0.1)
Deafness neurosensory	2 (0.0)	(0.0, 0.1)
Ear discomfort	2 (0.0)	(0.0, 0.1)
Deafness unilateral	1 (0.0)	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)
Sudden hearing loss	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	15 (0.1)	(0.1, 0.2)
Hypothyroidism	6 (0.0)	(0.0, 0.1)
Hyperthyroidism	2 (0.0)	(0.0, 0.1)
Hypogonadism	2 (0.0)	(0.0, 0.1)
Thyroid mass	2 (0.0)	(0.0, 0.1)
Goitre	1 (0.0)	(0.0, 0.0)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Hyperprolactinaemia	1 (0.0)	(0.0, 0.0)
Oestrogen deficiency	1 (0.0)	(0.0, 0.0)
Pituitary cyst	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	47 (0.4)	(0.3, 0.5)
Cataract	5 (0.0)	(0.0, 0.1)
Vision blurred	5 (0.0)	(0.0, 0.1)
Chalazion	3 (0.0)	(0.0, 0.1)
Eye irritation	3 (0.0)	(0.0, 0.1)
Eye pain	3 (0.0)	(0.0, 0.1)
Macular oedema	3 (0.0)	(0.0, 0.1)
Vitreous detachment	3 (0.0)	(0.0, 0.1)
Blepharitis	2 (0.0)	(0.0, 0.1)
Diplopia	2 (0.0)	(0.0, 0.1)
Dry eye	2 (0.0)	(0.0, 0.1)
Glaucoma	2 (0.0)	(0.0, 0.1)
Retinal tear	2 (0.0)	(0.0, 0.1)
Asthenopia	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)
Episcleritis	1 (0.0)	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.0)
Keratitis	1 (0.0)	(0.0, 0.0)
Ophthalmic vein thrombosis	1 (0.0)	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.0)
Retinal artery occlusion	1 (0.0)	(0.0, 0.0)
Scleral discolouration	1 (0.0)	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	407 (3.4)	(3.1, 3.7)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Nausea	140 (1.2)	(1.0, 1.4)
Diarrhoea	123 (1.0)	(0.9, 1.2)
Vomiting	35 (0.3)	(0.2, 0.4)
Toothache	18 (0.1)	(0.1, 0.2)
Abdominal pain	15 (0.1)	(0.1, 0.2)
Gastrooesophageal reflux disease	14 (0.1)	(0.1, 0.2)
Dyspepsia	13 (0.1)	(0.1, 0.2)
Abdominal pain upper	10 (0.1)	(0.0, 0.2)
Odynophagia	10 (0.1)	(0.0, 0.2)
Constipation	7 (0.1)	(0.0, 0.1)
Dental caries	6 (0.0)	(0.0, 0.1)
Irritable bowel syndrome	5 (0.0)	(0.0, 0.1)
Abdominal distension	4 (0.0)	(0.0, 0.1)
Flatulence	4 (0.0)	(0.0, 0.1)
Gastritis	4 (0.0)	(0.0, 0.1)
Hiatus hernia	4 (0.0)	(0.0, 0.1)
Large intestine polyp	4 (0.0)	(0.0, 0.1)
Aphthous ulcer	3 (0.0)	(0.0, 0.1)
Diverticulum	3 (0.0)	(0.0, 0.1)
Food poisoning	3 (0.0)	(0.0, 0.1)
Haemorrhoids	3 (0.0)	(0.0, 0.1)
Colitis	2 (0.0)	(0.0, 0.1)
Gastritis erosive	2 (0.0)	(0.0, 0.1)
Gastrointestinal disorder	2 (0.0)	(0.0, 0.1)
Glossodynia	2 (0.0)	(0.0, 0.1)
Haematochezia	2 (0.0)	(0.0, 0.1)
Impaired gastric emptying	2 (0.0)	(0.0, 0.1)
Oral pain	2 (0.0)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)
Abdominal discomfort	1 (0.0)	(0.0, 0.0)
Abdominal pain lower	1 (0.0)	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.0)
Angular cheilitis	1 (0.0)	(0.0, 0.0)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Cheilitis	1 (0.0)	(0.0, 0.0)
Coeliac disease	1 (0.0)	(0.0, 0.0)
Colitis microscopic	1 (0.0)	(0.0, 0.0)
Colitis ulcerative	1 (0.0)	(0.0, 0.0)
Crohn's disease	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	1 (0.0)	(0.0, 0.0)
Dry mouth	1 (0.0)	(0.0, 0.0)
Dysphagia	1 (0.0)	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.0)
Eructation	1 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)
Femoral hernia	1 (0.0)	(0.0, 0.0)
Gastric antral vascular ectasia	1 (0.0)	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.0)
Gingival pain	1 (0.0)	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.0)
Haematemesis	1 (0.0)	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.0)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.0)
Internal hernia	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	1 (0.0)	(0.0, 0.0)
Intestinal polyp	1 (0.0)	(0.0, 0.0)
Intra-abdominal fluid collection	1 (0.0)	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Oral lichenoid reaction	1 (0.0)	(0.0, 0.0)
Pancreatic calcification	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.0)
Rectal haemorrhage	1 (0.0)	(0.0, 0.0)
Rectal polyp	1 (0.0)	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)
Stomatitis	1 (0.0)	(0.0, 0.0)
Swollen tongue	1 (0.0)	(0.0, 0.0)
Tongue oedema	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2016 (16.8)	(16.1, 17.5)
Injection site pain	1191 (9.9)	(9.4, 10.5)
Pyrexia	633 (5.3)	(4.9, 5.7)
Chills	606 (5.0)	(4.7, 5.5)
Fatigue	598 (5.0)	(4.6, 5.4)
Pain	277 (2.3)	(2.0, 2.6)
Injection site erythema	91 (0.8)	(0.6, 0.9)
Injection site swelling	60 (0.5)	(0.4, 0.6)
Malaise	46 (0.4)	(0.3, 0.5)
Asthenia	20 (0.2)	(0.1, 0.3)
Injection site pruritus	19 (0.2)	(0.1, 0.2)
Chest pain	14 (0.1)	(0.1, 0.2)
Influenza like illness	10 (0.1)	(0.0, 0.2)
Injection site bruising	8 (0.1)	(0.0, 0.1)
Axillary pain	6 (0.0)	(0.0, 0.1)
Injection site warmth	6 (0.0)	(0.0, 0.1)
Feeling hot	5 (0.0)	(0.0, 0.1)
Injection site induration	5 (0.0)	(0.0, 0.1)
Oedema peripheral	5 (0.0)	(0.0, 0.1)
Peripheral swelling	4 (0.0)	(0.0, 0.1)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Injection site oedema	3 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	3 (0.0)	(0.0, 0.1)
Adverse drug reaction	2 (0.0)	(0.0, 0.1)
Cyst	2 (0.0)	(0.0, 0.1)
Face oedema	2 (0.0)	(0.0, 0.1)
Injection site discomfort	2 (0.0)	(0.0, 0.1)
Injection site haematoma	2 (0.0)	(0.0, 0.1)
Injection site nodule	2 (0.0)	(0.0, 0.1)
Injection site papule	2 (0.0)	(0.0, 0.1)
Swelling	2 (0.0)	(0.0, 0.1)
Application site erythema	1 (0.0)	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)
Chest discomfort	1 (0.0)	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)
Injection site mass	1 (0.0)	(0.0, 0.0)
Injection site paraesthesia	1 (0.0)	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)
Injection site reaction	1 (0.0)	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)
Sensation of foreign body	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.0)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Thirst	1 (0.0)	(0.0, 0.0)
Vaccination site induration	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	21 (0.2)	(0.1, 0.3)
Cholelithiasis	7 (0.1)	(0.0, 0.1)
Biliary colic	4 (0.0)	(0.0, 0.1)
Cholecystitis acute	3 (0.0)	(0.0, 0.1)
Bile duct stone	2 (0.0)	(0.0, 0.1)
Biliary dyskinesia	1 (0.0)	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)
Cholelithiasis obstructive	1 (0.0)	(0.0, 0.0)
Gallbladder disorder	1 (0.0)	(0.0, 0.0)
Hepatic steatosis	1 (0.0)	(0.0, 0.0)
Jaundice	1 (0.0)	(0.0, 0.0)
Portosplenomesenteric venous thrombosis	1 (0.0)	(0.0, 0.0)
Steatohepatitis	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	15 (0.1)	(0.1, 0.2)
Seasonal allergy	6 (0.0)	(0.0, 0.1)
Drug hypersensitivity	2 (0.0)	(0.0, 0.1)
Hypersensitivity	2 (0.0)	(0.0, 0.1)
Allergy to arthropod bite	1 (0.0)	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)
Food allergy	1 (0.0)	(0.0, 0.0)
Jarisch-Herxheimer reaction	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	295 (2.5)	(2.2, 2.7)
Urinary tract infection	57 (0.5)	(0.4, 0.6)
Tooth infection	20 (0.2)	(0.1, 0.3)
Sinusitis	16 (0.1)	(0.1, 0.2)
Appendicitis	10 (0.1)	(0.0, 0.2)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Herpes zoster	10 (0.1)	(0.0, 0.2)
Cellulitis	9 (0.1)	(0.0, 0.1)
Conjunctivitis	8 (0.1)	(0.0, 0.1)
Cystitis	8 (0.1)	(0.0, 0.1)
Ear infection	8 (0.1)	(0.0, 0.1)
Diverticulitis	7 (0.1)	(0.0, 0.1)
Gastroenteritis	7 (0.1)	(0.0, 0.1)
Tooth abscess	7 (0.1)	(0.0, 0.1)
Hordeolum	6 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	6 (0.0)	(0.0, 0.1)
Folliculitis	5 (0.0)	(0.0, 0.1)
Rhinitis	5 (0.0)	(0.0, 0.1)
Nasopharyngitis	4 (0.0)	(0.0, 0.1)
Oral herpes	4 (0.0)	(0.0, 0.1)
Otitis externa	4 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	4 (0.0)	(0.0, 0.1)
Fungal skin infection	3 (0.0)	(0.0, 0.1)
Gingivitis	3 (0.0)	(0.0, 0.1)
Onychomycosis	3 (0.0)	(0.0, 0.1)
Paronychia	3 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	3 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.1)
Pyelonephritis	3 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	3 (0.0)	(0.0, 0.1)
Device related infection	2 (0.0)	(0.0, 0.1)
Herpes simplex	2 (0.0)	(0.0, 0.1)
Influenza	2 (0.0)	(0.0, 0.1)
Kidney infection	2 (0.0)	(0.0, 0.1)
Laryngitis	2 (0.0)	(0.0, 0.1)
Localised infection	2 (0.0)	(0.0, 0.1)
Oral candidiasis	2 (0.0)	(0.0, 0.1)
Otitis media	2 (0.0)	(0.0, 0.1)
Otitis media acute	2 (0.0)	(0.0, 0.1)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Periodontitis	2 (0.0)	(0.0, 0.1)
Pustule	2 (0.0)	(0.0, 0.1)
Rash pustular	2 (0.0)	(0.0, 0.1)
Sepsis	2 (0.0)	(0.0, 0.1)
Sinusitis bacterial	2 (0.0)	(0.0, 0.1)
Skin infection	2 (0.0)	(0.0, 0.1)
Viral infection	2 (0.0)	(0.0, 0.1)
Abscess	1 (0.0)	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.0)
Abscess oral	1 (0.0)	(0.0, 0.0)
Acute sinusitis	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)
Arthritis bacterial	1 (0.0)	(0.0, 0.0)
Bacteraemia	1 (0.0)	(0.0, 0.0)
Bacterial blepharitis	1 (0.0)	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)
Bacterial vaginosis	1 (0.0)	(0.0, 0.0)
Bacterial vulvovaginitis	1 (0.0)	(0.0, 0.0)
Bartholinitis	1 (0.0)	(0.0, 0.0)
Bone abscess	1 (0.0)	(0.0, 0.0)
Bronchitis	1 (0.0)	(0.0, 0.0)
Cellulitis orbital	1 (0.0)	(0.0, 0.0)
Chronic sinusitis	1 (0.0)	(0.0, 0.0)
Clostridium difficile colitis	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)
Endocarditis	1 (0.0)	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)
Eye infection	1 (0.0)	(0.0, 0.0)
Fungal infection	1 (0.0)	(0.0, 0.0)
Furuncle	1 (0.0)	(0.0, 0.0)
Gangrene	1 (0.0)	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.0)
Gastrointestinal infection	1 (0.0)	(0.0, 0.0)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Genital herpes simplex	1 (0.0)	(0.0, 0.0)
Helicobacter gastritis	1 (0.0)	(0.0, 0.0)
Helicobacter infection	1 (0.0)	(0.0, 0.0)
Herpes zoster oticus	1 (0.0)	(0.0, 0.0)
Impetigo	1 (0.0)	(0.0, 0.0)
Infected bite	1 (0.0)	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)
Mastoiditis	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	1 (0.0)	(0.0, 0.0)
Mumps	1 (0.0)	(0.0, 0.0)
Papilloma viral infection	1 (0.0)	(0.0, 0.0)
Parasitic gastroenteritis	1 (0.0)	(0.0, 0.0)
Penile infection	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)
Peritonitis	1 (0.0)	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)
Pharyngitis	1 (0.0)	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.0)
Postoperative abscess	1 (0.0)	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.0)
Sialoadenitis	1 (0.0)	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.0)
Tinea versicolour	1 (0.0)	(0.0, 0.0)
Varicella	1 (0.0)	(0.0, 0.0)
Vulval abscess	1 (0.0)	(0.0, 0.0)
Vulvovaginitis	1 (0.0)	(0.0, 0.0)
Wound infection	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	207 (1.7)	(1.5, 2.0)
Fall	47 (0.4)	(0.3, 0.5)
Exposure during pregnancy	22 (0.2)	(0.1, 0.3)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Muscle strain	15 (0.1)	(0.1, 0.2)
Ligament sprain	13 (0.1)	(0.1, 0.2)
Contusion	12 (0.1)	(0.1, 0.2)
Procedural pain	11 (0.1)	(0.0, 0.2)
Road traffic accident	11 (0.1)	(0.0, 0.2)
Skin laceration	11 (0.1)	(0.0, 0.2)
Arthropod bite	7 (0.1)	(0.0, 0.1)
Limb injury	7 (0.1)	(0.0, 0.1)
Tooth fracture	6 (0.0)	(0.0, 0.1)
Ankle fracture	5 (0.0)	(0.0, 0.1)
Chest injury	5 (0.0)	(0.0, 0.1)
Foot fracture	5 (0.0)	(0.0, 0.1)
Hand fracture	5 (0.0)	(0.0, 0.1)
Joint dislocation	5 (0.0)	(0.0, 0.1)
Skin abrasion	5 (0.0)	(0.0, 0.1)
Joint injury	4 (0.0)	(0.0, 0.1)
Meniscus injury	4 (0.0)	(0.0, 0.1)
Wrist fracture	4 (0.0)	(0.0, 0.1)
Animal bite	3 (0.0)	(0.0, 0.1)
Arthropod sting	3 (0.0)	(0.0, 0.1)
Burns second degree	3 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	3 (0.0)	(0.0, 0.1)
Facial bones fracture	3 (0.0)	(0.0, 0.1)
Humerus fracture	3 (0.0)	(0.0, 0.1)
Patella fracture	3 (0.0)	(0.0, 0.1)
Tibia fracture	3 (0.0)	(0.0, 0.1)
Upper limb fracture	3 (0.0)	(0.0, 0.1)
Vaccination complication	3 (0.0)	(0.0, 0.1)
Concussion	2 (0.0)	(0.0, 0.1)
Craniocerebral injury	2 (0.0)	(0.0, 0.1)
Ligament rupture	2 (0.0)	(0.0, 0.1)
Radius fracture	2 (0.0)	(0.0, 0.1)
Rib fracture	2 (0.0)	(0.0, 0.1)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Thermal burn	2 (0.0)	(0.0, 0.1)
Bone contusion	1 (0.0)	(0.0, 0.0)
Bone fissure	1 (0.0)	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.0)
Burns first degree	1 (0.0)	(0.0, 0.0)
Burns third degree	1 (0.0)	(0.0, 0.0)
Cartilage injury	1 (0.0)	(0.0, 0.0)
Chemical burns of eye	1 (0.0)	(0.0, 0.0)
Corneal abrasion	1 (0.0)	(0.0, 0.0)
Eyelid injury	1 (0.0)	(0.0, 0.0)
Fibula fracture	1 (0.0)	(0.0, 0.0)
Foreign body in eye	1 (0.0)	(0.0, 0.0)
Fractured sacrum	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)
Jaw fracture	1 (0.0)	(0.0, 0.0)
Limb fracture	1 (0.0)	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)
Maternal exposure before pregnancy	1 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	1 (0.0)	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.0)
Muscle rupture	1 (0.0)	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)
Post concussion syndrome	1 (0.0)	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.0)
Post procedural swelling	1 (0.0)	(0.0, 0.0)
Procedural dizziness	1 (0.0)	(0.0, 0.0)
Spinal compression fracture	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)
Spinal fracture	1 (0.0)	(0.0, 0.0)
Stress fracture	1 (0.0)	(0.0, 0.0)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Subdural haematoma	1 (0.0)	(0.0, 0.0)
Sunburn	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)
Ulna fracture	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	94 (0.8)	(0.6, 1.0)
Body temperature increased	50 (0.4)	(0.3, 0.5)
Blood glucose increased	8 (0.1)	(0.0, 0.1)
SARS-CoV-2 antibody test positive	5 (0.0)	(0.0, 0.1)
Blood pressure increased	4 (0.0)	(0.0, 0.1)
Blood cholesterol increased	3 (0.0)	(0.0, 0.1)
Alanine aminotransferase increased	2 (0.0)	(0.0, 0.1)
Blood thyroid stimulating hormone increased	2 (0.0)	(0.0, 0.1)
Weight increased	2 (0.0)	(0.0, 0.1)
Aspartate aminotransferase increased	1 (0.0)	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)
Blood immunoglobulin E increased	1 (0.0)	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.0)
Blood triglycerides increased	1 (0.0)	(0.0, 0.0)
Body temperature decreased	1 (0.0)	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.0)
Haemoglobin decreased	1 (0.0)	(0.0, 0.0)
Heart rate increased	1 (0.0)	(0.0, 0.0)
Intraocular pressure increased	1 (0.0)	(0.0, 0.0)
Liver function test increased	1 (0.0)	(0.0, 0.0)
Lymphocyte count decreased	1 (0.0)	(0.0, 0.0)
Mean cell volume decreased	1 (0.0)	(0.0, 0.0)
Platelet count decreased	1 (0.0)	(0.0, 0.0)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Respiratory rate increased	1 (0.0)	(0.0, 0.0)
Troponin increased	1 (0.0)	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	81 (0.7)	(0.5, 0.8)
Decreased appetite	15 (0.1)	(0.1, 0.2)
Hyperlipidaemia	9 (0.1)	(0.0, 0.1)
Type 2 diabetes mellitus	9 (0.1)	(0.0, 0.1)
Vitamin D deficiency	8 (0.1)	(0.0, 0.1)
Hypercholesterolaemia	6 (0.0)	(0.0, 0.1)
Dyslipidaemia	5 (0.0)	(0.0, 0.1)
Glucose tolerance impaired	4 (0.0)	(0.0, 0.1)
Gout	3 (0.0)	(0.0, 0.1)
Hyperglycaemia	3 (0.0)	(0.0, 0.1)
Hypertriglyceridaemia	3 (0.0)	(0.0, 0.1)
Hypoglycaemia	3 (0.0)	(0.0, 0.1)
Hypokalaemia	3 (0.0)	(0.0, 0.1)
Dehydration	2 (0.0)	(0.0, 0.1)
Hyperkalaemia	2 (0.0)	(0.0, 0.1)
Hyperuricaemia	2 (0.0)	(0.0, 0.1)
Obesity	2 (0.0)	(0.0, 0.1)
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)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)
Insulin resistance	1 (0.0)	(0.0, 0.0)
Metabolic syndrome	1 (0.0)	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	905 (7.5)	(7.1, 8.0)
Myalgia	549 (4.6)	(4.2, 5.0)
Arthralgia	153 (1.3)	(1.1, 1.5)
Pain in extremity	93 (0.8)	(0.6, 0.9)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Back pain	62 (0.5)	(0.4, 0.7)
Neck pain	20 (0.2)	(0.1, 0.3)
Muscle spasms	19 (0.2)	(0.1, 0.2)
Osteoarthritis	14 (0.1)	(0.1, 0.2)
Tendonitis	9 (0.1)	(0.0, 0.1)
Musculoskeletal stiffness	8 (0.1)	(0.0, 0.1)
Intervertebral disc protrusion	6 (0.0)	(0.0, 0.1)
Arthritis	5 (0.0)	(0.0, 0.1)
Bursitis	5 (0.0)	(0.0, 0.1)
Muscular weakness	5 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	5 (0.0)	(0.0, 0.1)
Periarthritis	5 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	4 (0.0)	(0.0, 0.1)
Intervertebral disc degeneration	3 (0.0)	(0.0, 0.1)
Joint stiffness	3 (0.0)	(0.0, 0.1)
Muscle contracture	3 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	3 (0.0)	(0.0, 0.1)
Arthropathy	2 (0.0)	(0.0, 0.1)
Coccydynia	2 (0.0)	(0.0, 0.1)
Costochondritis	2 (0.0)	(0.0, 0.1)
Flank pain	2 (0.0)	(0.0, 0.1)
Joint range of motion decreased	2 (0.0)	(0.0, 0.1)
Limb discomfort	2 (0.0)	(0.0, 0.1)
Muscle twitching	2 (0.0)	(0.0, 0.1)
Musculoskeletal pain	2 (0.0)	(0.0, 0.1)
Pain in jaw	2 (0.0)	(0.0, 0.1)
Plantar fasciitis	2 (0.0)	(0.0, 0.1)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.1)
Tenosynovitis stenosans	2 (0.0)	(0.0, 0.1)
Bone disorder	1 (0.0)	(0.0, 0.0)
Bone pain	1 (0.0)	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.0)
Intervertebral disc compression	1 (0.0)	(0.0, 0.0)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Joint effusion	1 (0.0)	(0.0, 0.0)
Joint instability	1 (0.0)	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)
Mobility decreased	1 (0.0)	(0.0, 0.0)
Muscle fatigue	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)
Osteopenia	1 (0.0)	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)
Spondylitis	1 (0.0)	(0.0, 0.0)
Synovial cyst	1 (0.0)	(0.0, 0.0)
Temporomandibular joint syndrome	1 (0.0)	(0.0, 0.0)
Torticollis	1 (0.0)	(0.0, 0.0)
Trigger finger	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	53 (0.4)	(0.3, 0.6)
Prostate cancer	5 (0.0)	(0.0, 0.1)
Basal cell carcinoma	4 (0.0)	(0.0, 0.1)
Lipoma	4 (0.0)	(0.0, 0.1)
Malignant melanoma	4 (0.0)	(0.0, 0.1)
Breast cancer	3 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	2 (0.0)	(0.0, 0.1)
Skin papilloma	2 (0.0)	(0.0, 0.1)
Transitional cell carcinoma	2 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.0)
Adenoma benign	1 (0.0)	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)
Benign hydatidiform mole	1 (0.0)	(0.0, 0.0)
Benign uterine neoplasm	1 (0.0)	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.0)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.0)
Brain cancer metastatic	1 (0.0)	(0.0, 0.0)
Breast cancer in situ	1 (0.0)	(0.0, 0.0)
Carcinoid tumour of the stomach	1 (0.0)	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.0)
Colon adenoma	1 (0.0)	(0.0, 0.0)
Fibroma	1 (0.0)	(0.0, 0.0)
Gallbladder cancer stage II	1 (0.0)	(0.0, 0.0)
Gastric cancer	1 (0.0)	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.0)
Meningioma benign	1 (0.0)	(0.0, 0.0)
Non-small cell lung cancer stage IV	1 (0.0)	(0.0, 0.0)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.0)
Skin cancer	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma of skin	1 (0.0)	(0.0, 0.0)
Thyroid cancer	1 (0.0)	(0.0, 0.0)
Uterine cancer	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	726 (6.0)	(5.6, 6.5)
Headache	572 (4.8)	(4.4, 5.2)
Dizziness	43 (0.4)	(0.3, 0.5)
Paraesthesia	15 (0.1)	(0.1, 0.2)
Lethargy	14 (0.1)	(0.1, 0.2)
Migraine	14 (0.1)	(0.1, 0.2)
Sciatica	9 (0.1)	(0.0, 0.1)
Tension headache	9 (0.1)	(0.0, 0.1)
Syncope	8 (0.1)	(0.0, 0.1)
Presyncope	6 (0.0)	(0.0, 0.1)
Tremor	6 (0.0)	(0.0, 0.1)
Dysgeusia	5 (0.0)	(0.0, 0.1)
Somnolence	4 (0.0)	(0.0, 0.1)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Disturbance in attention	3 (0.0)	(0.0, 0.1)
Facial paralysis	3 (0.0)	(0.0, 0.1)
Hypoaesthesia	3 (0.0)	(0.0, 0.1)
Sinus headache	3 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.1)
Burning sensation	2 (0.0)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)
Cervical radiculopathy	2 (0.0)	(0.0, 0.1)
Dizziness postural	2 (0.0)	(0.0, 0.1)
Migraine without aura	2 (0.0)	(0.0, 0.1)
Nerve compression	2 (0.0)	(0.0, 0.1)
Optic neuritis	2 (0.0)	(0.0, 0.1)
Restless legs syndrome	2 (0.0)	(0.0, 0.1)
Seizure	2 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)
Aphasia	1 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)
Depressed level of consciousness	1 (0.0)	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)
Hyperaesthesia	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)
Intracranial aneurysm	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)
Neuralgia	1 (0.0)	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.0)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.0)
Peripheral nerve lesion	1 (0.0)	(0.0, 0.0)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.0)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.0)
Radiculopathy	1 (0.0)	(0.0, 0.0)
Seizure like phenomena	1 (0.0)	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)
Vocal cord paralysis	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	3 (0.0)	(0.0, 0.1)
Abortion spontaneous	2 (0.0)	(0.0, 0.1)
Exposure during pregnancy	1 (0.0)	(0.0, 0.0)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.0)
Device connection issue	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	65 (0.5)	(0.4, 0.7)
Insomnia	17 (0.1)	(0.1, 0.2)
Anxiety	16 (0.1)	(0.1, 0.2)
Depression	11 (0.1)	(0.0, 0.2)
Anxiety disorder	4 (0.0)	(0.0, 0.1)
Abnormal dreams	3 (0.0)	(0.0, 0.1)
Attention deficit hyperactivity disorder	3 (0.0)	(0.0, 0.1)
Irritability	3 (0.0)	(0.0, 0.1)
Sleep disorder	3 (0.0)	(0.0, 0.1)
Disorientation	2 (0.0)	(0.0, 0.1)
Nightmare	2 (0.0)	(0.0, 0.1)
Generalised anxiety disorder	1 (0.0)	(0.0, 0.0)
Libido increased	1 (0.0)	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)
Suicide attempt	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	42 (0.3)	(0.3, 0.5)
Nephrolithiasis	11 (0.1)	(0.0, 0.2)
Dysuria	6 (0.0)	(0.0, 0.1)
Pollakiuria	5 (0.0)	(0.0, 0.1)
Haematuria	3 (0.0)	(0.0, 0.1)
Acute kidney injury	2 (0.0)	(0.0, 0.1)
Bladder spasm	2 (0.0)	(0.0, 0.1)
Renal colic	2 (0.0)	(0.0, 0.1)
Urinary retention	2 (0.0)	(0.0, 0.1)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Bladder irritation	1 (0.0)	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.0)
Hypertonic bladder	1 (0.0)	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)
Obstructive nephropathy	1 (0.0)	(0.0, 0.0)
Renal cyst	1 (0.0)	(0.0, 0.0)
Renal haematoma	1 (0.0)	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)
Urethral stenosis	1 (0.0)	(0.0, 0.0)
Urinary tract obstruction	1 (0.0)	(0.0, 0.0)
Vesical fistula	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	36 (0.3)	(0.2, 0.4)
Dysmenorrhoea	4 (0.0)	(0.0, 0.1)
Ovarian cyst	3 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	2 (0.0)	(0.0, 0.1)
Breast pain	2 (0.0)	(0.0, 0.1)
Endometriosis	2 (0.0)	(0.0, 0.1)
Genital erythema	2 (0.0)	(0.0, 0.1)
Menorrhagia	2 (0.0)	(0.0, 0.1)
Menstruation irregular	2 (0.0)	(0.0, 0.1)
Amenorrhoea	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.0)
Endometrial thickening	1 (0.0)	(0.0, 0.0)
Haematospermia	1 (0.0)	(0.0, 0.0)
Mammary duct ectasia	1 (0.0)	(0.0, 0.0)
Menometrorrhagia	1 (0.0)	(0.0, 0.0)
Metrorrhagia	1 (0.0)	(0.0, 0.0)
Pelvic pain	1 (0.0)	(0.0, 0.0)
Polycystic ovaries	1 (0.0)	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Prostatitis	1 (0.0)	(0.0, 0.0)
Prostatomegaly	1 (0.0)	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.0)
Scrotal pain	1 (0.0)	(0.0, 0.0)
Testicular pain	1 (0.0)	(0.0, 0.0)
Testicular torsion	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	145 (1.2)	(1.0, 1.4)
Oropharyngeal pain	24 (0.2)	(0.1, 0.3)
Nasal congestion	21 (0.2)	(0.1, 0.3)
Cough	17 (0.1)	(0.1, 0.2)
Rhinorrhoea	12 (0.1)	(0.1, 0.2)
Rhinitis allergic	9 (0.1)	(0.0, 0.1)
Asthma	8 (0.1)	(0.0, 0.1)
Dyspnoea	6 (0.0)	(0.0, 0.1)
Pulmonary embolism	6 (0.0)	(0.0, 0.1)
Sleep apnoea syndrome	5 (0.0)	(0.0, 0.1)
Throat irritation	5 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	5 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	4 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	3 (0.0)	(0.0, 0.1)
Epistaxis	3 (0.0)	(0.0, 0.1)
Asthmatic crisis	2 (0.0)	(0.0, 0.1)
Bronchospasm	2 (0.0)	(0.0, 0.1)
Nasal polyps	2 (0.0)	(0.0, 0.1)
Productive cough	2 (0.0)	(0.0, 0.1)
Respiratory tract congestion	2 (0.0)	(0.0, 0.1)
Sinus congestion	2 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)
Wheezing	2 (0.0)	(0.0, 0.1)
Allergic sinusitis	1 (0.0)	(0.0, 0.0)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Atelectasis	1 (0.0)	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)
Emphysema	1 (0.0)	(0.0, 0.0)
Haemoptysis	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)
Nasal septum deviation	1 (0.0)	(0.0, 0.0)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)
Pneumothorax	1 (0.0)	(0.0, 0.0)
Reflux laryngitis	1 (0.0)	(0.0, 0.0)
Respiratory failure	1 (0.0)	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	153 (1.3)	(1.1, 1.5)
Rash	35 (0.3)	(0.2, 0.4)
Hyperhidrosis	16 (0.1)	(0.1, 0.2)
Pruritus	15 (0.1)	(0.1, 0.2)
Dermatitis contact	11 (0.1)	(0.0, 0.2)
Urticaria	11 (0.1)	(0.0, 0.2)
Night sweats	8 (0.1)	(0.0, 0.1)
Rash pruritic	6 (0.0)	(0.0, 0.1)
Erythema	5 (0.0)	(0.0, 0.1)
Dermal cyst	4 (0.0)	(0.0, 0.1)
Dermatitis	4 (0.0)	(0.0, 0.1)
Eczema	4 (0.0)	(0.0, 0.1)
Acne	3 (0.0)	(0.0, 0.1)
Actinic keratosis	3 (0.0)	(0.0, 0.1)
Dermatitis allergic	3 (0.0)	(0.0, 0.1)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Rash maculo-papular	3 (0.0)	(0.0, 0.1)
Alopecia	2 (0.0)	(0.0, 0.1)
Acne cystic	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 exfoliative	1 (0.0)	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)
Dry skin	1 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)
Erythema nodosum	1 (0.0)	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)
Intertrigo	1 (0.0)	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)
Onycholysis	1 (0.0)	(0.0, 0.0)
Onychomadesis	1 (0.0)	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.0)
Pityriasis	1 (0.0)	(0.0, 0.0)
Pseudofolliculitis	1 (0.0)	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.0)
Purpura	1 (0.0)	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)
Rash papular	1 (0.0)	(0.0, 0.0)
Rosacea	1 (0.0)	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)
Skin irritation	1 (0.0)	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)
Transient acantholytic dermatosis	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	2 (0.0)	(0.0, 0.1)
High risk sexual behaviour	1 (0.0)	(0.0, 0.0)
Miscarriage of partner	1 (0.0)	(0.0, 0.0)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
SURGICAL AND MEDICAL PROCEDURES	29 (0.2)	(0.2, 0.3)
Dental implantation	5 (0.0)	(0.0, 0.1)
Tooth extraction	3 (0.0)	(0.0, 0.1)
Wisdom teeth removal	2 (0.0)	(0.0, 0.1)
Botulinum toxin injection	1 (0.0)	(0.0, 0.0)
Cardioversion	1 (0.0)	(0.0, 0.0)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.0)
Drug titration	1 (0.0)	(0.0, 0.0)
Endodontic procedure	1 (0.0)	(0.0, 0.0)
Facet joint block	1 (0.0)	(0.0, 0.0)
Finger amputation	1 (0.0)	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.0)
Mammoplasty	1 (0.0)	(0.0, 0.0)
Meniscus operation	1 (0.0)	(0.0, 0.0)
Metabolic surgery	1 (0.0)	(0.0, 0.0)
Open reduction of fracture	1 (0.0)	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.0)
Radioactive iodine therapy	1 (0.0)	(0.0, 0.0)
Retinal operation	1 (0.0)	(0.0, 0.0)
Rotator cuff repair	1 (0.0)	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	78 (0.6)	(0.5, 0.8)
Hypertension	48 (0.4)	(0.3, 0.5)
Deep vein thrombosis	6 (0.0)	(0.0, 0.1)
Hot flush	6 (0.0)	(0.0, 0.1)
Aortic aneurysm	3 (0.0)	(0.0, 0.1)
Haematoma	3 (0.0)	(0.0, 0.1)
Flushing	2 (0.0)	(0.0, 0.1)
Hypotension	2 (0.0)	(0.0, 0.1)
Aortic dilatation	1 (0.0)	(0.0, 0.0)

Table 35. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Arterial occlusive disease	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.0)
Peripheral vascular disorder	1 (0.0)	(0.0, 0.0)
Systolic hypertension	1 (0.0)	(0.0, 0.0)
Thrombophlebitis superficial	1 (0.0)	(0.0, 0.0)
Varicose vein	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_all_bnt_pd2_p3_saf

12.2.3.4.2.2. Related Adverse Events by System Organ Class and Preferred Term – Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Participants

From Dose 1 to 6 months after Dose 2 during the blinded and open-label follow-up period, AEs assessed as related by the investigator during the blinded and open-label follow-up period were reported by 18.7% of participants in the BNT162b2 group (Table 33). Most related AEs were reactogenicity events and in the SOC of general disorders and administration site conditions (1944 [16.2%]) (Supplemental Table 14.149).

The AE of lymphadenopathy in 29 (0.2%) participants was assessed by the investigator as related to study intervention (Supplemental Table 14.149).

Related AEs in the younger and older age groups were reported in 20.8% and 16.1% of original BNT162b2 participants (Supplemental Tables 14.150 and 14.151, respectively).

12.2.3.5. Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2

12.2.3.5.1. Summary of Adverse Events – Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2

Overall, there are 19,525 original placebo participants who then were unblinded and received BNT162b2. An overview of AEs after vaccination with BNT162b2 to the data cutoff date for placebo participants who received BNT162b2 during the open-label follow-up period is presented in Table 36. The IRs for any AE and at least 1 related AE were 205.4 per 100 PY and 189.5 per 100 PY, respectively. IRs of severe AEs, SAEs, and AEs leading to withdrawal were 6.0 per 100 PY, 2.7 per 100 PY, and 0.8 per 100 PY. The IR for discontinuations because of related AEs was 0.5 per 100 PY, and 2 participants died (Section 12.2.4.1).

The IRs in Table 31 include all AEs reported for these participants including AEs reported while on placebo. Additionally, all of these placebo participants received open-label BNT162b2 and the exposure time is shorter for placebo participants who received BNT162b2 than those who originally were randomized to BNT162b2 (23.8 per 100 PY vs 83.4 per 100 PY, respectively [Table 36 and Table 31]). As expected, in comparison to participants randomized to BNT162b2 from Dose 1 to the unblinding date, the IR for any AE and at least 1 related AE and severe AE for participants who originally received placebo and then received BNT162b2 are greater (205.4 per 100 PY, 189.5 per 100 PY, 6.0 per 100 PY) than the IRs (83.2 per 100 PY, 62.9 per 100 PY, 4.3 per 100 PY) for participants who originally were randomized to BNT162b2, respectively (Table 36 and Table 31). However, the IRs for life-threatening AE, SAE, AEs leading to withdrawal and deaths were similar (0.5 per 100 PY, 2.7 per 100 PY, 0.8 per 100 PY, 0.1 per 100 PY vs 0.6 per 100 PY, 3.2 per 100 PY, 0.5 per 100 PY, 0.2 per 100 PY, respectively). There was 1 related SAE of anaphylactoid reaction for a placebo participant who was vaccinated with BNT162b2 (see Section 12.2.4.2.5).

The IRs of AEs for original placebo participants who then received BNT162b2 were observed by baseline SARS CoV-2 positive and negative status subgroups (Supplemental Tables 14.152 and 14.153). Overall, the IRs for AEs were similar between the baseline positive (222.9 per 100 PY; 95% CI: 186.5, 264.3) compared to baseline negative (205 per 100 PY; 95% CI 199.6, 211.3). There were 2 SAEs (not related), 1 AE leading to withdrawal and no deaths in the baseline positive group (Supplemental Table 14.152).

Table 36. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021) – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	4885	205.4	(199.6, 211.2)
Related[f]	4508	189.5	(184.0, 195.1)
Severe	142	6.0	(5.0, 7.0)
Life-threatening	11	0.5	(0.2, 0.8)
Any serious adverse event	65	2.7	(2.1, 3.5)
Related[f]	1	0.0	(0.0, 0.2)
Severe	37	1.6	(1.1, 2.1)
Life-threatening	11	0.5	(0.2, 0.8)
Any adverse event leading to withdrawal	19	0.8	(0.5, 1.2)
Related[f]	12	0.5	(0.3, 0.9)
Severe	2	0.1	(0.0, 0.3)
Life-threatening	4	0.2	(0.0, 0.4)
Death	2	0.1	(0.0, 0.3)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s092 cr cut p3x saf

12.2.3.5.2. Analysis of Adverse Events – Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2

12.2.3.5.2.1. Adverse Events by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2

From vaccination with BNT162b2 for placebo participants to the data cutoff date during the and open-label follow-up period, the IR for participants who reported at least 1 AE was 205.4 per 100 PY (Table 37).

Most AEs reported from Dose 3 (first dose of BNT162b2) to the data cutoff date were in SOCs with reactogenicity events.

- general disorders and administration site conditions (175.3 per 100 PY)
- musculoskeletal and connective tissue disorders (52.3 per 100 PY)
- nervous system disorders (50.5 per 100 PY)
- gastrointestinal disorders (14.3 per 100 PY)

As shown in Table 37, the most frequently reported AEs (IRs) overall were injection site pain (123.8 per 100 PY), fatigue (58.0 per 100 PY), headache (46.6 per 100 PY), chills (41.8 per 100 PY), myalgia (38.9 per 100 PY), and pyrexia (38.1 per 100 PY).

After participants who originally received placebo were unblinded and then received BNT162b2 after unblinding, events related to reactogenicity were not reported using an e diary but were instead reported as AEs. An analysis was conducted to evaluate if the imbalance in AEs observed from Dose 3 to the unblinding date was attributed to reactogenicity events. The analysis examined the AEs reported within 7 days after each dose (Dose 3 and Dose 4), which represented the reactogenicity reporting period.

PTs reported from Dose 3 to 7 days after Dose 3 and from Dose 4 to 7 days after Dose 4 in the SOCs of general disorders and administration site conditions (injection site pain, chills, fatigue, and pyrexia), musculoskeletal and connective tissue disorders (myalgia), and nervous system disorders (headache) represented the majority of PTs reported in those SOCs (Supplemental Tables 14.154 and 14.155).

Allergy to vaccine, anaphylactoid reaction, and deep vein thrombosis were reported in 1 participant each from Dose 3 to 7 days after Dose 3 (Supplemental Table 14.154 and Appendix 16.2.7.4.1):

- One participant reported an AE of Grade 2 allergy to vaccine, which occurred on the day of Dose 3 vaccination, had a duration of 2 days, and resolved; this AE was assessed by the investigator as related to the study intervention.

- One participant with an ongoing medical history significant for drug hypersensitivity and food and seasonal allergies (Appendix 16.2.5.4) reported a life-threatening SAE of anaphylactoid reaction, which occurred 2 days after Dose 3 and was resolved that same day; this SAE was assessed by the investigator as related to the study intervention (Section 12.2.4.4.1.1).

- One participant with a past medical history significant for deep vein thrombosis, hypertension, pulmonary arterial hypertension, right ventricular enlargement, hypercholesteremia, atherosclerosis and bilateral peripheral neuropathy (Appendix 16.2.5.4) reported a Grade 2 SAE of deep vein thrombosis (lower right extremity) and Grade 1 SAE of pulmonary embolism, which both occurred 2 days after Dose 3, had both resolved with a duration of 3 days; both SAEs were assessed by the investigator as not related to the study intervention.

In addition to analysis of AEs corresponding to e-diary terms, consideration was given to additional AEs that were reported within 7 days after Dose 3 or Dose 4 such as pain in extremity, decreased appetite, lethargy, asthenia, malaise, night sweats, and hyperhidrosis. Similar to the analysis that examined these events 7 days within Dose 1 and Dose 2 of BNT162b2 in blinded follow-up (Section 12.2.3.1.2.1), these events reported in open-label follow-up are interpreted as attributable to the experience of local reactions and systemic events after vaccination with Dose 3 and Dose 4 (first and second dose of BNT162b2).

These results are consistent with the pattern seen during the blinded placebo-controlled follow-up period from Dose 1 to 1 month after Dose 2 (Section 12.2.3.1.2.1), which confirms that the greater rates of AEs observed overall in the BNT162b2 group compared with the placebo group were largely attributable to reactogenicity events for that time period.

No clinically meaningful differences in IRs of AEs for original placebo participants who then received BNT162b2 were observed by baseline SARS-CoV-2 positive (222.9 per 100 PY) and negative (205.4 per 100 PY) status subgroups (Supplemental Tables 14.156 and 14.157). The IR for original baseline positive placebo participants who then received BNT162b2 was 222.9 per 100 PY (95% CI: 186.5, 264.3) which was similar to baseline negative placebo participants who then received BNT162b2 is 205.4 per 100 PY (95% CI: 199.6, 211.3). The IR between other SOC were similar in the baseline positive and baseline negative groups except for the musculoskeletal SOC which was higher in the baseline positive group. However, it was driven by myalgia 64.2 per 100 PY (95% CI: 45.4, 88.1) in baseline positive participants compared to 38.3 per 100 PY (95% CI: 35.8, 40.9) in baseline negative participants.

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	4885	205.4	(199.6, 211.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	88	3.7	(3.0, 4.6)
Anaemia	2	0.1	(0.0, 0.3)
Coagulopathy	1	0.0	(0.0, 0.2)
Iron deficiency anaemia	2	0.1	(0.0, 0.3)

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Lymph node pain	6	0.3	(0.1, 0.5)
Lymphadenitis	2	0.1	(0.0, 0.3)
Lymphadenopathy	76	3.2	(2.5, 4.0)
CARDIAC DISORDERS	17	0.7	(0.4, 1.1)
Acute myocardial infarction	1	0.0	(0.0, 0.2)
Angina pectoris	1	0.0	(0.0, 0.2)
Arrhythmia	1	0.0	(0.0, 0.2)
Arteriospasm coronary	1	0.0	(0.0, 0.2)
Atrial fibrillation	5	0.2	(0.1, 0.5)
Atrial flutter	1	0.0	(0.0, 0.2)
Cardiac failure congestive	1	0.0	(0.0, 0.2)
Cardio-respiratory arrest	1	0.0	(0.0, 0.2)
Cardiovascular disorder	1	0.0	(0.0, 0.2)
Coronary artery disease	1	0.0	(0.0, 0.2)
Ischaemic cardiomyopathy	1	0.0	(0.0, 0.2)
Myocardial infarction	1	0.0	(0.0, 0.2)
Palpitations	1	0.0	(0.0, 0.2)
Supraventricular tachycardia	1	0.0	(0.0, 0.2)
Tachycardia	2	0.1	(0.0, 0.3)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	4	0.2	(0.0, 0.4)
Atrial septal defect	1	0.0	(0.0, 0.2)
BRCA2 gene mutation	1	0.0	(0.0, 0.2)
Factor II mutation	1	0.0	(0.0, 0.2)
Hypertrophic cardiomyopathy	1	0.0	(0.0, 0.2)
EAR AND LABYRINTH DISORDERS	18	0.8	(0.4, 1.2)
Cerumen impaction	1	0.0	(0.0, 0.2)
Deafness neurosensory	1	0.0	(0.0, 0.2)
Deafness unilateral	1	0.0	(0.0, 0.2)
Ear discomfort	1	0.0	(0.0, 0.2)
Ear pain	4	0.2	(0.0, 0.4)
Eustachian tube dysfunction	2	0.1	(0.0, 0.3)
Hypoacusis	1	0.0	(0.0, 0.2)

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Meniere's disease	1	0.0	(0.0, 0.2)
Sudden hearing loss	1	0.0	(0.0, 0.2)
Tinnitus	2	0.1	(0.0, 0.3)
Vertigo	6	0.3	(0.1, 0.5)
ENDOCRINE DISORDERS	4	0.2	(0.0, 0.4)
Hypothyroidism	2	0.1	(0.0, 0.3)
Thyroid disorder	1	0.0	(0.0, 0.2)
Thyroid mass	1	0.0	(0.0, 0.2)
EYE DISORDERS	26	1.1	(0.7, 1.6)
Blepharitis	1	0.0	(0.0, 0.2)
Cataract	4	0.2	(0.0, 0.4)
Conjunctival haemorrhage	1	0.0	(0.0, 0.2)
Dacryostenosis acquired	1	0.0	(0.0, 0.2)
Diplopia	1	0.0	(0.0, 0.2)
Dry eye	1	0.0	(0.0, 0.2)
Erythema of eyelid	1	0.0	(0.0, 0.2)
Eye irritation	1	0.0	(0.0, 0.2)
Eye pain	5	0.2	(0.1, 0.5)
Eye swelling	1	0.0	(0.0, 0.2)
Keratitis	2	0.1	(0.0, 0.3)
Lacrimation increased	3	0.1	(0.0, 0.4)
Meibomianitis	1	0.0	(0.0, 0.2)
Ocular discomfort	1	0.0	(0.0, 0.2)
Visual impairment	1	0.0	(0.0, 0.2)
Vitreous floaters	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	339	14.3	(12.8, 15.9)
Abdominal discomfort	4	0.2	(0.0, 0.4)
Abdominal distension	1	0.0	(0.0, 0.2)
Abdominal pain	12	0.5	(0.3, 0.9)
Abdominal pain lower	2	0.1	(0.0, 0.3)
Abdominal pain upper	13	0.5	(0.3, 0.9)
Anal fistula	2	0.1	(0.0, 0.3)

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Anal prolapse	1	0.0	(0.0, 0.2)
Chronic gastritis	1	0.0	(0.0, 0.2)
Constipation	4	0.2	(0.0, 0.4)
Dental caries	1	0.0	(0.0, 0.2)
Diarrhoea	91	3.8	(3.1, 4.7)
Dry mouth	3	0.1	(0.0, 0.4)
Duodenitis	1	0.0	(0.0, 0.2)
Dyspepsia	5	0.2	(0.1, 0.5)
Gastric ulcer	1	0.0	(0.0, 0.2)
Gastritis	5	0.2	(0.1, 0.5)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.2)
Gastrointestinal necrosis	1	0.0	(0.0, 0.2)
Gastrointestinal sounds abnormal	1	0.0	(0.0, 0.2)
Gastrooesophageal reflux disease	7	0.3	(0.1, 0.6)
Gingival bleeding	1	0.0	(0.0, 0.2)
Haemorrhoids	1	0.0	(0.0, 0.2)
Hiatus hernia	2	0.1	(0.0, 0.3)
Hyperaesthesia teeth	1	0.0	(0.0, 0.2)
Hypoaesthesia oral	1	0.0	(0.0, 0.2)
Intestinal obstruction	1	0.0	(0.0, 0.2)
Intestinal ulcer perforation	1	0.0	(0.0, 0.2)
Irritable bowel syndrome	2	0.1	(0.0, 0.3)
Large intestine polyp	1	0.0	(0.0, 0.2)
Nausea	160	6.7	(5.7, 7.9)
Oedema mouth	1	0.0	(0.0, 0.2)
Oral mucosal blistering	1	0.0	(0.0, 0.2)
Oral pain	1	0.0	(0.0, 0.2)
Oral pruritus	1	0.0	(0.0, 0.2)
Pancreatitis acute	2	0.1	(0.0, 0.3)
Retching	1	0.0	(0.0, 0.2)
Small intestinal obstruction	1	0.0	(0.0, 0.2)
Stomatitis	2	0.1	(0.0, 0.3)
Submaxillary gland enlargement	1	0.0	(0.0, 0.2)

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Tongue disorder	1	0.0	(0.0, 0.2)
Tongue oedema	1	0.0	(0.0, 0.2)
Toothache	1	0.0	(0.0, 0.2)
Umbilical hernia	1	0.0	(0.0, 0.2)
Vomiting	48	2.0	(1.5, 2.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4169	175.3	(170.0, 180.7)
Application site pain	2	0.1	(0.0, 0.3)
Asthenia	36	1.5	(1.1, 2.1)
Axillary pain	3	0.1	(0.0, 0.4)
Chest discomfort	2	0.1	(0.0, 0.3)
Chest pain	4	0.2	(0.0, 0.4)
Chills	994	41.8	(39.2, 44.5)
Crying	1	0.0	(0.0, 0.2)
Discomfort	2	0.1	(0.0, 0.3)
Drug withdrawal syndrome	1	0.0	(0.0, 0.2)
Facial pain	1	0.0	(0.0, 0.2)
Fatigue	1379	58.0	(55.0, 61.1)
Feeling abnormal	6	0.3	(0.1, 0.5)
Feeling cold	2	0.1	(0.0, 0.3)
Feeling hot	6	0.3	(0.1, 0.5)
Gait disturbance	1	0.0	(0.0, 0.2)
Implant site pain	1	0.0	(0.0, 0.2)
Inflammation	1	0.0	(0.0, 0.2)
Influenza like illness	1	0.0	(0.0, 0.2)
Injection site bruising	16	0.7	(0.4, 1.1)
Injection site discomfort	3	0.1	(0.0, 0.4)
Injection site erythema	66	2.8	(2.1, 3.5)
Injection site haematoma	2	0.1	(0.0, 0.3)
Injection site haemorrhage	1	0.0	(0.0, 0.2)
Injection site hypersensitivity	1	0.0	(0.0, 0.2)
Injection site hypoaesthesia	2	0.1	(0.0, 0.3)
Injection site induration	1	0.0	(0.0, 0.2)

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site irritation	1	0.0	(0.0, 0.2)
Injection site lymphadenopathy	1	0.0	(0.0, 0.2)
Injection site mass	1	0.0	(0.0, 0.2)
Injection site nodule	2	0.1	(0.0, 0.3)
Injection site oedema	2	0.1	(0.0, 0.3)
Injection site pain	2944	123.8	(119.3, 128.3)
Injection site pruritus	18	0.8	(0.4, 1.2)
Injection site rash	4	0.2	(0.0, 0.4)
Injection site reaction	2	0.1	(0.0, 0.3)
Injection site swelling	65	2.7	(2.1, 3.5)
Injection site urticaria	1	0.0	(0.0, 0.2)
Injection site warmth	3	0.1	(0.0, 0.4)
Malaise	83	3.5	(2.8, 4.3)
Non-cardiac chest pain	1	0.0	(0.0, 0.2)
Oedema peripheral	2	0.1	(0.0, 0.3)
Pain	394	16.6	(15.0, 18.3)
Pelvic mass	1	0.0	(0.0, 0.2)
Peripheral swelling	7	0.3	(0.1, 0.6)
Pyrexia	906	38.1	(35.6, 40.6)
Swelling	3	0.1	(0.0, 0.4)
Swelling face	4	0.2	(0.0, 0.4)
Vaccination site pain	3	0.1	(0.0, 0.4)
Vaccination site reaction	1	0.0	(0.0, 0.2)
Vessel puncture site haematoma	1	0.0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	3	0.1	(0.0, 0.4)
Cholecystitis	1	0.0	(0.0, 0.2)
Cholelithiasis	1	0.0	(0.0, 0.2)
Hepatitis acute	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	7	0.3	(0.1, 0.6)
Allergy to vaccine	1	0.0	(0.0, 0.2)
Anaphylactoid reaction	1	0.0	(0.0, 0.2)
Hypersensitivity	1	0.0	(0.0, 0.2)

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Seasonal allergy	4	0.2	(0.0, 0.4)
INFECTIONS AND INFESTATIONS	136	5.7	(4.8, 6.8)
Abscess	1	0.0	(0.0, 0.2)
Appendicitis perforated	1	0.0	(0.0, 0.2)
Asymptomatic bacteriuria	1	0.0	(0.0, 0.2)
COVID-19 pneumonia	1	0.0	(0.0, 0.2)
Candida infection	1	0.0	(0.0, 0.2)
Cellulitis	3	0.1	(0.0, 0.4)
Chlamydial infection	1	0.0	(0.0, 0.2)
Clostridium difficile infection	1	0.0	(0.0, 0.2)
Conjunctivitis	6	0.3	(0.1, 0.5)
Cystitis	1	0.0	(0.0, 0.2)
Demodicidosis	1	0.0	(0.0, 0.2)
Diverticulitis	2	0.1	(0.0, 0.3)
Ear infection	8	0.3	(0.1, 0.7)
Eye infection	1	0.0	(0.0, 0.2)
Focal peritonitis	1	0.0	(0.0, 0.2)
Folliculitis	1	0.0	(0.0, 0.2)
Fungal skin infection	3	0.1	(0.0, 0.4)
Genital herpes	1	0.0	(0.0, 0.2)
Genital herpes simplex	2	0.1	(0.0, 0.3)
Helicobacter gastritis	1	0.0	(0.0, 0.2)
Herpes simplex	2	0.1	(0.0, 0.3)
Herpes zoster	8	0.3	(0.1, 0.7)
Hordeolum	2	0.1	(0.0, 0.3)
Infected cyst	1	0.0	(0.0, 0.2)
Infection	1	0.0	(0.0, 0.2)
Labyrinthitis	1	0.0	(0.0, 0.2)
Localised infection	2	0.1	(0.0, 0.3)
Mastitis	1	0.0	(0.0, 0.2)
Onychomycosis	1	0.0	(0.0, 0.2)
Oral candidiasis	1	0.0	(0.0, 0.2)

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Oral herpes	3	0.1	(0.0, 0.4)
Osteomyelitis	1	0.0	(0.0, 0.2)
Otitis externa	2	0.1	(0.0, 0.3)
Otitis media	2	0.1	(0.0, 0.3)
Pelvic abscess	1	0.0	(0.0, 0.2)
Pneumonia	2	0.1	(0.0, 0.3)
Postoperative wound infection	1	0.0	(0.0, 0.2)
Rhinitis	2	0.1	(0.0, 0.3)
Sinusitis	7	0.3	(0.1, 0.6)
Subcutaneous abscess	2	0.1	(0.0, 0.3)
Suspected COVID-19	1	0.0	(0.0, 0.2)
Taeniasis	1	0.0	(0.0, 0.2)
Tinea infection	1	0.0	(0.0, 0.2)
Tinea pedis	2	0.1	(0.0, 0.3)
Tonsillitis	2	0.1	(0.0, 0.3)
Tooth abscess	4	0.2	(0.0, 0.4)
Tooth infection	12	0.5	(0.3, 0.9)
Urinary tract infection	30	1.3	(0.9, 1.8)
Urosepsis	1	0.0	(0.0, 0.2)
Vulvitis	1	0.0	(0.0, 0.2)
Vulvovaginal candidiasis	3	0.1	(0.0, 0.4)
Vulvovaginal mycotic infection	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	90	3.8	(3.0, 4.7)
Animal bite	1	0.0	(0.0, 0.2)
Ankle fracture	2	0.1	(0.0, 0.3)
Arthropod bite	3	0.1	(0.0, 0.4)
Chest injury	1	0.0	(0.0, 0.2)
Contusion	9	0.4	(0.2, 0.7)
Corneal abrasion	1	0.0	(0.0, 0.2)
Exposure during pregnancy	5	0.2	(0.1, 0.5)
Eye contusion	1	0.0	(0.0, 0.2)
Facial bones fracture	1	0.0	(0.0, 0.2)

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Fall	20	0.8	(0.5, 1.3)
Fibula fracture	2	0.1	(0.0, 0.3)
Foot fracture	4	0.2	(0.0, 0.4)
Frostbite	1	0.0	(0.0, 0.2)
Hand fracture	3	0.1	(0.0, 0.4)
Head injury	1	0.0	(0.0, 0.2)
Injection related reaction	1	0.0	(0.0, 0.2)
Joint dislocation	1	0.0	(0.0, 0.2)
Ligament injury	1	0.0	(0.0, 0.2)
Ligament sprain	6	0.3	(0.1, 0.5)
Limb injury	4	0.2	(0.0, 0.4)
Lip injury	1	0.0	(0.0, 0.2)
Lower limb fracture	1	0.0	(0.0, 0.2)
Maternal exposure during pregnancy	3	0.1	(0.0, 0.4)
Meniscus injury	1	0.0	(0.0, 0.2)
Muscle rupture	1	0.0	(0.0, 0.2)
Muscle strain	2	0.1	(0.0, 0.3)
Postoperative ileus	1	0.0	(0.0, 0.2)
Procedural pain	6	0.3	(0.1, 0.5)
Radius fracture	1	0.0	(0.0, 0.2)
Road traffic accident	2	0.1	(0.0, 0.3)
Scapula fracture	1	0.0	(0.0, 0.2)
Seroma	1	0.0	(0.0, 0.2)
Skin abrasion	2	0.1	(0.0, 0.3)
Skin laceration	10	0.4	(0.2, 0.8)
Spinal fracture	1	0.0	(0.0, 0.2)
Subdural haematoma	1	0.0	(0.0, 0.2)
Tendon injury	1	0.0	(0.0, 0.2)
Tendon rupture	1	0.0	(0.0, 0.2)
Thermal burn	2	0.1	(0.0, 0.3)
Tooth fracture	6	0.3	(0.1, 0.5)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.2)
Upper limb fracture	2	0.1	(0.0, 0.3)

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Wound	1	0.0	(0.0, 0.2)
Wrist fracture	1	0.0	(0.0, 0.2)
INVESTIGATIONS	107	4.5	(3.7, 5.4)
Alanine aminotransferase increased	2	0.1	(0.0, 0.3)
Antinuclear antibody positive	1	0.0	(0.0, 0.2)
Aspartate aminotransferase increased	2	0.1	(0.0, 0.3)
Blood cholesterol increased	3	0.1	(0.0, 0.4)
Blood pressure increased	6	0.3	(0.1, 0.5)
Blood testosterone decreased	2	0.1	(0.0, 0.3)
Body temperature increased	91	3.8	(3.1, 4.7)
C-reactive protein increased	1	0.0	(0.0, 0.2)
Heart rate increased	1	0.0	(0.0, 0.2)
SARS-CoV-2 antibody test positive	1	0.0	(0.0, 0.2)
Troponin increased	1	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	29	1.2	(0.8, 1.8)
Decreased appetite	14	0.6	(0.3, 1.0)
Diabetes mellitus	1	0.0	(0.0, 0.2)
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.2)
Dyslipidaemia	2	0.1	(0.0, 0.3)
Glucose tolerance impaired	2	0.1	(0.0, 0.3)
Gout	1	0.0	(0.0, 0.2)
Hypercholesterolaemia	1	0.0	(0.0, 0.2)
Hyperglycaemia	2	0.1	(0.0, 0.3)
Insulin resistance	2	0.1	(0.0, 0.3)
Lactic acidosis	1	0.0	(0.0, 0.2)
Type 2 diabetes mellitus	2	0.1	(0.0, 0.3)
Vitamin D deficiency	1	0.0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1245	52.3	(49.5, 55.3)
Arthralgia	149	6.3	(5.3, 7.4)
Arthritis	3	0.1	(0.0, 0.4)
Back pain	32	1.3	(0.9, 1.9)
Bursitis	1	0.0	(0.0, 0.2)

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Flank pain	2	0.1	(0.0, 0.3)
Foot deformity	1	0.0	(0.0, 0.2)
Groin pain	1	0.0	(0.0, 0.2)
Intervertebral disc protrusion	2	0.1	(0.0, 0.3)
Joint range of motion decreased	2	0.1	(0.0, 0.3)
Joint swelling	1	0.0	(0.0, 0.2)
Limb discomfort	1	0.0	(0.0, 0.2)
Mobility decreased	1	0.0	(0.0, 0.2)
Muscle fatigue	2	0.1	(0.0, 0.3)
Muscle spasms	1	0.0	(0.0, 0.2)
Muscular weakness	4	0.2	(0.0, 0.4)
Musculoskeletal chest pain	1	0.0	(0.0, 0.2)
Musculoskeletal pain	1	0.0	(0.0, 0.2)
Musculoskeletal stiffness	12	0.5	(0.3, 0.9)
Myalgia	925	38.9	(36.4, 41.5)
Neck pain	11	0.5	(0.2, 0.8)
Osteoarthritis	9	0.4	(0.2, 0.7)
Osteoporosis	1	0.0	(0.0, 0.2)
Pain in extremity	154	6.5	(5.5, 7.6)
Periarthritis	1	0.0	(0.0, 0.2)
Plantar fasciitis	3	0.1	(0.0, 0.4)
Rheumatoid arthritis	1	0.0	(0.0, 0.2)
Rotator cuff syndrome	2	0.1	(0.0, 0.3)
Sacroiliitis	1	0.0	(0.0, 0.2)
Sjogren's syndrome	1	0.0	(0.0, 0.2)
Synovial cyst	1	0.0	(0.0, 0.2)
Temporomandibular joint syndrome	1	0.0	(0.0, 0.2)
Tendonitis	1	0.0	(0.0, 0.2)
Trigger finger	1	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	13	0.5	(0.3, 0.9)
Bladder neoplasm	1	0.0	(0.0, 0.2)
Bowen's disease	1	0.0	(0.0, 0.2)

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Brain neoplasm	1	0.0	(0.0, 0.2)
Breast cancer	1	0.0	(0.0, 0.2)
Breast cancer stage II	1	0.0	(0.0, 0.2)
Hepatic cancer	1	0.0	(0.0, 0.2)
Lipoma	1	0.0	(0.0, 0.2)
Meningioma	1	0.0	(0.0, 0.2)
Neoplasm	1	0.0	(0.0, 0.2)
Non-small cell lung cancer stage III	1	0.0	(0.0, 0.2)
Rectal cancer	1	0.0	(0.0, 0.2)
Seborrhoeic keratosis	1	0.0	(0.0, 0.2)
Skin papilloma	1	0.0	(0.0, 0.2)
Squamous cell carcinoma	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	1201	50.5	(47.7, 53.4)
Amnesia	1	0.0	(0.0, 0.2)
Arachnoid cyst	1	0.0	(0.0, 0.2)
Balance disorder	2	0.1	(0.0, 0.3)
Brachial plexopathy	1	0.0	(0.0, 0.2)
Carpal tunnel syndrome	1	0.0	(0.0, 0.2)
Cerebrovascular accident	4	0.2	(0.0, 0.4)
Cervical radiculopathy	1	0.0	(0.0, 0.2)
Cognitive disorder	1	0.0	(0.0, 0.2)
Disturbance in attention	4	0.2	(0.0, 0.4)
Dizziness	47	2.0	(1.5, 2.6)
Dysgeusia	2	0.1	(0.0, 0.3)
Encephalopathy	1	0.0	(0.0, 0.2)
Facial paralysis	3	0.1	(0.0, 0.4)
Head discomfort	1	0.0	(0.0, 0.2)
Headache	1108	46.6	(43.9, 49.4)
Hemiplegia	1	0.0	(0.0, 0.2)
Hyperaesthesia	2	0.1	(0.0, 0.3)
Hypoaesthesia	2	0.1	(0.0, 0.3)
Hypogeusia	1	0.0	(0.0, 0.2)

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Lethargy	9	0.4	(0.2, 0.7)
Loss of consciousness	1	0.0	(0.0, 0.2)
Mental impairment	2	0.1	(0.0, 0.3)
Migraine	6	0.3	(0.1, 0.5)
Migraine with aura	1	0.0	(0.0, 0.2)
Nerve compression	1	0.0	(0.0, 0.2)
Paraesthesia	14	0.6	(0.3, 1.0)
Parosmia	1	0.0	(0.0, 0.2)
Piriformis syndrome	1	0.0	(0.0, 0.2)
Presyncope	1	0.0	(0.0, 0.2)
Radiculopathy	1	0.0	(0.0, 0.2)
Sciatica	1	0.0	(0.0, 0.2)
Seizure	1	0.0	(0.0, 0.2)
Somnolence	13	0.5	(0.3, 0.9)
Speech disorder	1	0.0	(0.0, 0.2)
Syncope	4	0.2	(0.0, 0.4)
Transient ischaemic attack	2	0.1	(0.0, 0.3)
Tremor	2	0.1	(0.0, 0.3)
Visual field defect	1	0.0	(0.0, 0.2)
PSYCHIATRIC DISORDERS	43	1.8	(1.3, 2.4)
Abnormal dreams	1	0.0	(0.0, 0.2)
Alcohol withdrawal syndrome	1	0.0	(0.0, 0.2)
Anxiety	9	0.4	(0.2, 0.7)
Attention deficit hyperactivity disorder	3	0.1	(0.0, 0.4)
Bipolar disorder	1	0.0	(0.0, 0.2)
Completed suicide	1	0.0	(0.0, 0.2)
Confusional state	2	0.1	(0.0, 0.3)
Depression	3	0.1	(0.0, 0.4)
Generalised anxiety disorder	1	0.0	(0.0, 0.2)
Insomnia	12	0.5	(0.3, 0.9)
Irritability	2	0.1	(0.0, 0.3)
Major depression	1	0.0	(0.0, 0.2)

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Mental fatigue	1	0.0	(0.0, 0.2)
Mental status changes	1	0.0	(0.0, 0.2)
Restlessness	2	0.1	(0.0, 0.3)
Sleep disorder	2	0.1	(0.0, 0.3)
Suicidal ideation	1	0.0	(0.0, 0.2)
Suicide attempt	1	0.0	(0.0, 0.2)
Thinking abnormal	1	0.0	(0.0, 0.2)
RENAL AND URINARY DISORDERS	21	0.9	(0.5, 1.3)
Acute kidney injury	1	0.0	(0.0, 0.2)
Bladder neck obstruction	1	0.0	(0.0, 0.2)
Chronic kidney disease	1	0.0	(0.0, 0.2)
Dysuria	6	0.3	(0.1, 0.5)
Haematuria	1	0.0	(0.0, 0.2)
Hypertonic bladder	2	0.1	(0.0, 0.3)
Nephrolithiasis	4	0.2	(0.0, 0.4)
Pollakiuria	1	0.0	(0.0, 0.2)
Urinary bladder polyp	1	0.0	(0.0, 0.2)
Urinary hesitation	1	0.0	(0.0, 0.2)
Urinary retention	1	0.0	(0.0, 0.2)
Urinary tract obstruction	1	0.0	(0.0, 0.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	12	0.5	(0.3, 0.9)
Benign prostatic hyperplasia	3	0.1	(0.0, 0.4)
Breast cyst	1	0.0	(0.0, 0.2)
Breast discharge	1	0.0	(0.0, 0.2)
Endometriosis	1	0.0	(0.0, 0.2)
Metrorrhagia	2	0.1	(0.0, 0.3)
Ovarian cyst	1	0.0	(0.0, 0.2)
Pelvic pain	1	0.0	(0.0, 0.2)
Sexual dysfunction	1	0.0	(0.0, 0.2)
Testicular pain	1	0.0	(0.0, 0.2)
Uterine haemorrhage	1	0.0	(0.0, 0.2)
Vaginal lesion	1	0.0	(0.0, 0.2)

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	37	1.6	(1.1, 2.1)
Acute respiratory failure	2	0.1	(0.0, 0.3)
Asthma	1	0.0	(0.0, 0.2)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.2)
Cough	3	0.1	(0.0, 0.4)
Dyspnoea	2	0.1	(0.0, 0.3)
Epistaxis	3	0.1	(0.0, 0.4)
Immune-mediated pneumonitis	1	0.0	(0.0, 0.2)
Nasal congestion	5	0.2	(0.1, 0.5)
Nasal septum deviation	1	0.0	(0.0, 0.2)
Oropharyngeal pain	1	0.0	(0.0, 0.2)
Paranasal sinus discomfort	1	0.0	(0.0, 0.2)
Pleuritic pain	1	0.0	(0.0, 0.2)
Pulmonary embolism	4	0.2	(0.0, 0.4)
Rhinitis allergic	4	0.2	(0.0, 0.4)
Rhinorrhoea	6	0.3	(0.1, 0.5)
Sinus congestion	1	0.0	(0.0, 0.2)
Upper respiratory tract congestion	1	0.0	(0.0, 0.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	85	3.6	(2.9, 4.4)
Acne	1	0.0	(0.0, 0.2)
Actinic keratosis	3	0.1	(0.0, 0.4)
Alopecia	2	0.1	(0.0, 0.3)
Angioedema	1	0.0	(0.0, 0.2)
Cold sweat	1	0.0	(0.0, 0.2)
Dermatitis	2	0.1	(0.0, 0.3)
Dermatitis contact	6	0.3	(0.1, 0.5)
Dry skin	1	0.0	(0.0, 0.2)
Ecchymosis	3	0.1	(0.0, 0.4)
Erythema	2	0.1	(0.0, 0.3)
Erythema nodosum	1	0.0	(0.0, 0.2)
Hyperhidrosis	15	0.6	(0.4, 1.0)
Ingrowing nail	3	0.1	(0.0, 0.4)

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Lichen sclerosus	1	0.0	(0.0, 0.2)
Night sweats	7	0.3	(0.1, 0.6)
Petechiae	1	0.0	(0.0, 0.2)
Pruritus	6	0.3	(0.1, 0.5)
Rash	16	0.7	(0.4, 1.1)
Rash erythematous	2	0.1	(0.0, 0.3)
Rash pruritic	1	0.0	(0.0, 0.2)
Rash vesicular	1	0.0	(0.0, 0.2)
Skin lesion	4	0.2	(0.0, 0.4)
Skin ulcer	1	0.0	(0.0, 0.2)
Urticaria	7	0.3	(0.1, 0.6)
SURGICAL AND MEDICAL PROCEDURES	9	0.4	(0.2, 0.7)
Blepharoplasty	1	0.0	(0.0, 0.2)
Chondroplasty	1	0.0	(0.0, 0.2)
Finger repair operation	1	0.0	(0.0, 0.2)
Hysterectomy	2	0.1	(0.0, 0.3)
Injection	1	0.0	(0.0, 0.2)
Spinal fusion surgery	1	0.0	(0.0, 0.2)
Tooth extraction	2	0.1	(0.0, 0.3)
VASCULAR DISORDERS	45	1.9	(1.4, 2.5)
Aortic aneurysm	1	0.0	(0.0, 0.2)
Aortic arteriosclerosis	1	0.0	(0.0, 0.2)
Aortic stenosis	1	0.0	(0.0, 0.2)
Blood pressure fluctuation	1	0.0	(0.0, 0.2)
Deep vein thrombosis	3	0.1	(0.0, 0.4)
Flushing	5	0.2	(0.1, 0.5)
Haematoma	2	0.1	(0.0, 0.3)
Hot flush	2	0.1	(0.0, 0.3)
Hypertension	25	1.1	(0.7, 1.6)
Hypotension	1	0.0	(0.0, 0.2)
Peripheral coldness	1	0.0	(0.0, 0.2)
Thrombosis	1	0.0	(0.0, 0.2)

Table 37. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Venous thrombosis limb	1	0.0	(0.0, 0.2)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (17:36)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 exp age p3x saf

12.2.3.5.2.2. Related Adverse Events by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2

From vaccination with BNT162b2 to the data cutoff date for placebo participants, the IR of AEs assessed as related by the investigator during the open-label follow-up period was 189.5 per 100 PY (Table 36). The IRs of related AEs were highest for reactogenicity events and in the SOC of general disorders and administration site conditions (4147 [174.3 per 100 PY]) for the following PTs (Supplemental Table 14.158):

- injection site pain (2938 [123.5 per 100 PY])
- pyrexia (905 [38.0 per 100 PY])
- fatigue (1373 [57.7 per 100 PY])
- chills (993 [41.7 per 100 PY])

12.2.3.5.2.3. Immediate Adverse Events – Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2

After vaccination with BNT162b2 (Dose 3/4), placebo participants who received BNT162b2 with immediate AEs were low in frequency (0.6%). Most immediate AEs after BNT162b2 doses were in the SOC of general disorders and administration site conditions, primarily injection site reactions, with injection site pain (0.4%) most frequently reported (Supplemental Table 14.159).

Other immediate AEs were reported in the following participants, and were assessed by the investigator as related to study intervention (Appendix 16.2.7.4.1):

- One participant in the younger age group reported 2 immediate AEs of oedema mouth and tongue edema (both mild in severity) after Dose 4; both AEs were assessed by the investigator as related to study intervention. The AE of tongue oedema resolved the same day and the AE of oedema mouth resolved the following day.

- One participant in the younger age group reported an immediate AE of hypoaesthesia oral (mild) after Dose 3 and resolved the same day.

- One participant in the younger age group reported 3 immediate AEs of swelling face, allergy to vaccine, and flushing after Dose 3, which were all were moderate in severity. All 3 AEs resolved the following day. The participant also reported nausea and urticaria (hives abdomen) (both mild in severity) on the same day but were not immediate. The AE of nausea resolved the same day and the AE of urticaria resolved the following day. These 2 AEs were also assessed by the investigator as related to study intervention.

- One participant in the older age group reported an immediate AE of urticaria (hive on back of neck; moderate in severity) after Dose 4 and is ongoing at the time of the data cutoff date.

12.2.3.5.2.4. Severe or Life-Threatening Adverse Events – Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2

Severe Adverse Events

From Dose 3 (first Dose of BNT162b2) to the data cutoff date, the severe AE IR was 6.0 per 100 PY in original placebo participants (Supplemental Table 14.160). Severe AEs included (Appendix 16.2.7.4.1):

- One participant in the younger age group reported a severe AE of hypersensitivity on 13 days after Dose 3, which resolved the following day and was assessed by the investigator as not related to study intervention.

- One participant in the older age group reported a severe SAE of COVID-19 pneumonia 8 days after Dose 3, which resolved 4 days later and was assessed by the investigator as not related to study intervention.

- One participant in the older age group reported a severe SAE of cerebrovascular accident 16 days after Dose 4, which was assessed by the investigator as not related to study intervention and ongoing at the time of the data cutoff date.

- One participant in the younger age group reported a severe SAE of pulmonary embolism 5 days after Dose 4, which resolved the following day and was assessed by the investigator as not related to study intervention.

- One participant in the older age group reported 1 severe SAE each of pulmonary embolism and thrombosis (occlusive thrombus in the right calf) 2 days after Dose 3. Both events resolved the following day, and both were assessed by the investigator as not related to study intervention.

- One participant in the younger age group reported 2 AEs of urticaria (moderate and severe) at 3 and 4 days after Dose 3, respectively. The moderate AE of urticaria (intermittent generalized) resolved the same day. The severe AE of urticaria (left arm) resolved 8 days later. Both events were assessed by the investigator as related to study intervention.

Life-Threatening Adverse Events

The IR for original placebo participants who had at least 1 life-threatening AE from Dose 3 to the data cutoff date was 0.5 per 100 PY (Supplemental Table 14.161). The following life-threatening events were reported and with the exception of anaphylactoid reaction, all were considered unrelated to vaccine as assessed by the investigator (Appendix 16.2.7.4.1).

- A Grade 4 life-threatening SAE of cardio-respiratory arrest was reported in one participant in the older age group. The event occurred 25 days after Dose 3 and the outcome was fatal.

- One participant in the younger age group had a Grade 4 life-threatening SAE of gastrointestinal necrosis 29 days after Dose 4. The outcome was not recovered/not resolved at the time of this report.

- One participant in the younger age group had a Grade 4 life-threatening SAE of pulmonary embolism and a Grade 4 life-threatening SAE of deep vein thrombosis. Both events of pulmonary embolism and deep vein thrombosis occurred 11 days after Dose 4 and the outcome for both events was recovering/resolving.

- A Grade 4 life-threatening SAE of anaphylactoid reaction was reported in one participant in the younger age group 2 days after Dose 3. The outcome was recovered/resolved and the event was considered related to vaccine. This participant is also discussed under Section 12.2.4.4.1.1.

12.2.3.6. Open-Label Follow-Up Period – Original Placebo Participants, had COVID-19 Occurrence After Dose 1, and Then Received BNT162b2

12.2.3.6.1. Summary of Adverse Events – Original Placebo Participants, had COVID-19 Occurrence After Dose 1, and Then Received BNT162b2

There were 853 original placebo participants who developed COVID-19 and subsequently were vaccinated with BNT162b2 (Supplemental Table 14.162). For original placebo participants who had COVID-19 occurrence after Dose 1 and then received BNT162b2, IRs for any AE and at least 1 related AE from Dose 3 (first dose of BNT162b2 30 µg) were 256.8 per 100 PY and 240.9 per 100 PY, respectively (Supplemental Table 14.162). IRs of severe AEs, SAEs, and AEs leading to withdrawal were 4.6 per 100 PY, 3.4 per 100 PY, and 3.4 per 100 PY. The IR for discontinuations because of related AEs was 3.4 per 100 PY, and no participants died.

IRs for SAEs were similar for the placebo participants who developed COVID-19 and subsequently were vaccinated with BNT162b2 (3.4 per 100 PY; 95% CI: 0.7, 10.0) and participants originally randomized to BNT162b2 (3.2 per 100 PY; 95% CI: 2.8, 3.6) (Table 31), respectively. None of the SAEs in the original placebo participants who developed COVID-19 and subsequently were vaccinated with BNT162b2 were related to BNT162b2 (Supplemental Table 14.162). There were 3 participants with AEs leading to withdrawal that were assessed as related to BNT162b2: 1 participant with an AE of allergy to vaccine, 1 participant with an AE of pain, and 1 participant with 5 AEs (chills, injection site pain, myalgia, headache, and diarrhea) (Appendix 16.2.7.4.1 and Appendix 16.2.8.1). No deaths were reported in placebo participants who developed COVID-19 and subsequently were vaccinated with BNT162b2.

While the exposure time between the placebo participants who developed COVID-19 and subsequently were vaccinated with BNT162b2 is small (0.9) (Supplemental Table 14.162) compared to the exposure time for the blinded placebo-controlled period (83.4) (Table 31), direct comparisons must be interpreted with caution; the rate of SAE were similar between the groups (3.4 per 100 PY vs 3.2 per 100 PY, respectively).

12.2.3.6.2. Analysis of Adverse Events – Original Placebo Participants, had COVID-19 Occurrence After Dose 1, and Then Received BNT162b2

For original placebo participants who had COVID-19 occurrence after Dose 1 and then received BNT162b2, the IR for at least 1 AE was 256.8 per 100 PY (Supplemental Table 14.163).

Most AEs reported from Dose 3 (the first dose of BNT162b2) to the data cutoff date were in SOCs with reactogenicity events.

- general disorders and administration site conditions (236.3 per 100 PY)
- musculoskeletal and connective tissue disorders (47.9 per 100 PY)
- nervous system disorders (66.2 per 100 PY)
- gastrointestinal disorders (17.1 per 100 PY).

12.2.4. Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events – Phase 2/3 Participants ≥16 Years of Age

12.2.4.1. Deaths

There were 15 deaths in the BNT162b2 group and 14 deaths in the placebo group from Dose 1 to the unblinding date during the blinded placebo-controlled follow-up period (Table 38). None of these deaths were assessed by the investigator as related to study intervention (Appendix 16.2.7.6).

Table 38. Incidence Rates of Deaths From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Deaths	15	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.3)
Cause of death[f]						
Acute respiratory failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Aortic rupture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Arteriosclerosis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary cancer metastatic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac arrest	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardio-respiratory arrest	1	0.0	(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	(0.0, 0.0)
Death	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dementia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Emphysematous cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haemorrhagic stroke	0	0.0	(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, 0.0)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to liver	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Missing	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Myocardial infarction	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Overdose	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pneumonia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)

Table 38. Incidence Rates of Deaths From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Septic shock	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Shigella sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Unevaluable event	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified cause of death.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Multiple causes of death can be reported for each subject.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: dd Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/addd s001 p3 saf

From the unblinding date to the data cutoff date of the open-label follow-up period, there were 3 deaths in original BNT162b2 participants (all in the older age group, one each due to road traffic accident, lung metastases, and myocardial infarction) (Appendix 16.2.7.7) and 2 deaths in original placebo participants who then received BNT162b2 (all in the older age group, one each due to cardiorespiratory arrest or completed suicide) (Appendix 16.2.7.5 and Appendix 16.2.7.7). None of these deaths were assessed by the investigator as related to study intervention (Appendix 16.2.7.6).

Among participants with confirmed stable HIV disease, 2 deaths were reported as of the cutoff date, and none of these deaths were assessed by the investigator as related to study intervention (Appendix 16.2.7.6):

- One female participant in the younger age group died due to COVID-19 pneumonia reported 75 days after receiving Dose 2 of placebo. This participant was diagnosed based on a local COVID-19 test that could not be confirmed as protocol-approved and was not confirmed by a test result from the central laboratory. Therefore, this participant was not included in efficacy analyses.

- One female participant in the older age group died due to a road traffic accident occurring 73 days after receiving Dose 2 (Appendix 16.2.7.7).

12.2.4.1.1. Death Narratives

Narratives for the participants who died through the data cutoff date (13 March 2021) are provided in Section 14.

12.2.4.2. Serious Adverse Events

12.2.4.2.1. Blinded Placebo-Controlled Follow-Up From Dose 1 to 1 Month After Dose 2

From Dose 1 to 1 month after Dose 2 the proportions of participants who reported at least 1 SAE was similar in the BNT162b2 group (0.6%) and in the placebo group (0.5%) (Table 39). The numbers of participants who reported at least 1 SAE were lower in the younger age group (52 [0.4%] and 49 [0.4%] for the BNT162b2 and placebo groups, respectively) than in the older age group (75 [0.8%] and 67 [0.8%] for the BNT162b2 and placebo groups, respectively) (Supplemental Tables 14.164 and 14.165, respectively).

Three of the SAEs in the BNT162b2 group and none in the placebo group were assessed by the investigator as related to study intervention (Table 29).

In the BNT162b2 group, there were 2 participants in the younger age group (previously reported in the final analysis interim C4591001 CSR dated 03 December 2020) and 1 participant in the older age group with an SAE each assessed by the investigator as related to study intervention (Appendix 16.2.7.5):

- One participant in the younger age group had an SAE of lymphadenopathy (right axilla) 13 days after Dose 1 which lasted 66 days and resolved. The participant was a 48-year-old woman with a relevant medical history of eczema and topical crisaborole use who was administered BNT162b2 vaccine in the left deltoid and had right axillary pain and lymphadenopathy. She had no injuries to the right arm, no fever, and no history of a similar incident. Her WBC was normal with a normal lymphocyte count and a right axilla ultrasound showed 4 enlarged lymph nodes (largest 2.5 × 1.1 × 2.4 cm). A biopsy was performed and was reported to be normal and without markers for lymphoma or other cancer. A follow-up visit with oncology (and possible repeat ultrasound) was planned for 3 months' time.

- One participant in the younger age group had an SAE of shoulder injury related to vaccine administration (SIRVA, erroneously administered into or near the shoulder joint capsule) after Dose 2, which lasted 153 days and resolved.

- One participant in the older age group with a past medical history significant for AV block with pacemaker, sinus node dysfunction, atrial fibrillation, and supraventricular tachycardia had an SAE of ventricular arrhythmia that occurred 1 day after Dose 2 and lasted for 8 days and resolved.

Table 39. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	127 (0.6)	(0.5, 0.7)	116 (0.5)	(0.4, 0.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	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)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	20 (0.1)	(0.1, 0.1)	21 (0.1)	(0.1, 0.1)
Atrial fibrillation	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Acute myocardial infarction	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Coronary artery disease	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac arrest	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure congestive	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)	0	(0.0, 0.0)
Angina pectoris	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)
Arrhythmia supraventricular	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)
Cardiac failure acute	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)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Junctional ectopic tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial ischaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	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)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Congenital bladder neck obstruction	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)

Table 39. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
EAR AND LABYRINTH DISORDERS	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	9 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal adhesions	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	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)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal mucosa hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Incarcerated inguinal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal varices haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Umbilical hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Volvulus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 39. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	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	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Cholecystitis acute	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cholelithiasis	3 (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)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (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)
Anaphylactic shock	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	27 (0.1)	(0.1, 0.2)	21 (0.1)	(0.1, 0.1)
Appendicitis	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Pneumonia	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Cellulitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Urinary tract infection	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diverticulitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonsillar abscess	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	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (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)
Anal abscess	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)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 39. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
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)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shigella sepsis	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)
Subacute endocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subcutaneous 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)
Upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	8 (0.0)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Overdose	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial bones fracture	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Road traffic accident	1 (0.0)	(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)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon 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)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head injury	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)
Humerus fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal column injury	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)
Subdural haematoma	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)

Table 39. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Traumatic haemothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	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	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blood glucose abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Osteoarthritis	2 (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)
Back pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscular weakness	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)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	13 (0.1)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Prostate cancer	2 (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	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	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)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	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 ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 39. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Leydig cell tumour of the testis	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)
Metastases to liver	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatic carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile neoplasm	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)
Thyroid cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	14 (0.1)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Subarachnoid haemorrhage	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Cerebrovascular accident	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient ischaemic attack	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amyotrophic lateral sclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervicogenic headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord compression	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	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abortion spontaneous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

Table 39. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute kidney injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	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 bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(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)
Ovarian cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian mass	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	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Acute respiratory failure	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Deep vein thrombosis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypertension	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

Table 39. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
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)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive crisis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_ser_all_pd2_p3_saf

12.2.4.2.1.1. Participants with Confirmed Stable HIV Disease

No participants with confirmed stable HIV disease reported an SAE from Dose 1 to 1 month after Dose 2.

12.2.4.2.2. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date

From Dose 1 to the unblinding date, IRs of at least 1 SAE were similar in the BNT162b2 group (3.2 per 100 PY) and in the placebo group (3.3 per 100 PY) (Supplemental Table 14.166). The IR was lower in the younger age groups (2.1 per 100 PY and 2.4 per 100 PY for the BNT162b2 and placebo groups, respectively) than in the older age groups (4.9 per 100 PY and 4.6 per 100 PY for the BNT162b2 and placebo groups respectively) (Supplemental Tables 14.167 and 14.168, respectively).

Four of the SAEs in the BNT162b2 group and 1 in the placebo group were assessed by the investigator as related to study intervention. In addition to the 3 related SAEs in the BNT162b2 group described in Section 12.2.4.2.1, there were 2 related SAEs that occurred to the unblinding date (Appendix 16.2.7.5):

- One participant in the BNT162b2 younger age group with a medical history significant for occipital neuralgia and migraines (Appendix 16.2.5.4) had an SAE of paraesthesia (right leg) 47 days after Dose 2 which was recovering/resolving at the data cutoff date.

- One participant in the placebo younger age group had an SAE of psoriatic arthropathy 38 days after Dose 2 which was continuing at the data cutoff date.

Subgroup Analyses

Overall, no clinically meaningful differences in IRs of SAEs were observed by baseline SARS-CoV-2 status, ethnicity, race, or sex subgroups:

IRs of SAEs were similar by baseline SARS-CoV-2 status in the BNT162b2 and placebo groups for baseline positive (4.0 per 100 PY [95% CI: 1.9, 7.3] and 1.9 per 100 PY [95% CI: 0.6, 4.4]) and baseline negative (3.2 per 100 PY [95% CI: 2.8, 3.6] and 3.3 per 100 PY [95% CI: 2.9, 3.7]) participants (Supplemental Tables 14.169 and 14.170, respectively). IRs of SAEs in the baseline positive BNT162b2 group were similar (4.0 per 100 PY [95% CI: 1.9, 7.3]) to those in the baseline negative BNT162b2 group (3.2 per 100 PY [95% CI: 2.8, 3.6]) (Supplemental Tables 14.169 and 14.170, respectively), and similar to what was observed in the overall SAE analysis irrespective of baseline status (Table 31).

While there are differences in exposure (2.5 vs 80.4) by baseline SARS-CoV-2 positive and negative status, respectively, IRs were numerically low or similar by baseline SARS-CoV-2 status, so there is no evidence that individuals who are positive at baseline report AEs at a higher frequency than those who are negative at baseline (Supplemental Tables 14.122 and 14.123, respectively).

IRs of SAEs were similar in the BNT162b2 and placebo groups for Hispanic/Latino (3.5 per 100 PY [95% CI: 2.8, 4.3] and 3.6 per 100 PY [95% CI: 2.9, 4.5]), Non-Hispanic/Non-Latino (3.1 per 100 PY [95% CI: 2.7, 3.6] for each), and Not Reported (2.4 per 100 PY [95% CI: 0.1, 13.1] and 2.3 per 100 PY [95% CI: 0.1, 12.7]) participants (Supplemental Tables 14.171, 14.172, and 14.173, respectively).

IRs of SAEs were similar in the BNT162b2 and placebo groups for White (3.3 per 100 PY [95%CI: 2.9, 3.8]and 3.5 per 100 PY [95% CI: 3.1, 4.0]), Black or African American (2.5 per 100 PY [95% CI: 1.6, 3.9] and 2.6 per 100 PY [95% CI: 1.6, 4.0]), and greater in the BNT162b2 group for All Others compared to placebo (2.7 per 100 PY [95% CI: 1.6, 4.3] and 1.4 per 100 PY [95% CI: 0.6, 2.7]) (Supplemental Tables 14.174, 14.175, and 14.176, respectively).

IRs of SAEs were similar by sex in the BNT162b2 and placebo groups for males (3.5 per 100 PY[95% CI: 3.0, 4.1] and 3.4 per 100 PY [95% CI: 2.8, 4.0]) and females (2.9 per 100 PY [95% CI: 2.4, 3.5] and 3.2 per 100 PY [95% CI: 2.6, 3.7]) (Supplemental Tables 14.177 and 14.178, respectively).

12.2.4.2.2.1. Participants with Confirmed Stable HIV Disease

From Dose 1 to the unblinding date, IRs of at least 1 SAE in participants with stable HIV disease were similar in the BNT162b2 group (6.6 per 100 PY [95% CI: 0.8, 23.9]) and the placebo group (6.9 per 100 PY [95% CI: 0.8, 25.1]) with 2 participants reporting at least 1 SAE in each group (Supplemental Table 14.179). None of the SAEs were assessed by the investigator as related to study intervention (Appendix 16.2.7.5).

- One older participant in the BNT162b2 group had an SAE of pneumonia 86 days after Dose 2 which lasted 8 days and resolved.

- One older participant in the BNT162b2 group had a fatal SAE of road traffic accident 73 days after Dose 2.

- One younger participant in the placebo group had an SAE of breast cancer 71 days after Dose 2 that was continuing at the data cutoff date.

- One younger participant in the placebo group had an SAE of diabetes mellitus 68 days after Dose 2, and COVID-19 pneumonia 72 days after Dose 2 which lasted 4 days and resulted in death (see Section 12.2.4.1). The participant had a history of asthma, HIV, hypertension, and obesity and then was diagnosed with diabetes mellitus 68 days after Dose 2. Four days after the diagnosis, the participant presented in the ER with an elevated blood glucose level and was admitted. Laboratory tests on the following day included a SARS-CoV-2 PCR test, which was positive. Two days later, a second test confirmed the COVID-19 positive diagnosis. The following day, 75 days after Dose 2, the participant died due to disease progression and COVID-19 pneumonia. The investigator concluded that the diabetes mellitus and COVID-19 pneumonia were not related to study intervention. This participant was diagnosed based on a local COVID-19 test that could not be confirmed as protocol-approved and was not confirmed by a test result from the central laboratory. Therefore, this participant was not included in efficacy analyses.

12.2.4.2.3. Open-Label Follow-Up Period – Original BNT162b2 Participants

From unblinding date to the data cutoff date, the IR of at least 1 SAE was 2.0 per 100 PY (95% CI: 1.5, 2.6) in original BNT162b2 participants (Supplemental Table 14.180).

One younger participant with no past medical history had a life-threatening SAE of myocardial infarction 71 days after Dose 2 that was assessed by the investigator as related to study intervention, which lasted 1 day and resolved the same day (Appendix 16.2.7.5).

12.2.4.2.4. Blinded Placebo-Controlled and Open-Label Follow-Up Periods to 6 Months After Dose 2 – Original BNT162b2 Participants

From Dose 1 to 6 months after Dose 2, during the blinded and open-label follow-up periods, 190 (1.6%) participants in the BNT162b2 group reported at least 1 SAE (Table 40).

Two of the SAEs in the BNT162b2 group (SIRVA and paraesthesia, see Section 12.2.4.2.1 and Section 12.2.4.2.2) were assessed by the investigator as related to study intervention (Table 33).

The number of participants who reported at least 1 SAE was 73 (1.1%) and 117 (2.2%) in the younger and older age groups, respectively (Supplemental Tables 14.181 and 14.182, respectively).

Comparison of SAEs reported from Dose 1 to 1 month after Dose 2 to SAEs reported from 1 month after Dose 2 to 6 months after Dose 2 shows that the frequency of SAEs increased from 0.5% to 1.1%, respectively (Supplemental Table 14.183). The following SOCs had the largest increase in SAEs (Dose 1 to 1 month after Dose 2 vs 1 month after Dose 2 to 6 months after Dose 2):

- Neoplasms, benign, malignant, and unspecified (including cysts and polyps): 4 (0.0%) vs 21 (0.2%)
- Injury, poisoning, and procedural complications: 2 (0.0%) vs 14 (0.1%)
- Infections and infestations: 14 (0.1%) vs 22 (0.2%)
- Gastrointestinal disorders: 4 (0.0%) vs 10 (0.1%)
- Respiratory, thoracic, and mediastinal disorders: 2 (0.0%) vs 8 (0.1%)
- Hepatobiliary disorders: 3 (0.0%) vs 8 (0.1%)

Table 40. 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 – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12006) n[b] (%)	(95% CI[c])
Any event	190 (1.6)	(1.4, 1.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)
Pancytopenia	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	27 (0.2)	(0.1, 0.3)
Acute myocardial infarction	4 (0.0)	(0.0, 0.1)
Atrial fibrillation	4 (0.0)	(0.0, 0.1)
Myocardial infarction	4 (0.0)	(0.0, 0.1)
Angina pectoris	3 (0.0)	(0.0, 0.1)
Angina unstable	2 (0.0)	(0.0, 0.1)

Table 40. 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 – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Cardiac failure congestive	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)
Atrial flutter	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)
Cardiac arrest	1 (0.0)	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)
Coronary artery occlusion	1 (0.0)	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.0)
Ventricular tachycardia	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	4 (0.0)	(0.0, 0.1)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)
Ophthalmic vein thrombosis	1 (0.0)	(0.0, 0.0)
Retinal tear	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	14 (0.1)	(0.1, 0.2)
Colitis	2 (0.0)	(0.0, 0.1)
Gastritis	2 (0.0)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)
Food poisoning	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)
Haematemesis	1 (0.0)	(0.0, 0.0)
Haemorrhoids	1 (0.0)	(0.0, 0.0)
Impaired gastric emptying	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	7 (0.1)	(0.0, 0.1)

Table 40. 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 – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Chest pain	2 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)
Asthenia	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	11 (0.1)	(0.0, 0.2)
Cholecystitis acute	3 (0.0)	(0.0, 0.1)
Cholelithiasis	3 (0.0)	(0.0, 0.1)
Bile duct stone	2 (0.0)	(0.0, 0.1)
Biliary colic	2 (0.0)	(0.0, 0.1)
Cholecystitis	1 (0.0)	(0.0, 0.0)
Cholelithiasis obstructive	1 (0.0)	(0.0, 0.0)
Portosplenomesenteric venous thrombosis	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	36 (0.3)	(0.2, 0.4)
Appendicitis	10 (0.1)	(0.0, 0.2)
Diverticulitis	3 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)
Pyelonephritis	2 (0.0)	(0.0, 0.1)
Abscess	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)
Arthritis bacterial	1 (0.0)	(0.0, 0.0)
Bacteraemia	1 (0.0)	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)
Clostridium difficile colitis	1 (0.0)	(0.0, 0.0)
Device related infection	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)
Endocarditis	1 (0.0)	(0.0, 0.0)

Table 40. 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 – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)
Gangrene	1 (0.0)	(0.0, 0.0)
Gastroenteritis	1 (0.0)	(0.0, 0.0)
Herpes zoster oticus	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	1 (0.0)	(0.0, 0.0)
Penile infection	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)
Peritonitis	1 (0.0)	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)
Postoperative abscess	1 (0.0)	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.0)
Urinary tract infection	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	16 (0.1)	(0.1, 0.2)
Ankle fracture	2 (0.0)	(0.0, 0.1)
Road traffic accident	2 (0.0)	(0.0, 0.1)
Wrist fracture	2 (0.0)	(0.0, 0.1)
Burns second degree	1 (0.0)	(0.0, 0.0)
Burns third degree	1 (0.0)	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	1 (0.0)	(0.0, 0.0)
Facial bones fracture	1 (0.0)	(0.0, 0.0)
Fall	1 (0.0)	(0.0, 0.0)
Head injury	1 (0.0)	(0.0, 0.0)
Humerus fracture	1 (0.0)	(0.0, 0.0)
Patella fracture	1 (0.0)	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.0)
Procedural dizziness	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)
Tibia fracture	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)
Upper limb fracture	1 (0.0)	(0.0, 0.0)

Table 40. 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 – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
INVESTIGATIONS	1 (0.0)	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	3 (0.0)	(0.0, 0.1)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)
Hypoglycaemia	1 (0.0)	(0.0, 0.0)
Hypokalaemia	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	9 (0.1)	(0.0, 0.1)
Osteoarthritis	4 (0.0)	(0.0, 0.1)
Arthritis	1 (0.0)	(0.0, 0.0)
Intervertebral disc compression	1 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	25 (0.2)	(0.1, 0.3)
Breast cancer	2 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	2 (0.0)	(0.0, 0.1)
Prostate cancer	2 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)
Benign hydatidiform mole	1 (0.0)	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.0)
Brain cancer metastatic	1 (0.0)	(0.0, 0.0)
Breast cancer in situ	1 (0.0)	(0.0, 0.0)
Carcinoid tumour of the stomach	1 (0.0)	(0.0, 0.0)
Colon adenoma	1 (0.0)	(0.0, 0.0)
Gallbladder cancer stage II	1 (0.0)	(0.0, 0.0)
Gastric cancer	1 (0.0)	(0.0, 0.0)
Malignant melanoma	1 (0.0)	(0.0, 0.0)

Table 40. 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 – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Non-small cell lung cancer stage IV	1 (0.0)	(0.0, 0.0)
Skin cancer	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.0)
Thyroid cancer	1 (0.0)	(0.0, 0.0)
Transitional cell carcinoma	1 (0.0)	(0.0, 0.0)
Uterine cancer	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	23 (0.2)	(0.1, 0.3)
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)
Dizziness	2 (0.0)	(0.0, 0.1)
Optic neuritis	2 (0.0)	(0.0, 0.1)
Syncope	2 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)
Intracranial aneurysm	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)
Paraesthesia	1 (0.0)	(0.0, 0.0)
Peripheral nerve lesion	1 (0.0)	(0.0, 0.0)
Seizure	1 (0.0)	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2 (0.0)	(0.0, 0.1)
Abortion spontaneous	2 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.0)
Suicide attempt	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	9 (0.1)	(0.0, 0.1)
Nephrolithiasis	5 (0.0)	(0.0, 0.1)
Acute kidney injury	2 (0.0)	(0.0, 0.1)
Renal colic	1 (0.0)	(0.0, 0.0)

Table 40. 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 – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	3 (0.0)	(0.0, 0.1)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)
Endometrial thickening	1 (0.0)	(0.0, 0.0)
Endometriosis	1 (0.0)	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	10 (0.1)	(0.0, 0.2)
Pulmonary embolism	4 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	2 (0.0)	(0.0, 0.1)
Dyspnoea	1 (0.0)	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)
Pneumonitis	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)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.0)
Finger amputation	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	6 (0.0)	(0.0, 0.1)
Aortic aneurysm	3 (0.0)	(0.0, 0.1)
Deep vein thrombosis	2 (0.0)	(0.0, 0.1)
Arterial occlusive disease	1 (0.0)	(0.0, 0.0)
Hypertension	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 pd2 ser p3 saf

12.2.4.2.5. Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2

From Dose 3 (first dose of BNT162b2) to the data cutoff date, the IR of at least 1 SAE in original placebo participants who then received BNT162b2 was 2.7 per 100 PY (95% CI: 2.1, 3.5) (Table 41). One SAE was assessed by the investigator as related to study intervention (Table 36).

- One participant in the younger age group with a history of food and seasonal allergies and drug hypersensitivity (Appendix 16.2.5.4), who was originally randomized to the placebo group and unblinded to receive BNT162b2, had an anaphylactoid reaction 2 days post Dose 3 (first dose of BNT162b2), with an event duration of 1 day; the event was reported as an SAE, reported as resolved, and the participant withdrew from the study (Appendix 16.2.7.5). This participant is also discussed in Section 12.2.4.4.1.1.

There were 2 participants who reported SAEs for baseline positive original placebo participants who then received BNT162b2. A meaningful comparison with baseline negative participants is not possible (Supplemental Tables 14.184 and 14.185).

Table 41. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	65	2.7	(2.1, 3.5)
CARDIAC DISORDERS	8	0.3	(0.1, 0.7)
Acute myocardial infarction	1	0.0	(0.0, 0.2)
Arrhythmia	1	0.0	(0.0, 0.2)
Arteriospasm coronary	1	0.0	(0.0, 0.2)
Atrial fibrillation	2	0.1	(0.0, 0.3)
Cardiac failure congestive	1	0.0	(0.0, 0.2)
Cardio-respiratory arrest	1	0.0	(0.0, 0.2)
Cardiovascular disorder	1	0.0	(0.0, 0.2)
Ischaemic cardiomyopathy	1	0.0	(0.0, 0.2)
Myocardial infarction	1	0.0	(0.0, 0.2)

Table 41. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.2)
Hypertrophic cardiomyopathy	1	0.0	(0.0, 0.2)
EAR AND LABYRINTH DISORDERS	1	0.0	(0.0, 0.2)
Vertigo	1	0.0	(0.0, 0.2)
EYE DISORDERS	1	0.0	(0.0, 0.2)
Diplopia	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	8	0.3	(0.1, 0.7)
Anal prolapse	1	0.0	(0.0, 0.2)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.2)
Gastrointestinal necrosis	1	0.0	(0.0, 0.2)
Gastrooesophageal reflux disease	1	0.0	(0.0, 0.2)
Intestinal obstruction	1	0.0	(0.0, 0.2)
Intestinal ulcer perforation	1	0.0	(0.0, 0.2)
Pancreatitis acute	2	0.1	(0.0, 0.3)
Small intestinal obstruction	1	0.0	(0.0, 0.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3	0.1	(0.0, 0.4)
Drug withdrawal syndrome	1	0.0	(0.0, 0.2)
Fatigue	1	0.0	(0.0, 0.2)
Pelvic mass	1	0.0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	2	0.1	(0.0, 0.3)
Cholecystitis	1	0.0	(0.0, 0.2)
Hepatitis acute	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	1	0.0	(0.0, 0.2)
Anaphylactoid reaction	1	0.0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	4	0.2	(0.0, 0.4)
Appendicitis perforated	1	0.0	(0.0, 0.2)
COVID-19 pneumonia	1	0.0	(0.0, 0.2)
Clostridium difficile infection	1	0.0	(0.0, 0.2)
Focal peritonitis	1	0.0	(0.0, 0.2)
Pelvic abscess	1	0.0	(0.0, 0.2)
Pneumonia	1	0.0	(0.0, 0.2)

Table 41. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Urosepsis	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	6	0.3	(0.1, 0.5)
Ankle fracture	1	0.0	(0.0, 0.2)
Fall	1	0.0	(0.0, 0.2)
Lower limb fracture	1	0.0	(0.0, 0.2)
Postoperative ileus	1	0.0	(0.0, 0.2)
Scapula fracture	1	0.0	(0.0, 0.2)
Spinal fracture	1	0.0	(0.0, 0.2)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	1	0.0	(0.0, 0.2)
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4	0.2	(0.0, 0.4)
Myalgia	1	0.0	(0.0, 0.2)
Osteoarthritis	3	0.1	(0.0, 0.4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5	0.2	(0.1, 0.5)
Brain neoplasm	1	0.0	(0.0, 0.2)
Breast cancer	1	0.0	(0.0, 0.2)
Breast cancer stage II	1	0.0	(0.0, 0.2)
Hepatic cancer	1	0.0	(0.0, 0.2)
Non-small cell lung cancer stage III	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	9	0.4	(0.2, 0.7)
Brachial plexopathy	1	0.0	(0.0, 0.2)
Cerebrovascular accident	4	0.2	(0.0, 0.4)
Seizure	1	0.0	(0.0, 0.2)
Syncope	1	0.0	(0.0, 0.2)
Transient ischaemic attack	2	0.1	(0.0, 0.3)
PSYCHIATRIC DISORDERS	5	0.2	(0.1, 0.5)
Alcohol withdrawal syndrome	1	0.0	(0.0, 0.2)
Anxiety	1	0.0	(0.0, 0.2)
Bipolar disorder	1	0.0	(0.0, 0.2)

Table 41. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Completed suicide	1	0.0	(0.0, 0.2)
Depression	1	0.0	(0.0, 0.2)
Major depression	1	0.0	(0.0, 0.2)
Suicide attempt	1	0.0	(0.0, 0.2)
RENAL AND URINARY DISORDERS	2	0.1	(0.0, 0.3)
Nephrolithiasis	1	0.0	(0.0, 0.2)
Urinary tract obstruction	1	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	8	0.3	(0.1, 0.7)
Acute respiratory failure	2	0.1	(0.0, 0.3)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.2)
Dyspnoea	1	0.0	(0.0, 0.2)
Pulmonary embolism	4	0.2	(0.0, 0.4)
VASCULAR DISORDERS	5	0.2	(0.1, 0.5)
Aortic stenosis	1	0.0	(0.0, 0.2)
Deep vein thrombosis	2	0.1	(0.0, 0.3)
Hypertension	1	0.0	(0.0, 0.2)
Thrombosis	1	0.0	(0.0, 0.2)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sae exp p3x saf

12.2.4.2.6. Open-Label Follow-Up Period – Original Placebo Participants, had COVID-19 Occurrence After Dose 1, and Then Received BNT162b2

For original placebo participants who had COVID-19 occurrence after Dose 1 and then received BNT162b2, the IR for at least 1 SAE was 3.4 per 100 PY (95% CI: 0.7, 10.0) (Supplemental Table 14.186). These SAEs occurred in 3 participants (Appendix 16.2.7.5).

- One participant with a significant past history of a deep vein thrombosis and COVID-19 in the placebo-controlled follow-up period (Appendix 16.2.5.4 and Appendix 16.2.8.1), had a Grade 3 SAE of pulmonary embolism, 6 days post Dose 4, which lasted 2 days and resolved with sequelae. The SAE was assessed as not related to the study intervention by the investigator.

- One participant with a past medical history of hypertension, hypercholesterolemia, coronary artery disease, and a coronary artery bypass in 2006 (Appendix 16.2.5.4), had a Grade 3 SAE of myocardial infarction, 16 days post Dose 3, which lasted 4 days and resolved with sequelae. The SAE was assessed and not related to the study intervention by the investigator.

- One participant in the older age group had 4 SAEs:
  - 2 Grade 3 SAEs, urosepsis and acute hypoxic respiratory failure, both occurred 7 days post Dose 3, lasted 5 days, and resolved. These SAEs were assessed as not related to the study intervention by the investigator.

  - Grade 3 SAE of non-small cell lung cancer (stage III), occurred 31 days post Dose 4 and was continuing at the data cutoff date. This SAE was assessed as not related to the study intervention by the investigator.

  - Grade 2 SAE of *Clostridium difficile* infection occurred 47 days post Dose 4 and was continuing at the data cutoff date. This SAE was assessed as not related to the study intervention by the investigator.

12.2.4.2.7. Serious Adverse Event Narratives – Phase 2/3

Narratives for the Phase 2/3 participants who reported SAEs assessed as related to study intervention by the investigator who completed their visit at 1 month after Dose 2 and through the data cutoff date (13 March 2021) are provided in Section 14.

12.2.4.3. Safety-Related Participant Withdrawals – Phase 2/3

In this ongoing study, tables summarizing participant withdrawals may include some participants who were reported as withdrawn but remain in the study and are continuing to be evaluated. These participants are documented in the Errata.

12.2.4.3.1. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2

From Dose 1 to 1 month after Dose 2, few participants in the BNT162b2 group (0.1%) and in the placebo group (0.2%) were withdrawn because of AEs (Table 42).

There were 32 participants in the BNT162b2 group and 36 participants in the placebo group had an AE leading to withdrawal, which included:

- 6 participants in the BNT162b2 group and 2 participants in the placebo group who withdrew from the study due to AEs in the SOC of General Disorders and Administration Site Conditions (BNT162b2 group: injection site pain [2 participants] and chills, facial pain, injection site dermatitis, injection site swelling, pyrexia, and swelling face [1 participant each]; placebo group: death and fatigue [1 participant each]).

- 5 participants in the BNT162b2 group and 6 participants in the placebo group withdrew from the study due to AEs in the SOC of Injury, Poisoning and Procedural Complications (BNT162b2 group: exposure during pregnancy, maternal exposure during pregnancy [2 participants each] and alcohol poisoning [1 participant]; placebo group: exposure during pregnancy [5 participants] and overdose [1 participant].

- 3 participants in the BNT162b2 group and 5 participants in the placebo group withdrew from the study due to AEs in the SOC Cardiac Disorders (BNT162b2 group: cardiac arrest, coronary artery disease and tachycardia [1 participant each]; placebo group: atrial fibrillation [2 participants], cardiac failure congestive, coronary artery occlusion, and myocardial infarction [1 participant each]).

- 3 participants in the BNT162b2 group and 6 participants in the placebo group withdrew from the study due to AEs in the SOC of Nervous System Disorders (BNT162b2 group: headache [3 participants]; placebo group: dizziness [2 participants], amnesia, cerebral infarction, hemorrhagic stroke, paraparesis, and Parkinsonism [1 participant each]).

- 3 participants in the BNT162b2 group and 6 participants in the placebo group withdrew from the study due to AEs in the SOC of Gastrointestinal Disorders (BNT162b2 group: abdominal pain upper, gastrointestinal haemorrhage, and paraesthesia oral [1 participant each]; placebo group: diarrhoea [2 participants], diverticular perforation, dry mouth, dysphagia, and nausea [1 participant each]).

- 3 participants in the BNT162b2 group and 1 participant in the placebo group withdrew from the study due to AEs in the SOC of Neoplasms Benign, Malignant and Unspecified (incl Cysts and Polyps) (BNT162b2 group:adenocarcinoma gastric, lymphoproliferative disorder, and metastases to central nervous system [1 participant each]; placebo group: biliary cancer metastatic and metastases to liver [1 participant each]).

- 1 participant each in the BNT162b2 group and the placebo group withdrew from the study due to AEs in the SOC of Ear and Labyrinth Disorders (BNT162b2 group: deafness unilateral [1 participant]; placebo group: vertigo [1 participant]).

- 1 participant each in the BNT162b2 group and the placebo group withdrew from the study due to AEs in the SOC of Musculoskeletal and Connective Tissue Disorders (myalgia [1 participant in each group]).

- No participant in the BNT162b2 group and 2 participants in the placebo group withdrew from the study due to AEs in the SOC of Immune System Disorders (placebo group: drug hypersensitivity [2 participants]).

- 1 participant in the BNT162b2 group and no participants in the placebo group withdrew from the study due to an AE in the SOC of Blood and Lymphatic System Disorders (BNT162b2 group: lymphadenopathy [1 participant]).

- 1 participant each in the BNT162b2 group and the placebo group withdrew from the study due to AEs in the SOC of Eye Disorders (BNT162b2 group: eye pain [1 participant]; placebo group: visual impairment [1 participant]).

- 1 participant in the BNT162b2 group and no participants in the placebo group withdrew from the study due to an AE in the SOC of Infections and Infestations (BNT162b2 group: Shigella sepsis [1 participant]).

- No participants in the BNT162b2 group and 1 participant in the placebo group withdrew from the study due to an AE in the SOC of Investigations (placebo group: irregular heart rate [1 participant]).

No clinically meaningful differences in AEs leading to withdrawal were observed by age subgroups (Supplemental Tables 14.187 and 14.188).

Table 42. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	32 (0.1)	(0.1, 0.2)	36 (0.2)	(0.1, 0.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	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	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cardiac arrest	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure congestive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 42. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Diarrhoea	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	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)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Injection site pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chills	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial pain	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)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyrexia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Drug hypersensitivity	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shigella sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 42. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Exposure during pregnancy	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Overdose	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)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myalgia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	3 (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)
Biliary cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphoproliferative disorder	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 liver	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Headache	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pulmonary embolism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 42. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eczema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypertension	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_1md2_wd_p3_saf

12.2.4.3.2. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date

From Dose 1 to the unblinding date, the IRs of participants withdrawn because of AEs were 0.5 per 100 PY in the BNT162b2 group and 0.6 per 100 PY in the placebo group (Supplemental Table 14.189).

There were 45 participants in the BNT162b2 group and 51 participants in the placebo group had an AE leading to withdrawal, which included:

- 9 participants in the BNT162b2 group and 8 participants in the placebo group withdrew from the study due to AEs in the SOC Cardiac Disorders (BNT162b2 group: cardiac arrest [4 participants], cardiac failure congestive, cardio-respiratory arrest, coronary artery disease, hypertensive heart disease and tachycardia [1 participant each]; placebo group: atrial fibrillation [2 participants], cardiac arrest, cardiac failure congestive,

cardio-respiratory arrest,coronary artery occlusion, [1 participant each] and myocardial infarction [2 participants]).

- 3 participants in the BNT162b2 group and 6 participants in the placebo group withdrew from the study due to AEs in the SOC of Gastrointestinal Disorders (BNT162b2 group: abdominal pain upper, gastrointestinal haemorrhage, and paraesthesia oral [1 participant each]; placebo group: diarrhoea [2 participants], diverticular perforation, dry mouth, dysphagia, and nausea [1 participant each]).

- 7 participants in the BNT162b2 group and 2 participants in the placebo group withdrew from the study due to AEs in the SOC of General Disorders and Administration Site Conditions (BNT162b2 group: injection site pain [2 participants], chills, facial pain, injection site dermatitis, injection site swelling, pyrexia, sudden cardiac death and swelling face [1 participant each]; placebo group: death and fatigue [1 participant each]).

- 4 participants in the BNT162b2 group and 3 participants in the placebo group withdrew from study due to AEs in the SOC Infections and Infestations (BNT162b2 group: COVID-19 pneumonia, emphysematous cholecystitis, sepsis, septic shock and Shigella sepsis [1 participant each]; placebo group: COVID-19, pneumonia, and septic shock [1 participant each]).

No clinically meaningful differences in IRs of AEs leading to withdrawal were observed in the younger and older age groups (Supplemental Tables 14.190 and 14.191, respectively).

12.2.4.3.3. Open-Label Follow-Up Period – Original BNT162b2 Participants

From the unblinding date to the data cutoff date, IRs of original BNT162b2 participants withdrawn because of AEs were 0.1 (Supplemental Table 14.192).

12.2.4.3.4. Blinded Placebo-Controlled and Open-Label Follow-Up Periods to 6 Months After Dose 2 – Original BNT162b2 Participants

From Dose 1 to 6 months after Dose 2 during the blinded and open-label follow-up period, 1 participant in the older BNT162b2 group was reported as withdrawn because of AEs (dermatitis) (Table 43, and Supplemental Tables 14.193 and 14.194). However, this participant remains in the study as the withdrawal was subsequently queried and corrected. This participant is documented in the Errata.

Table 43. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)
Dermatitis	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 pd2 wd p3 saf

12.2.4.3.5. Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2

From Dose 3 (first dose of BNT162b2 30 µg) administration to the data cutoff date, IR of original placebo participants withdrawn because of AEs was 0.8 per 100 PY (Table 44).

Table 44. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	19	0.8	(0.5, 1.2)
CARDIAC DISORDERS	2	0.1	(0.0, 0.3)
Angina pectoris	1	0.0	(0.0, 0.2)
Cardio-respiratory arrest	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	2	0.1	(0.0, 0.3)
Diarrhoea	1	0.0	(0.0, 0.2)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	7	0.3	(0.1, 0.6)
Chills	2	0.1	(0.0, 0.3)
Fatigue	2	0.1	(0.0, 0.3)
Injection site pain	3	0.1	(0.0, 0.4)
Pain	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	2	0.1	(0.0, 0.3)
Allergy to vaccine	1	0.0	(0.0, 0.2)
Anaphylactoid reaction	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3	0.1	(0.0, 0.4)
Maternal exposure during pregnancy	3	0.1	(0.0, 0.4)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1	0.0	(0.0, 0.2)
Myalgia	1	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1	0.0	(0.0, 0.2)
Hepatic cancer	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	2	0.1	(0.0, 0.3)
Headache	2	0.1	(0.0, 0.3)
PSYCHIATRIC DISORDERS	1	0.0	(0.0, 0.2)
Completed suicide	1	0.0	(0.0, 0.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1	0.0	(0.0, 0.2)
Angioedema	1	0.0	(0.0, 0.2)
Urticaria	1	0.0	(0.0, 0.2)

Table 44. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 31MAR2021 (18:33)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA1/adae s131 wd exp p3x saf

12.2.4.3.6. Open-Label Follow-Up Period – Original Placebo Participants, had COVID-19 Occurrence After Dose 1, and Then Received BNT162b2

There were 3 participants with AEs leading to withdrawal, of which those 3 participants reported AEs that were assessed as related to BNT162b2 (Supplemental Table 14.162): 1 participant with an AE of allergy to vaccine, 1 participant with an AE of pain, and 1 participant with 5 AEs (chills, injection site pain, myalgia, headache, and diarrhea) (Appendix 16.2.7.4.1 and Appendix 16.2.8.1).

12.2.4.3.7. Narratives of Safety-Related Participant Withdrawals – Phase 2/3

Narratives for the Phase 2/3 participants with any AEs leading to withdrawal from the study through the data cutoff date (13 March 2021) are provided in Section 14.

12.2.4.4. Other Significant Adverse Events – Phase 2/3

AEs of clinical interest were evaluated based on regulatory agency feedback and sponsor medical review. Terms requested for analysis by the FDA were summarize and detailed for any such cases reported. Other terms of clinical interest, such as the CDC's list of AESIs for COVID-19 vaccines, which both include terms potentially indicative of severe COVID-19 or serious autoimmune and neuroinflammatory disorders, were considered in the review of

reported events. Numerical imbalances for AESIs were based on the evaluation of AEs in the blinded placebo-controlled period. These safety evaluations are summarized below.

12.2.4.4.1. FDA-Requested Adverse Events of Clinical Interest

Safety evaluations were conducted for AEs of clinical interest: anaphylaxis, Bell's Palsy, lymphadenopathy, and appendicitis based on feedback from the FDA. These are summarized by term below.

12.2.4.4.1.1. Hypersensitivity/Anaphylaxis

During the blinded placebo-controlled follow-up period in participants ≥16 years of age, there were 3 allergic reactions reported as SAEs (previously reported at 14 November 2020 cutoff date):

- Anaphylactic reaction following a bee sting in a BNT162b2 recipient (8 days after Dose 2)
- Drug hypersensitivity to an antibiotic in a BNT162b2 recipient (9 days after Dose 2)
- Anaphylactic shock due to an ant bite in a placebo recipient (18 days after Dose 2).

All 3 cases of allergic reaction above were considered by the investigator as not related to study treatment (Appendix 16.2.7.5).

During the open-label observational follow-up period of this study in participants ≥16 years of age, 1 participant who received BNT162b2 at Dose 3 (after originally being randomized to placebo) experienced an SAE of anaphylactoid reaction, which was assessed as related to study intervention. This participant was a female adolescent with a medical history significant for multiple allergies since infancy (Subject C4591001 1129 11291260). Two days after Dose 3, the participant experienced hives on the left arm (deltoid) and self-administered an epinephrine pen 24 minutes later (given the history of anaphylaxis to multiple allergens). Six minutes after injection, the participant experienced shortness of breath. Hives and shortness of breath resolved within 10 and 30 minutes, respectively, of epinephrine treatment. The participant did not seek additional medical attention. As a result of the anaphylactoid reaction, the participant was permanently withdrawn from the study.

Narratives for the events of anaphylactic reaction and anaphylactic shock are located in Section 14 Anaphylaxis (see Subject C4591001 1261 12611006 for the participant with the SAE of drug hypersensitivity).

Hypersensitivity is also assessed as a CDC-defined AESI in Section 12.2.4.4.2.

12.2.4.4.1.2. Bell's Palsy/Facial Paralysis

During the blinded placebo-controlled follow-up period in participants ≥16 years of age, there were 6 adults who developed one-sided facial paralysis (Bell's palsy, including facial paresis): 4 were randomized to BNT162b2 (all male) and 2 were randomized to placebo (1 male; 1 female) (Supplemental Tables 14.130 and 14.131). Regarding the 4 vaccinated participants (previously reported at 14 November 2020 cutoff date), their ages ranged from 40 to 70 (71 to 73 years of age in placebo participants). Events began from 3 to 48 days after their last dose, were mild to moderate in severity (moderate in the placebo participants), and

duration ranged from 3 to 68 days (15 days in 1 placebo participant and ongoing in the other). Of the 4 cases in participants randomized to BNT162b2, 2 were considered by the investigator to be related to study intervention (Supplemental Table 14.133). The remaining 4 cases (2 in participants originally randomized to BNT162b2 and 2 in participants originally randomized to placebo) were assessed as not related to study intervention.

During the open-label observational follow-up period in participants ≥16 years of age, 3 participants who received BNT162b2 at Dose 3 or Dose 4 (were originally randomized to placebo) experienced facial paralysis (Subjects 12471244, 10071441, and 12181015). All were female and their ages ranged from 19 to 34 years. Events began 3 to 8 days after Dose 3 and were mild to severe in severity. One case had a duration of 12 days while the other 2 were ongoing as of the data cutoff date. All these events of facial paralysis were considered by the investigator as related to study intervention (Appendix 16.2.7.4.1).

During the open-label follow-up period for participants originally randomized to BNT162b2, a 51 year old male developed Bell's palsy 154 days after receiving Dose 2 (Appendix 16.2.7.4.1).

Narratives for these events are located in Section 14 Bell's Palsy.

Bell's palsy is also assessed as an AESI in Section 12.2.4.4.3.

12.2.4.4.1.3. Lymphadenopathy

During the blinded placebo-controlled follow-up period in participants ≥16 years of age, lymphadenopathy was reported in 87 (1.0 per 100 PY) participants in the BNT162b2 group compared to 8 (0.1 per 100 PY) participants in the placebo group (Supplemental Table 14.119). The majority of events were mild to moderate; only 3 severe events of lymphadenopathy were reported (all in the BNT162b2 group) (Supplemental Table 14.195). The median onset of lymphadenopathy after Dose 1 and before Dose 2 was 5.5 days in the BNT162b2 group and 5.0 days in the placebo group; median onset after Dose 2 was shorter in the BNT162b2 group versus the placebo group (2.0 days vs 7.0 days). The median duration of lymphadenopathy was 5.5 days in the BNT162b2 group and 4.0 days in the placebo group. As previously reported in the final analysis interim C4591001 CSR dated 03 December 2020, 1 was a related SAE.

Narratives for these events (including those reported during the open-label follow-up period) are located in Section 14 Lymphadenopathy (see Subject C4591001 1178 11781107 for the narrative of the participant with the related SAE).

12.2.4.4.1.4. Appendicitis

Cases of appendicitis were examined in the placebo-controlled period of the study (including PTs of appendicitis perforated and complicated appendicitis). There were 14 cases of appendicitis and 1 case of appendicitis perforated in the BNT162b2 group, and 9 cases of appendicitis, 2 cases of complicated appendicitis, and 1 appendicitis perforated in the placebo group (Supplemental Table 14.119). Appendicitis cases were all reported as SAEs, and none of the cases were considered related to study intervention (Appendix 16.2.7.5).

Narratives for these events are located in Section 14 Appendicitis.

12.2.4.4.2. CDC Adverse Events of Special Interest – Select Standard MedDRA Queries for COVID-19

CDC-defined AESIs associated with COVID-19 vaccination were evaluated in the blinded placebo-controlled period of the study, where reported in the Phase 2/3 safety population.

After a review of AEs using the CDC's AESI list, the following terms were not found reported in the study: acute disseminated encephalomyelitis, transverse myelitis, multiple sclerosis, chronic inflammatory demyelinating polyneuropathy, encephalitis, myelitis, encephalomyelitis, meningoencephalitis, ataxia, narcolepsy, cataplexy, immune thrombocytopenia, thrombotic thrombocytopenic purpura, disseminated intravascular coagulation, Kawasaki disease, multisystem inflammatory syndrome in children (MIS-C) and in adults (MIS-A), and acute respiratory distress syndrome.

There were 2 cases of bacterial meningitis reported but they were not analyzed further as there is an immediate and self-evident cause to their illness (Appendix 16.2.7.5).

Terms that were present in the safety population are summarized below. For a given SMQ, if there was no imbalance between the BNT162b2 group versus placebo, the PTs within the SMQ were not further examined. In the case of an imbalance, the PTs responsible for the imbalance are further described and the nature of the events characterized with regard to plausible associated with vaccination.

Overall, the number and percentage of participants with any unsolicited AEs within the selected SMQs was similar in the BNT162b2 (224 [1.02%]) and placebo (217 [0.99%]) groups from Dose 1 to the unblinding date (Table 45).

From analysis of terms corresponding to AESIs from the CDC's list, individual SMQs are discussed below.

Table 45. Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Subjects with any unsolicited adverse events within SMQ	224 (1.02)	217 (0.99)
Angioedema (SMQ)	Any unsolicited adverse events within Angioedema (SMQ)	30 (0.14)	29 (0.13)
	Eye disorders	2 (0.01)	2 (0.01)
	Conjunctival oedema	0	1 (0.00)
	Eye swelling	0	1 (0.00)
	Eyelid oedema	1 (0.00)	0
	Swelling of eyelid	1 (0.00)	0
	Gastrointestinal disorders	6 (0.03)	3 (0.01)
	Gingival swelling	0	1 (0.00)
	Lip oedema	1 (0.00)	0
	Lip swelling	2 (0.01)	1 (0.00)
	Swollen tongue	2 (0.01)	1 (0.00)
	Tongue oedema	1 (0.00)	0
	General disorders and administration site conditions	4 (0.02)	7 (0.03)
	Face oedema	2 (0.01)	0
	Swelling face	2 (0.01)	7 (0.03)
	Respiratory, thoracic and mediastinal disorders	1 (0.00)	3 (0.01)
	Pharyngeal swelling	1 (0.00)	3 (0.01)
	Skin and subcutaneous tissue disorders	21 (0.10)	18 (0.08)
	Angioedema	3 (0.01)	2 (0.01)
	Urticaria	18 (0.08)	15 (0.07)
	Urticaria papular	0	1 (0.00)
Arthritis (SMQ)	Any unsolicited adverse events within Arthritis (SMQ)	35 (0.16)	48 (0.22)
	Infections and infestations	1 (0.00)	0
	Arthritis bacterial	1 (0.00)	0
	Metabolism and nutrition disorders	5 (0.02)	3 (0.01)
	Gout	5 (0.02)	3 (0.01)
	Musculoskeletal and connective tissue disorders	29 (0.13)	45 (0.21)
	Arthritis	6 (0.03)	6 (0.03)
	Arthritis reactive	1 (0.00)	0
	Osteoarthritis	15 (0.07)	23 (0.10)
	Patellofemoral pain syndrome	0	1 (0.00)

Table 45. Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Periarthritis	4 (0.02)	1 (0.00)
	Polyarthritis	0	1 (0.00)
	Rheumatoid arthritis	0	2 (0.01)
	Spinal osteoarthritis	2 (0.01)	4 (0.02)
	Spondylitis	1 (0.00)	1 (0.00)
	Synovitis	0	2 (0.01)
	Temporomandibular joint syndrome	1 (0.00)	4 (0.02)
Convulsions (SMQ)	Any unsolicited adverse events within Convulsions (SMQ)	2 (0.01)	2 (0.01)
	Nervous system disorders	2 (0.01)	2 (0.01)
	Generalised tonic-clonic seizure	0	1 (0.00)
	Seizure	2 (0.01)	1 (0.00)
Demyelination (SMQ)	Any unsolicited adverse events within Demyelination (SMQ)	2 (0.01)	1 (0.00)
	Nervous system disorders	2 (0.01)	1 (0.00)
	Guillain-Barre syndrome	0	1 (0.00)
	Optic neuritis	2 (0.01)	0
Hypersensitivity (SMQ)	Any unsolicited adverse events within Hypersensitivity (SMQ)	182 (0.83)	161 (0.73)
	Ear and labyrinth disorders	0	1 (0.00)
	Allergic otitis media	0	1 (0.00)
	Eye disorders	5 (0.02)	5 (0.02)
	Conjunctival oedema	0	1 (0.00)
	Conjunctivitis allergic	3 (0.01)	2 (0.01)
	Eye allergy	0	1 (0.00)
	Eye swelling	0	1 (0.00)
	Eyelid oedema	1 (0.00)	0
	Swelling of eyelid	1 (0.00)	0
	Gastrointestinal disorders	6 (0.03)	3 (0.01)
	Gingival swelling	0	1 (0.00)
	Lip oedema	1 (0.00)	0
	Lip swelling	2 (0.01)	1 (0.00)
	Swollen tongue	2 (0.01)	1 (0.00)
	Tongue oedema	1 (0.00)	0

Table 45. Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	General disorders and administration site conditions	8 (0.04)	9 (0.04)
	Application site rash	0	1 (0.00)
	Face oedema	2 (0.01)	0
	Injection site dermatitis	1 (0.00)	0
	Injection site rash	2 (0.01)	1 (0.00)
	Injection site urticaria	1 (0.00)	0
	Swelling face	2 (0.01)	7 (0.03)
	Immune system disorders	10 (0.05)	13 (0.06)
	Anaphylactic reaction	1 (0.00)	0
	Anaphylactic shock	0	1 (0.00)
	Drug hypersensitivity	7 (0.03)	7 (0.03)
	Hypersensitivity	2 (0.01)	5 (0.02)
	Infections and infestations	5 (0.02)	1 (0.00)
	Dermatitis infected	0	1 (0.00)
	Pustule	3 (0.01)	0
	Rash pustular	2 (0.01)	0
	Injury, poisoning and procedural complications	3 (0.01)	0
	Administration related reaction	2 (0.01)	0
	Stoma site rash	1 (0.00)	0
	Investigations	1 (0.00)	0
	Blood immunoglobulin E increased	1 (0.00)	0
	Respiratory, thoracic and mediastinal disorders	19 (0.09)	21 (0.10)
	Allergic respiratory disease	0	1 (0.00)
	Allergic sinusitis	2 (0.01)	0
	Bronchospasm	3 (0.01)	3 (0.01)
	Pharyngeal swelling	1 (0.00)	3 (0.01)
	Rhinitis allergic	13 (0.06)	14 (0.06)
	Skin and subcutaneous tissue disorders	134 (0.61)	119 (0.54)
	Angioedema	3 (0.01)	2 (0.01)
	Dermatitis	5 (0.02)	4 (0.02)
	Dermatitis acneiform	1 (0.00)	0
	Dermatitis allergic	3 (0.01)	5 (0.02)
	Dermatitis atopic	0	1 (0.00)

Table 45. Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Dermatitis bullous	0	1 (0.00)
	Dermatitis contact	14 (0.06)	21 (0.10)
	Dermatitis exfoliative	1 (0.00)	0
	Drug eruption	0	2 (0.01)
	Eczema	7 (0.03)	3 (0.01)
	Erythema nodosum	1 (0.00)	0
	Fixed eruption	1 (0.00)	0
	Hand dermatitis	2 (0.01)	2 (0.01)
	Perioral dermatitis	0	1 (0.00)
	Pruritus allergic	0	2 (0.01)
	Rash	62 (0.28)	52 (0.24)
	Rash erythematous	2 (0.01)	3 (0.01)
	Rash maculo-papular	7 (0.03)	4 (0.02)
	Rash papular	1 (0.00)	0
	Rash pruritic	8 (0.04)	6 (0.03)
	Urticaria	18 (0.08)	15 (0.07)
	Urticaria contact	0	1 (0.00)
	Urticaria papular	0	1 (0.00)
Peripheral neuropathy (SMQ)	Any unsolicited adverse events within Peripheral neuropathy (SMQ)	3 (0.01)	6 (0.03)
	Nervous system disorders	3 (0.01)	6 (0.03)
	Guillain-Barre syndrome	0	1 (0.00)
	Neuralgia	1 (0.00)	1 (0.00)
	Neuritis	0	1 (0.00)
	Neuropathy peripheral	1 (0.00)	3 (0.01)
	Peripheral sensory neuropathy	1 (0.00)	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 event," n = the number of subjects reporting at least 1 occurrence of any event.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 14APR2021 (10:22)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA_RR/adae_smq_nzud_16_saf

Angioedema

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of angioedema were low and similar in the BNT162b2 group (30 [0.14%]) and placebo group (29 [0.13%]) (Table 45). AEs were most frequently reported in the SOC of skin and subcutaneous tissue disorders (21 [0.10%] BNT162b2 vs 18 [0.08%] placebo) with urticaria the most frequently reported PT.

In the SOC of gastrointestinal disorders within the SMQ of angioedema, lip edema, or lip swelling was observed in 3 participants in the BNT162b2 group versus 1 participant in the placebo group. Swollen tongue or tongue edema was observed in 3 participants in the BNT162b2 group versus 1 participant in the placebo group. Lip swelling in 1 participant in the BNT162b2 group and swollen tongue in 1 participant in the placebo group were considered as related to the study intervention (Supplemental Table 14.133):

- In the BNT162b2 group, 1 participant experienced mild upper and lower lip swelling 14 and 19 days after Dose 1 which lasted 2 days before resolving and was considered as related to the study intervention. This same participant also experienced upper lip swelling and drug hypersensitivity 2 days after Dose 2, which were recovering/resolving as of the data cutoff date and were assessed by the investigator as related to study intervention (Appendix 16.2.7.4.1).

- In the placebo group, 1 participant experienced moderate swollen tongue as well as moderate pharyngeal swelling 21 days after Dose 2; both resolved after 9 days; this participant also experienced moderate drug hypersensitivity and mild rash (on chin, elbows, knees, neck and back) 2 days after Dose 2 which lasted for 28 days and 30 days, respectively, and resolved. Swollen tongue as well as these other AEs were all assessed by the investigator as related to the study intervention (Appendix 16.2.7.4.1).

Narratives of participants with angioedema SMQ events are located in Section 14 for the following participants:

Subject C4591001 1044 10441139
Subject C4591001 1111 11111099
Subject C4591001 1246 12461025
Subject C4591001 1005 10051214
Subject C4591001 1111 11111092
Subject C4591001 1027 10271105
Subject C4591001 1068 10681066
Subject C4591001 1090 10901507
Subject C4591001 1117 11171121
Subject C4591001 1091 10911274
Subject C4591001 1092 10921123
Subject C4591001 1140 11401035

Angioedema events in the other SMQs were all reported at low percentages in the BNT162b2 (≤0.02) and placebo groups (≤0.03%) (Table 45).

Arthritis

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of arthritis was lower in the BNT162b2 group (35 [0.16%]) than in placebo group (48 [0.22%]) (Table 45). AEs were most frequently reported within the SOC of

musculoskeletal and connective tissue disorders (0.13% BNT162b2 vs 0.21% placebo) with osteoarthritis the most frequently reported PT.

Convulsions

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of convulsions was low and equal in the BNT162b2 group and placebo group (2 participants [0.01%] in each group) (Table 45). All events were in the SOC of nervous system disorders: seizure (2 participants in the BNT162b2 group and 1 participant in the placebo group) and generalized tonic-clonic seizure (1 participant in the placebo group).

Demyelination

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of demyelination was low: 2 (0.01%) participants in the BNT162b2 group and 1 (0.00%) participant in the placebo group. All events were in the SOC of nervous system disorders.

Optic neuritis was observed in 2 participants in the BNT162b2 group and none in the placebo group (Supplemental Table 14.119); 1 case occurring in a male participant and 1 case occurring in a female participant (Supplemental Tables 14.130 and 14.131). Both participants were in the younger age group (Supplemental Table 14.120). These events occurred 79 and 81 days after their last vaccination of BNT162b2 (Appendix 16.2.7.5). Both were considered not related to BNT162b2. Both events were reported as SAEs. Narratives for optic neuritis cases are located in Section 14 (Subject C4591001 1008 10081152 and Subject C4591001 1231 12313028).

Guillain-Barre syndrome was reported as an SAE in 1 participant in the placebo group. A narrative is located in Section 14 (see Subject C4591001 1135 11351368).

These events of optic neuritis and Guillain-Barre syndrome are also included in safety analyses by medical category (SMQ and SOC) in Section 12.2.4.4.3.

Hypersensitivity

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of hypersensitivity was higher in the BNT162b2 group (182 [0.83%]) than in the placebo group (161 [0.73%]) (Table 45).

The difference was mainly due to:

Skin and subcutaneous tissue disorders (134 [0.61%] BNT162b2 vs 119 [0.54%] placebo):

- rash (62 [0.28%] BNT162b2 vs 52 [0.24%] placebo)
- rash maculo-papular (7 [0.03%] BNT162b2 vs 4 [0.02%] placebo)
- rash papular (1 [0.00%] BNT162b2 vs 0 placebo)

Rash was assessed as related to study intervention at a higher IR in the BNT162b2 group (0.3) than in the placebo group (0.1) (Supplemental Table 14.132).

In the SMQ of hypersensitivity in the SOC of infections and infestations: pustule and rash pustular were reported only in the BNT162b2 group by 3 (0.01%) and 2 (0.01%) participants, respectively. In the SOC of injury, poisoning and procedural complications, administration related reaction (2 participants) and stoma site rash (1 participant) were reported only in the BNT162b2 group.

Additionally, in the SMQ of hypersensitivity in the SOC of gastrointestinal disorders, lip edema, lip swelling, swollen tongue, and tongue edema were observed more frequently in the BNT162b2 group versus the placebo group. Refer to the Angioedema SMQ section for details and Supplemental Table 14.133.

Anaphylactic reaction was observed in 1 participant in the BNT162b2 group (refer to Section 12.2.4.4.1.1 for more detail).

In the SMQ of hypersensitivity in the SOC of investigations, increased blood IgE was observed in 1 participant in the BNT162b2 group.

Peripheral Neuropathy

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of peripheral neuropathy was lower in the BNT162b2 group (3 [0.01%]) than in the placebo group (6 [0.03%]). All PTs were in the SOC of nervous system disorders (Table 45).

12.2.4.4.3. Other Non-CDC Adverse Events of Special Interest – Select Standard MedDRA Queries for COVID-19

Additional terms beyond those designated by the CDC as AESIs were evaluated to assess potential imbalances between the BNT162b2 and placebo groups, and further characterized such an imbalance. PTs associated with these AE categories and by SOC/PT were identified during the blinded placebo-controlled follow-up period (Table 46 and Supplemental Table 14.196). These events are summarized below.

Table 46. Incidence Rates of at Least 1 Adverse Event Category of Special Interest From Dose 1 to Unblinding Date, by Adverse Event Category and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)			Difference	
Adverse Event Category Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])	IRD (/100 PY)[f]	(95% CI[g])
ACUTE MYOCARDIAL INFARCTION								

Table 46. Incidence Rates of at Least 1 Adverse Event Category of Special Interest From Dose 1 to Unblinding Date, by Adverse Event Category and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)			Difference	
Adverse Event Category Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])	IRD (/100 PY)[f]	(95% CI[g])
Acute coronary syndrome	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)	-0.04	(-0.09, 0.02)
Acute myocardial infarction	6	0.1	(0.0, 0.2)	4	0.0	(0.0, 0.1)	0.02	(-0.05, 0.10)
Coronary artery occlusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Myocardial infarction	4	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)	-0.05	(-0.13, 0.03)
ANAPHYLAXIS								
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Anaphylactic shock	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
APPENDICITIS								
Appendicitis	14	0.2	(0.1, 0.3)	9	0.1	(0.1, 0.2)	0.06	(-0.06, 0.17)
Appendicitis perforated	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	-0.00	(-0.03, 0.03)
Complicated appendicitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)	-0.02	(-0.06, 0.01)
ARTHRITIS/ARTHRALGIA								
Arthralgia	281	3.4	(3.0, 3.8)	122	1.5	(1.2, 1.8)	1.88	(1.41, 2.36)
Arthritis	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)	-0.00	(-0.08, 0.08)
Arthritis reactive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
BELL'S PALSY								
Facial paralysis	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.04	(-0.02, 0.09)
Facial paresis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
COVID-19 DISEASE								
COVID-19	0	0.0	(0.0, 0.0)	13	0.2	(0.1, 0.3)	-0.16	(-0.24, -0.07)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	-0.00	(-0.03, 0.03)
DEATH								
Death	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
ENCEPHALOPATHY								
Toxic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
GUILLAIN-BARRE SYNDROME								
Guillain-Barre syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (MIS-C) AND IN ADULTS (MIS-A)								

Table 46. Incidence Rates of at Least 1 Adverse Event Category of Special Interest From Dose 1 to Unblinding Date, by Adverse Event Category and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)			Difference	
Adverse Event Category Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])	IRD (/100 PY)[f]	(95% CI[g])
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
MYOCARDITIS								
Myocarditis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
NON-ANAPHYLACTIC ALLERGIC REACTIONS								
Angioedema	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)	0.01	(-0.04, 0.06)
Hypersensitivity	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)	-0.04	(-0.10, 0.03)
Lip swelling	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.01	(-0.03, 0.05)
Pruritus	24	0.3	(0.2, 0.4)	20	0.2	(0.1, 0.4)	0.04	(-0.11, 0.20)
Rash	62	0.7	(0.6, 1.0)	52	0.6	(0.5, 0.8)	0.11	(-0.14, 0.36)
Rash pruritic	8	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)	0.02	(-0.07, 0.11)
Swelling face	2	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)	-0.06	(-0.13, 0.01)
Swollen tongue	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.01	(-0.03, 0.05)
Urticaria	18	0.2	(0.1, 0.3)	15	0.2	(0.1, 0.3)	0.03	(-0.10, 0.17)
OPTIC NEURITIS								
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.02	(-0.01, 0.06)
PERICARDITIS								
Pericarditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
PULMONARY EMBOLISM								
Pulmonary embolism	8	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)	-0.00	(-0.10, 0.09)
SEIZURE/CONVULSION								
Generalised tonic-clonic seizure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Seizure	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.01	(-0.03, 0.05)
STROKE, HEMORRHAGIC								
Haemorrhagic stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Intraventricular haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Subarachnoid haemorrhage	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.04	(-0.02, 0.09)
STROKE, ISCHEMIC								
Cerebellar infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Cerebral infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Cerebrovascular accident	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.04	(-0.02, 0.09)

Table 46. Incidence Rates of at Least 1 Adverse Event Category of Special Interest From Dose 1 to Unblinding Date, by Adverse Event Category and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)			Difference	
Adverse Event Category Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])	IRD (/100 PY)[f]	(95% CI[g])
Ischaemic stroke	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)	-0.00	(-0.05, 0.05)
Transient ischaemic attack	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)	-0.01	(-0.07, 0.04)
THROMBOCYTOPENIA								
Platelet count decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Thrombocytopenia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)	-0.01	(-0.05, 0.03)
VACCINATION DURING PREGNANCY AND ADVERSE PREGNANCY OUTCOMES								
Abortion incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Abortion spontaneous	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)	-0.01	(-0.07, 0.04)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Exposure during pregnancy	30	0.4	(0.2, 0.5)	42	0.5	(0.4, 0.7)	-0.15	(-0.35, 0.05)
Retained products of conception	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
VENOUS THROMBOEMBOLISM								
Coagulopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Deep vein thrombosis	7	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)	-0.00	(-0.09, 0.09)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Penile vein thrombosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Venous thrombosis limb	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)

Note: MedDRA (v23.1) coding dictionary applied.
Note: The 95% confidence interval quantifies the precision of the incidence rate difference estimate. Confidence intervals are not adjusted for multiplicity. They should only be used to identify potentially important adverse events.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Difference in incidence rate (BNT162b2 [30 µg] - placebo).
g. 2-sided Wald CI for the incidence rate difference.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 16APR2021 (13:49)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA1/adae_s131_aesi_cat_p3_saf

Acute Myocardial Infarction

Acute myocardial infarctions were searched with the PTs of acute myocardial infarction, acute coronary syndrome, coronary artery occlusion, and myocardial infarction. A total of 6 acute myocardial infarctions, 4 myocardial infarctions and 1 acute coronary syndrome (total of 11 events) were identified in the BNT162b2 group, and 4 acute myocardial infarctions, 8 myocardial infarctions, 4 acute coronary syndrome, and 1 coronary artery occlusion in the placebo group (total of 17 events), respectively (Supplemental Table 14.119). Slightly more than half of these events had onset distant to (ie, >30 days following) receipt of vaccine or placebo (Appendix 16.2.7.4.1) . None of these events were assessed by the investigator as related to study intervention. Outcome was resolved in all participants in the BNT162b2 group; outcome in the placebo group was fatal in 2 and resolved in the other participants (Appendix 16.2.7.4.1).

Anaphylaxis

Overall, the category of anaphylaxis included 1 participant with anaphylactic reaction in the BNT162b2 group and 1 participant with anaphylactic shock in the placebo group. These events are further described in Section 12.2.4.4.1.1.

Appendicitis

Overall, the category of appendicitis (including appendicitis perforated and complicated appendicitis) included 15 participants in the BNT162b2 group and 12 participants in the placebo group. These events are further described in Section 12.2.4.4.1.4.

Arthritis/Arthralgia

Arthralgia not associated with reactogenicity was evaluated starting from Day 8 after either dose of BNT162b2. The IR of arthralgia assessed from Day 8 (ie, beyond the 7-day reactogenicity period in which arthralgia is recorded in e-dairies for the reactogenicity subset) after each dose was lower in the BNT162b2 group (0.6) than in the placebo group (0.8) (Supplemental Table 14.197).

Autoimmune Disease

There are no search term SMQ that would reliably capture all potential autoimmune diseases. Hence a comprehensive manual medical review of all reported AEs in the blinded placebo-controlled period was undertaken to identify PTs potentially indicative of autoimmune disease. These PTs are summarized by vaccine group.

In the BNT162b2 group there were 10 autoimmune disease cases identified. There was 1 case each in the BNT162b2 group: autoimmune thyroiditis, ulcerative colitis, Crohn's disease, reactive arthritis, fibromyalgia, systemic lupus erythematosus, alopecia areata, psoriasis, and 2 cases of psoriatic arthropathy.

In the placebo group there were 15 autoimmune cases identified. There was 1 case each in the placebo group: autoimmune thyroiditis, celiac disease, alopecia areata, psoriasis,

Raynaud's phenomenon, and 2 cases of psoriatic arthropathy, 2 cases of psoriasis, 2 cases of ulcerative colitis, 2 cases of rheumatoid arthritis, 3 cases of fibromyalgia.

Bell's Palsy/Facial Paralysis

Overall, the category of Bell's Palsy (facial paralysis and facial paresis) included 4 participants in the BNT162b2 group and 2 participants in the placebo group during blinded placebo-controlled follow-up. These events are further described in Section 12.2.4.4.1.2.

Multiple Cases of COVID-19

There were 5 participants ≥16 years of age, all randomized to placebo, who developed 2 separate and clinically symptomatic instances of COVID-19 confirmed by NAAT at the central laboratory (Appendix 16.2.8.4). All of the second confirmed COVID-19 cases occurred during the period before their first dose of BNT162b2 except for 1 participant (Subject 12211002) who developed his second COVID-19 diagnosis 4 days after his second dose of BNT162b2. All participants were N-binding antibody negative prior to their first instance of COVID-19. The time interval between the first and second COVID-19 episode varied from 1 to 5 months. Narratives for these cases are located in Section 14 COVID-19 Case (Severe and/or Multiple).

Death

One death in the placebo group was captured as a potential AESI as there was no reported primary cause of death at the time of the data cutoff. A narrative is located in Section 14 (see Subject C4591001 1152 11521085). This death is also captured in Table 38 in the analysis of deaths reported from Dose 1 to the unblinding date (Section 12.2.4.1).

Encephalopathy

Overall, the category of encephalopathy included 2 participants in the BNT162b2 group and none in the placebo group. One participant reported an SAE of toxic encephalopathy 64 days after Dose 2 in the setting of diverticulosis and a urinary tract infection, which resolved 8 days later, and the other participant reported an SAE of uraemic encephalopathy 36 days after Dose 2, which resolved 3 days later (Appendix 16.2.7.4.1). Both events were assessed by the investigator as not related to study intervention.

Guillain-Barre Syndrome

One participant in the placebo group reported an SAE of Guillain-Barre syndrome. This case was also captured as a CDC AESI in Section 12.2.4.4.2.

Multisystem Inflammatory Syndrome

One participant in the placebo group reported an SAE of multiple organ dysfunction syndrome.

Myocarditis

One case in the placebo group was identified (Supplemental Table 14.119).

Non-Anaphylactic Allergic Reactions

Overall, there was no imbalance in each of the PTs in non-anaphylactic allergic reactions (123 in the BNT162b2 group and 109 in the placebo group) (Table 46). Selected events are also captured as CDC AESIs under SMQ of Angioedema and Hypersensitivity in Section 12.2.4.4.2.

Optic Neuritis

Two participants in the BNT162b2 group reported an SAE each of optic neuritis. This case was also captured as a CDC AESI in Section 12.2.4.4.2.

Pericarditis

There was 1 participant in the older BNT162b2 age group with pericarditis (Supplemental Table 14.121). The event had an onset of 28 days after Dose 2, was ongoing at the data cutoff date, and was assessed by the investigator as not related to the study intervention (Appendix 16.2.7.4.1). A narrative for this event is located in Section 14 (Subject C4591001 1231 12315632).

Pulmonary Embolism

PTs associated with pulmonary embolism were searched in the blinded placebo-controlled period: Pulmonary embolism, Pulmonary thrombosis, Pulmonary venous thrombosis, and Pulmonary artery thrombosis. There were 8 cases of pulmonary embolism in the BNT162b2 group and 8 cases in the placebo group (see Supplemental Tables 14.119 and 14.120).

Stroke, Hemorrhagic

PTs associated with hemorrhagic stroke were searched in the blinded placebo-controlled follow-up period: Haemorrhagic stroke, Cerebral haemorrhage, Haemorrhagic cerebral infarction, Basal ganglia haemorrhage, Brain stem haemorrhage, Cerebellar haemorrhage, subarachnoid hemorrrhage, and Intraventricular hemorrhage.

Overall, there were 4 hemorraghic strokes in the BNT162b2 and 3 in the placebo group. In the BNT162b2 group there were 4 subarachnoid haemorrhages and in the placebo group there was 1 subarachnoid haemorrhage, 1 intraventricular haemorrhage, and 1 haemorrhagic stroke (Table 46). Narratives for these events are located in Section 14:

Subject C4591001 1111 11111130
Subject C4591001 1226 12261571
Subject C4591001 1042 10421166
Subject C4591001 1054 10541173
Subject C4591001 1156 11561001
Subject C4591001 1090 10901175
Subject C4591001 1231 12313972

Stroke, Ischemic

PTs associated with ischemic stroke were searched in the blinded placebo-controlled follow-up period: Ischaemic stroke, Ischaemic cerebral infarction, Cerebral infarction, Lacunar infarction, Cerebral ischaemia, Cerebellar stroke, Brain stem stroke, Vertebrobasilar stroke, Embolic stroke, Thrombotic stroke, Thrombotic and cerebral infarction, Cerebral vascular accident, transient ischemic attack, and Cerebellelar infarction.

There are a total of 8 of these PTs in the BNT162b2 group and 8 in the placebo group. There were 2 ischemic strokes, 4 cerebral vascular accidents, 2 transient ischemic attacks identified in the BNT162b2 group (Supplemental Table 14.119). In the placebo group there are 2 ischemic strokes, 3 transient ischemic attacks, 1 cerebral vascular accident, 1 cerebral infarction and 1 cerebellar infarction.

Thrombocytopenia

PTs associated with thrombocytopenia were searched in the blinded placebo-controlled period and included Thrombocytopenia and platelet count decreased. The BNT162b2 group had 1 case of thrombocytopenia and 1 case of platelet count decreased, and the placebo group had 2 cases of thrombocytopenia.

Vaccination During Pregnancy and Pregnancy Outcomes

There was no imbalance between the BNT162b2 group versus the placebo group with regard to pregnancy and maternal exposure. Pregnancy and maternal exposure reported during the study is discussed in Section 12.2.4.5.2. Narratives for these events are located in Section 14 Pregnancy.

Venous Thromboembolism

PTs associated with venous thromboembolism were searched in the blinded placebo-controlled period: Cerebral venous sinus thrombosis, Cerebral venous thrombosis, Cerebral thrombosis, Superior sagittal sinus thrombosis, Deep vein thrombosis, Venous thrombosis limb, Retinal vein thrombosis, Retinal vein occlusion, Mesenteric vein thrombosis, Thrombosis mesenteric vessel, Splenic thrombosis, Splenic vein thrombosis, Splenic embolism, Visceral venous thrombosis, Hepatic vein thrombosis, Hepatic vein embolism, Vena cava thrombosis, Vena cava embolism, Renal vein thrombosis, Renal vein embolism, Venous thrombosis, Thrombosis, Embolism, and Thrombotic microangiopathy.

Overall, there were 9 thrombotic events in the BNT162b2 group and 9 in the placebo group. In the BNT162b2 group included 7 deep vein thromboses, 1 coagulopathy, and 1 ophthalmic vein thrombosis, and in the placebo group included 7 deep vein thromboses, 1 penile vein

thrombosis, and 1 venous thrombosis limb (Table 46). None of the venous events were associated with thrombocytopenia.

12.2.4.4.4. Narratives of Other Significant Adverse Events – Phase 2/3

Narratives of other significant AEs for Phase 2/3 participants through the data cutoff date (13 March 2021) are provided in Section 14.

12.2.4.5. Other Safety Assessments – Phase 2/3

12.2.4.5.1. Severe COVID-19 Illness – Phase 2/3

The protocol had prespecified stopping rules that included monitoring of severe COVID-19 cases, and these stopping criteria were not met. The confinement of the majority of severe cases to the placebo groups suggests no evidence for vaccine-associated enhanced disease (VAED) including vaccine-associated enhanced respiratory disease (VAERD).

A description of severe COVID-19 cases in the updated analysis of efficacy in Phase 2/3 is presented in Section 11.1.2.2.1.

12.2.4.5.2. Pregnancy – Phase 2/3 (BNT162b2 Recipients)

At the time of the data cutoff date (13 March 2021), a total of 50 participants who had received BNT162b2 had reported pregnancies, including 42 participants originally randomized to the BNT162b2 group and 8 participants originally randomized to the placebo group who then recevied BNT162b2 (Appendix 16.2.7.8). In total, 12 participants (n=6 each in the randomized BNT162b2 and placebo groups) withdrew from the blinded placebo-controlled vaccination period of the study due to pregnancy, and 4 participants originally randomized to placebo who then received BNT162b2 withdrew from the open-label vaccination period due to pregnancy (Table 5). These participants continue to be followed for pregnancy outcomes.

Narratives for participants who reported a pregnancy during the study, including any reported outcomes, are provided in Section 14.

12.2.4.6. Analysis and Discussion of Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events – Phase 2/3

During the blinded and open-label follow-up periods, frequencies/IRs of participants with SAEs and participants withdrawn because of AEs were low.

There were 15 deaths in the BNT162b2 group and 14 in the placebo group from Dose 1 to the unblinding date during the blinded placebo-controlled follow-up period, and there were 3 deaths in original BNT162b2 participants and 2 deaths in original placebo participants who then received BNT162b2 from the unblinding date to the cutoff date during the open-label follow-up period. None of the deaths in this study were assessed by the investigator as related to study intervention (Section 12.2.4.1).

12.2.5. Phase 2/3 Safety Conclusions

12.2.5.1. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2

- Local reactions were generally similar in frequency after each dose, and systemic events generally increased in frequency and severity after Dose 2 compared to Dose 1. Local and systemic reactogenicity events were well-tolerated and short-lived (median durations of 1.0 to 2.0 days).

- Reactogenicity events after each dose of BNT162b2 in older adults were generally milder and less frequent than those observed in younger adults. The majority of reactogenicity events were mild or moderate in severity. No Grade 4 events were reported other than fever in 1 participant.

- For blinded placebo-controlled follow-up from Dose 1 to 1 month afer Dose 2, most AEs were mild or moderate in severity.

- Most AEs from Dose 1 to 1 month after Dose 2 were mild or moderate in severity. The number of participants with AEs in the BNT162b2 group (30.2%) was greater as compared with the placebo group (13.9%), which upon analysis, was attributed to reactogenicity events reported as AEs within 7 days after each dose.

- A number of events were identified as occurring at a higher frequency than placebo within the 7-day period after either dose of BNT162b2 when reactogenicity is expected to be reported such as pain in extremity, decreased appetite, lethargy, asthenia, malaise, night sweats, and hyperhidrosis. These events are interpreted as attributable to the experience of local reactions and systemic events after vaccination with BNT162b2.

- SAEs were similar in the BNT162b2 (0.6%) and placebo (0.5%) groups. There were 3 SAEs reported in the BNT162b2 group that were assessed by the investigator as related to study intervention (lymphadenopathy; shoulder injury related to vaccine administration [SIRVA], erroneously administered into or near the shoulder joint capsule; and ventricular arrhythmia).

- Few participants in the BNT162b2 group (0.1%) and placebo group (0.2%) were withdrawn because of AEs. There were 3 deaths in the BNT162b2 group (cardiac arrest, Shigella sepsis, and atherosclerosis) and 5 deaths in the placebo group (death [undetermined], myocardial infarction [2 participants], haemorrhagic stroke, and overdose); none were assessed as related to study intervention.

- For the subset of HIV-positive participants, local reactions, systemic events, and AEs showed generally similar trends as the overall population.

12.2.5.2. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date

- Most AEs from Dose 1 to the unblinding date were mild or moderate in severity. The IR of at least 1 AE in the BNT162b2 group (83.2 per 100 PY) was greater as compared with the placebo group (43.4 per 100 PY), which upon analysis, was attributed to reactogenicity events reported as AEs within 7 days after each dose.

- In addition to the 3 related SAEs reported from Dose 1 to 1 month after Dose 2, there were 2 additional related SAEs reported to after 1 month post Dose 2 up to the unblinding date in the BNT162b2 group that were assessed by the investigator as related to study intervention: paraesthesia (BNT162b2 group) and psoriatic arthropathy (placebo).

- IRs of participants withdrawn because of AEs were 0.5 per 100 PY in the BNT162b2 group and 0.6 per 100 PY in the placebo group. From Dose 1 to the unblinding date, there were a total of 15 deaths in the BNT162b2 group and 14 in the placebo group (which included 12 in the BNT162b2 group and 9 in the placebo group from 1 month after Dose 2 to the unblinding date); none of these deaths were assessed by the investigator as related to study intervention.

- For the subset of HIV-positive participants, IRs of AEs showed generally similar trends as the overall population.

- For the subset of participants who were SARS-CoV-2 positive at baseline, IR of AEs followed similar trends found in the overall AE analysis.

12.2.5.3. Open-Label Follow-Up Period – Original BNT162b2 Participants

- Most AEs were mild or moderate in severity. The IR of at least 1 AE in the BNT162b2 group was 8.8 per 100 PY, which was markedly reduced relative to any AEs reported from Dose 1 to the unblinding date (83.2 per 100 PY).

- One participant in the younger age group had 1 SAE of myocardial infarction assessed by the investigator as related to study intervention.

- The IR of participants withdrawn because of AEs was 0.1 per 100 PY. There were 3 additional deaths (road traffic accident, lung metastases, and myocardial infarction); none of these deaths were assessed by the investigator as related to study intervention.

12.2.5.4. Blinded Placebo-Controlled and Open-Label Follow-Up Periods to 6 Months After Dose 2 – Original BNT162b2 Participants

For the 12,006 participants with at least 6 months of follow-up time:

- Most AEs were mild or moderate in severity. The number of participants with AEs was 28.8%.

- The number of participants with SAEs increased from 0.5% (Dose 1 to 1 month after the Dose 2) to 1.1% (1 month after Dose 2 to 6 months after Dose 2). However, the number

of related SAEs remained low. There were 2 participants with related SAEs reported: SIRVA, erroneously administered into or near the shoulder joint capsule reported from Dose 1 to 1 month after Dose 2; and paraesthesia, reported from 1 month after Dose 2 to 6 months after Dose 2.

- There were no deaths.
- AE frequencies decreased over time from 1 month after the second dose to 6 months after the second dose without an increase by SOC.
- Overall, BNT162b2 at 30 μg was well tolerated with at least 6 months of follow-up after Dose 2.

12.2.5.5. Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2

For the 19,525 original placebo participants who then received BNT162b2 after unblinding:

- Most AEs were mild or moderate in severity. The IR of at least 1 AE was 205.4 per 100 PY, which was greater than the IR in original BNT162b2 participants (83.2 per 100 PY), due to the shorter exposure time in original placebo participants compared with original BNT162b2 participants (23.8 per 100 PY vs 83.4 per 100 PY).
- Overall, AEs after receipt of BNT162b2 in placebo participants showed a similar safety profile as the observed in the participant originally randomized to BNT162b2.
- One participant had 1 SAE of anaphylactoid reaction 2 days after receiving BNT162b2 that was assessed as related to study intervention.
- The IR of participants withdrawn because of AEs was 0.8 per 100 PY. There were 2 deaths (cardiorespiratory arrest and completed suicide); none of these deaths were assessed by the investigator as related to study intervention.

12.2.5.6. Open-Label Follow-Up Period – Original Placebo Participants, had COVID-19 Occurrence After Dose 1, and Then Received BNT162b2

- A similar safety profile is observed for this population compared to those originally randomized to BNT162b2.
- SAE rates were similar in these participants compared to those originally randomized to BNT162b2.

13. DISCUSSION AND OVERALL CONCLUSIONS

13.1. Discussion

13.1.1. Phase 1

BNT162b2 at 30 µg induced a robust immune response at 1 month after Dose 2 in both younger and older adults. The immune responses decreased relative to those observed at 1 month after Dose 2, but remained higher than values observed at prevaccination and compared with the placebo group . BNT162b2 30 µg was safe and well tolerated up to 6 months after Dose 2, consistent with the safety profile previously reported in the final analysis interim C4591001 CSR dated 03 December 2020.

13.1.2. Phase 2/3

Efficacy was demonstrated for the primary and secondary efficacy endpoints and reported in the final analysis interim C4591001 CSR dated 03 December 2020. Estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 in participants without evidence of SARS-CoV-2 infection before and during vaccination regimen was 95.0% (95% credible interval: 90.3%, 97.6%), with 8 COVID-19 cases in the BNT162b2 group compared to 162 COVID-19 cases in the placebo group. For the updated descriptive analysis of efficacy in participants meeting the same criteria, estimated VE was 91.3% (95% CI: 89.0%. 93.2%), with 77 cases in the BNT162b2 group and 850 cases in the placebo group. Results were similar among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen.

The estimated VE against COVID cases occurring from 7 days after Dose 2 was 91.2% and remained high ≥4 months after Dose 2 (83.7%) among the all-available (modified intention-to-treat) population regardless of evidence of infection before or during the vaccination regimen. High estimated VE was also observed against severe cases of COVID-19 using the FDA definition of severe (95.3%) and the CDC definition of severe (100.0%) both in participants without and in participants with or without evidence of prior infection prior to 7 days after Dose 2. Moreover, BNT162b2 uniformly showed high efficacy irrespective of age, race, sex, ethnicity, comorbidity status (including participants with a history of malignancies) and by country of origin. Importantly, the B.1.351 variant in South Africa is known to be the predominant variant when efficacy was being measured in the study. The observed 100.0% efficacy shown in South Africa suggests that BNT162b2 likely protects against this important variant. Sequencing is in progress to determine what strains were present in the breakthrough COVID-19 cases reported in the BNT162b2 group compared with placebo.

In the Phase 2/3 portion of the study, safety data in participants ≥16 years of age are available for ~44,000 participants, of which ~12,000 had a total exposure time of ≥6 months after Dose 2 of BNT162b2 at the time of the data cutoff date (13 March 2021). The prompted local and systemic reactogenicity profile was consistent with results results previously reported in the final analysis interim C4591001 CSR dated 03 December 2020. Increases in systemic reactogenicity were observed after Dose 2 compared with after Dose 1. Older adults generally reported milder and lower frequencies of local and systemic reactogenicity events compared with younger adults. Most prompted local and systemic reactogenicity events

were short-lived, and only 1 Grade 4 event of fever lasting 1 day was reported. Median onset day for most local and systemic reactions occurred within the first 3 days following vaccination and resolved with median durations within 3 days without sequela. This pattern of reactogenicity is also observed in participants with stable HIV infection.

The Phase 2/3 AE profile of BNT162b2 at 30 μg was also consistent with results previously reported in the final analysis interim C4591001 CSR dated 03 December 2020. During the blinded placebo-controlled follow-up period, AEs from Dose 1 to 1 month after Dose 2 and from Dose 1 to the unblinding date of AEs were mostly mild or moderate with higher frequencies/IRs in the BNT162b2 group than in the placebo group. Since many AEs were in SOCs that contain AEs consistent with reactogenicity events, an analyses of AEs within 7 days after each dose showed that the AEs during this time period in the BNT162b2 group were largely attributed to reactogenicity events. For participants who did not have an e-diary, they reported their experience as AEs. As such they were not prompted to report specific terms within 7 days after either dose. The analysis of AEs reported in the placebo-controlled period of the study identified several terms that are reported more frequently in the vaccine group than placebo. These include pain in the extremity, decreased appetite, lethargy, asthenia, malaise, night sweats and hyperhidrosis. The majority of the events started soon after vaccination and for most of these events the rates were higher after Dose 2 than Dose 1. This suggest that these terms describe the partipants unprompted experience of reactogenicity within 7 days after each dose.

Cumulative safety data for 12,006 Phase 2/3 participants with at least 6 months follow-up after Dose 2 for participants originally randomized to BNT162b2, comprising the combined blinded and open-label periods, showed no new safety signals arising from longer-term follow-up. Importantly, the additional follow-up time allowed for more opportunity to collect SAEs. However, related SAEs did not increase during this time period and it remained very low.

Similarly, open-label observational follow-up of original BNT162b2 participants after unblinding and original placebo participants who then received BNT162b2 after unblinding showed no new safety signals or concerns.

CDC-defined AESI were evaluated in the blinded placebo-controlled follow-up period. MedDRA search terms were used to identify AE that fit the medical concept and then the resultant events were evaluated for numerical imbalances where the events were higher in the vaccine group than placebo and then narratives were provide only for those AESIs with the numerical imbalance.

The analysis showed that most AESI are reported in higher numbers in the placebo group or were equal in the BNT162b2 and placebo groups. The allergic reaction evaluation did not identify analphylaxis reactions associated with the vaccine. Note, there was an anaphylactoid reaction reported 2 days after receiving open-label BNT162b2(Dose 3) in an originally placebo-randomized participant who was unblinded to receive BNT162b2, and who had a significant ongoing medical history of drug hypersensitivity and other allergies. For angioedema the frequencies were low and very similar in the BNT162b2 (0.14%) and placebo (0.13%) groups. For hypersensitivity reactions most of the reactions were due to

rash, rash maculo-papular, and rash papular and were not reported within 7 days after either dose. Overall, the evaluation of cases reporting allergic reactions supports standard precautions for allergic reactions should be taken in the clinic when vaccinating.

There were 2 cases of optic neuritis reported in the BNT162b2 group that occurred 79 and 81 days after vaccination with BNT162b2. Both were considered not related to vaccine. Given the few number of events, non-proximity to vaccination and investigators judgement, there is not enough information to assess causality at this time.

AESI evaluations were performed for blinded placebo-controlled follow-up. There were 4 cases of Bell's palsy reported in the BNT162b2 group (previously reported in the final analysis interim C4591001 CSR dated 03 December 2020). Since then there have been 2 additional cases in the placebo group during blinded placebo-controlled follow-up, and there have been 4 additional cases of Bell's palsy identified during the open-label follow-up period that are included for completeness: 3 cases in placebo participants who became unblinded and were then vaccinated with BNT162b2, and 1 participant who was originally randomized to BNT162b2, was unblinded, and developed Bell's palsy 154 days after the second dose of BNT162b2.

There were 2 cases of encephalopathy in the vaccine group and none in the placebo. Both cases had clear etiologic causes (uremia and toxic encephalopathy after a fall with hypotension, diverticulum, and a urinary tract infection) and hence are not associated with the vaccine.

SAEs assessed by the investigator as related to study intervention were:

- 5 SAEs total during blinded placebo-controlled follow-up: 3 SAEs (lymphadenopathy, shoulder injury related to vaccine administration [SIRVA], and ventricular arrhythmia) in the BNT162b2 group from Dose 1 to 1 month after Dose 2, and 2 SAEs (paraesthesia [BNT162b2 group] and psoriatic arthropathy [placebo]) to the unblinding date.

- 2 SAEs total during open-label follow-up: 1 SAE of myocardial infarction in 1 original BNT162b2 participant and 1 SAE of anaphylactoid reaction in 1 original placebo participant who then received BNT162b2.

During blinded placebo-controlled follow-up, there were a total of 15 deaths in the BNT162b2 group and 14 deaths in the placebo group, with 3 and 5 deaths occurring from Dose 1 to 1 month after Dose 2 in the BNT162b2 and placebo groups, respectively. Of these, there were 2 deaths in participants (1 BNT162b2 and 1 placebo) with confirmed stable HIV disease.

During the open-label follow-up period, there were 3 deaths in original BNT162b2 participants and 2 deaths in original placebo participants who then received BNT162b2.

None of the deaths were assessed by the investigator as related to study intervention.

Subgroup analyses by baseline SARS-CoV-2 status, ethnicity, race, and sex did not reveal any clinically meaningful differences in safety results. Analysis of participants originally randomized to placebo who then received BNT162b2 (Dose 3) by demographic subgroups and based on prior evidence of SARS-CoV-2 infection or prior COVID-19 did not suggest any safety concerns. Importantly, there were 5 cases of individuals ≥16 years of age randomized to placebo who developed COVID-19 twice (ie, a new clinical episode with different symptoms and separated by at least a month apart confirmed by NAAT by the central laboratory). Each of these participants received BNT162b2 after unblinding without reported safety events. Taken together individuals who had evidence of infection with SARS-CoV-2 at baseline or developed COVID-19 once or twice before receiving BNT162b2 tolerated the vaccine well.

Overall, the available long-term evidence from the Phase 2/3 continues to support the safety, tolerability, and effectiveness of BNT162b2 at 30 μg administered as a 2-dose regimen (21 days apart) to individuals ≥16 years of age for the prevention of COVID-19.

13.2. Overall Conclusions

- In Phase 1, BNT162b2 at 30 μg induced a robust immune response 1 month after Dose 2 which decreased relative to those observed at 1 month after Dose 2, but remained higher than values observed at prevaccination and compared with the placebo group. The safety profile was satisfactory in both younger and older adults up to the unblinding date (approximately 6 months after Dose 2).

- In Phase 2/3, updated efficacy analysis continued to show that BNT162b2 at 30 μg provided a high level of protection against COVID-19. This was shown in participants irrespective of evidence of prior infection with SARS-CoV-2 and across various demographic subgroups. Severe cases were observed predominantly in the placebo group.

- The tolerability and safety profile of BNT162b2 30 μg in participants ≥16 years of age at up to 6 months after Dose 2 was acceptable throughout the follow-up period (to the data cutoff date) and consistent with results previously reported.

14. TABLES AND FIGURES

In this ongoing study, tables summarizing participant withdrawals may include some participants who were reported as withdrawn but remain in the study and are continuing to be evaluated. These participants are documented in the Errata.

SUPPLEMENTAL TABLES

Phase 1

Conduct of Study

14.1. Disposition of All Randomized Subjects – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo

	Vaccine Group (as Randomized)			
	18-55 Years of Age		65-85 Years of Age	
	BNT162b2 (30 µg) (N[a]=12) n[b] (%)	Placebo (N[a]=3) n[b] (%)	BNT162b2 (30 µg) (N[a]=12) n[b] (%)	Placebo (N[a]=3) n[b] (%)
Randomized	12 (100.0)	3 (100.0)	12 (100.0)	3 (100.0)
Original blinded placebo-controlled follow-up period				
Vaccinated	12 (100.0)	3 (100.0)	12 (100.0)	3 (100.0)
Dose 1	12 (100.0)	3 (100.0)	12 (100.0)	3 (100.0)
Dose 2	12 (100.0)	3 (100.0)	12 (100.0)	3 (100.0)
Completed 1-month post–Dose 2 visit	12 (100.0)	3 (100.0)	12 (100.0)	3 (100.0)
Completed 6-month post–Dose 2 visit	1 (8.3)	0	2 (16.7)	0
Unblinded before 6-month post–Dose 2 visit	11 (91.7)	3 (100.0)	10 (83.3)	3 (100.0)
Open-label follow-up period				
Originally randomized to BNT162b2	12 (100.0)		12 (100.0)	
Completed 6-month post–Dose 2 visit	11 (91.7)		10 (83.3)	
Originally randomized to placebo		3 (100.0)		3 (100.0)
Received Dose 3 (first dose of BNT162b2 [30 µg])		3 (100.0)		3 (100.0)
Received Dose 4 (second dose of BNT162b2 [30 µg])		3 (100.0)		3 (100.0)
Completed 1-month post–Dose 4 visit		3 (100.0)		3 (100.0)

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.
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(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
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14.2. Immunogenicity Populations – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo

	Vaccine Group (as Randomized)			
	18-55 Years of Age		65-85 Years of Age	
	BNT162b2 (30 µg)	Placebo	BNT162b2 (30 µg)	Placebo
	n[a] (%)	n[a] (%)	n[a] (%)	n[a] (%)
Randomized[b]	12 (100.0)	3 (100.0)	12 (100.0)	3 (100.0)
Dose 1 all-available immunogenicity population	12 (100.0)	3 (100.0)	12 (100.0)	3 (100.0)
Dose 1 evaluable immunogenicity population	12 (100.0)	2 (66.7)	11 (91.7)	3 (100.0)
Subjects excluded from Dose 1 evaluable immunogenicity population	0	1 (33.3)	1 (8.3)	0
Reason for exclusion[c]				
Not eligible for the study at randomization	0	1 (33.3)	1 (8.3)	0
Had major protocol deviation(s) as determined by the clinician	0	1 (33.3)	1 (8.3)	0
Dose 2 all-available immunogenicity population	12 (100.0)	3 (100.0)	12 (100.0)	3 (100.0)
Dose 2 evaluable immunogenicity population	11 (91.7)	2 (66.7)	11 (91.7)	3 (100.0)
Subjects excluded from Dose 2 evaluable immunogenicity population	1 (8.3)	1 (33.3)	1 (8.3)	0
Reason for exclusion[c]				
Not eligible for the study at randomization	0	1 (33.3)	1 (8.3)	0
Did not have blood collection within 6-8 days after Dose 2	1 (8.3)	0	0	0
Had major protocol deviation(s) as determined by the clinician	0	1 (33.3)	1 (8.3)	0

a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.
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(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adva s008 imm pop b2 p1

14.3. Immunogenicity Blood Samples Drawn – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – All Randomized Subjects

	Vaccine Group (as Randomized)			
	18-55 Years of Age		65-85 Years of Age	
	BNT162b2 (30 µg) (N[a]=12) n[b] (%)	Placebo (N[a]=3) n[b] (%)	BNT162b2 (30 µg) (N[a]=12) n[b] (%)	Placebo (N[a]=3) n[b] (%)
Randomized	12 (100.0)	3 (100.0)	12 (100.0)	3 (100.0)
Not vaccinated	0	0	0	0
Vaccinated at Dose 1	12 (100.0)	3 (100.0)	12 (100.0)	3 (100.0)
Blood sample drawn before Dose 1[c]	12 (100.0)	3 (100.0)	12 (100.0)	3 (100.0)
Blood sample drawn 7 days after Dose 1[c]				
6 to 8 Days	12 (100.0)	3 (100.0)	12 (100.0)	3 (100.0)
Blood sample drawn 21 days after Dose 1 (before Dose 2)[c]				
19 to 23 Days	12 (100.0)	3 (100.0)	12 (100.0)	3 (100.0)
Vaccinated at Dose 2	12 (100.0)	3 (100.0)	12 (100.0)	3 (100.0)
Blood sample drawn 7 days after Dose 2[c]				
<6 Days	1 (8.3)	0	0	0
6 to 8 Days	11 (91.7)	3 (100.0)	12 (100.0)	3 (100.0)
Blood sample drawn 14 days after Dose 2[c]				
12 to 16 Days	10 (83.3)	3 (100.0)	12 (100.0)	3 (100.0)
Not obtained	2 (16.7)	0	0	0
Blood sample drawn 1 month after Dose 2[c]				
<28 Days	1 (8.3)	0	0	0
28 to 35 Days	11 (91.7)	3 (100.0)	12 (100.0)	2 (66.7)
Not obtained	0	0	0	1 (33.3)
Blood sample drawn 6 months after Dose 2[c]				
<175 Days	1 (8.3)	0	1 (8.3)	0
175 to 189 Days	11 (91.7)	0	11 (91.7)	0
Not obtained	0	3 (100.0)	0	3 (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.
c. Protocol-specified time frame.
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Immunogenicity

14.4. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		18-55 Years of Age				65-85 Years of Age			
		BNT162b2 (30 µg)		Placebo		BNT162b2 (30 µg)		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	2	10.0 (10.0, 10.0)	11	10.0 (10.0, 10.0)	3	10.0 (10.0, 10.0)
	1/Day 21	12	29.1 (14.2, 59.6)	2	10.0 (10.0, 10.0)	11	16.8 (10.9, 25.8)	3	10.0 (10.0, 10.0)
	2/1 Month	11	179.2 (102.3, 313.8)	2	10.0 (10.0, 10.0)	11	151.6 (58.6, 392.1)	2	10.0 (10.0, 10.0)
	2/6 Months	10	54.7 (24.7, 121.1)	0	NE (NE, NE)	11	29.0 (19.4, 43.5)	0	NE (NE, NE)
S1-binding IgG level assay (U/mL)	1/Prevax	12	0.6 (0.6, 0.6)	2	0.6 (0.6, 0.6)	11	0.6 (0.6, 0.6)	3	0.9 (0.2, 4.9)
	1/Day 21	12	565.5 (372.5, 858.5)	2	0.6 (0.6, 0.6)	11	352.2 (160.1, 775.2)	3	1.0 (0.1, 6.9)
	2/1 Month	11	5925.6 (4457.2, 7877.7)	2	0.6 (0.6, 0.6)	11	4835.4 (2756.1, 8483.3)	2	1.4 (0.0, 47501.5)
	2/6 Months	10	960.8 (483.8, 1908.1)	0	NE (NE, NE)	11	559.6 (363.0, 862.8)	0	NE (NE, NE)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation;
NE = not estimable; NT50 = 50% neutralizing titer; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: The Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2 and the Dose 2 evaluable population was used for time points after Dose 2.
Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.
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, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentrations 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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14.5. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		18-55 Years of Age				65-85 Years of Age			
		BNT162b2 (30 µg)		Placebo		BNT162b2 (30 µg)		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	3	10.0 (10.0, 10.0)	12	10.0 (10.0, 10.0)	3	10.0 (10.0, 10.0)
	1/Day 21	12	29.1 (14.2, 59.6)	3	10.0 (10.0, 10.0)	12	16.1 (10.8, 24.0)	3	10.0 (10.0, 10.0)
	2/1 Month	12	180.1 (108.7, 298.7)	3	10.0 (10.0, 10.0)	12	145.0 (61.2, 343.5)	2	10.0 (10.0, 10.0)
	2/6 Months	11	52.7 (25.8, 107.6)	0	NE (NE, NE)	12	28.5 (19.7, 41.1)	0	NE (NE, NE)
S1-binding IgG level assay (U/mL)	1/Prevax	12	0.6 (0.6, 0.6)	3	0.6 (0.6, 0.6)	12	0.6 (0.6, 0.6)	3	0.9 (0.2, 4.9)
	1/Day 21	12	565.5 (372.5, 858.5)	3	0.6 (0.6, 0.6)	12	402.6 (186.5, 869.4)	3	1.0 (0.1, 6.9)
	2/1 Month	12	6127.4 (4690.9, 8003.9)	3	0.6 (0.6, 0.6)	12	5108.5 (3033.7, 8602.4)	2	1.4 (0.0, 47501.5)
	2/6 Months	11	934.8 (505.7, 1727.8)	0	NE (NE, NE)	12	601.4 (394.6, 916.5)	0	NE (NE, NE)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation;
NE = not estimable; NT50 = 50% neutralizing titer; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: The Dose 1 all-available population was used for time points after Dose 1 and before Dose 2 and the Dose 2 all-available population was used for time points after Dose 2.
Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.
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, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentrations 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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(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adva_s001_gm_b2_aai_p1

14.6. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		18-55 Years of Age				65-85 Years of Age			
		BNT162b2 (30 µg)		Placebo		BNT162b2 (30 µg)		Placebo	
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 - NT50 (titer)	1/Day 21	12	2.9 (1.4, 6.0)	2	1.0 (1.0, 1.0)	11	1.7 (1.1, 2.6)	3	1.0 (1.0, 1.0)
	2/1 Month	11	17.9 (10.2, 31.4)	2	1.0 (1.0, 1.0)	11	15.2 (5.9, 39.2)	2	1.0 (1.0, 1.0)
	2/6 Months	10	5.5 (2.5, 12.1)	0	NE (NE, NE)	11	2.9 (1.9, 4.3)	0	NE (NE, NE)
S1-binding IgG level assay (U/mL)	1/Day 21	12	893.0 (588.2, 1355.7)	2	1.0 (1.0, 1.0)	11	556.3 (252.7, 1224.2)	3	1.1 (0.8, 1.4)
	2/1 Month	11	9357.4 (7038.6, 12440.1)	2	1.0 (1.0, 1.0)	11	7635.8 (4352.3, 13396.5)	2	1.3 (0.1, 26.9)
	2/6 Months	10	1517.2 (764.0, 3013.2)	0	NE (NE, NE)	11	883.7 (573.2, 1362.5)	0	NE (NE, NE)

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NE = not estimable;
NT50 = 50% neutralizing titer; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: The Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2 and the Dose 2 evaluable population was used for time points after Dose 2.
Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay both before vaccination and at the given dose/sampling time point.
c. GMFRs and the corresponding 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.
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./nda2 unblinded/C4591001 BLA/adva s002 gmfr b2 eval p1

14.7. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		18-55 Years of Age				65-85 Years of Age			
		BNT162b2 (30 µg)		Placebo		BNT162b2 (30 µg)		Placebo	
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 - NT50 (titer)	1/Day 21	12	2.9 (1.4, 6.0)	3	1.0 (1.0, 1.0)	12	1.6 (1.1, 2.4)	3	1.0 (1.0, 1.0)
	2/1 Month	12	18.0 (10.9, 29.9)	3	1.0 (1.0, 1.0)	12	14.5 (6.1, 34.4)	2	1.0 (1.0, 1.0)
	2/6 Months	11	5.3 (2.6, 10.8)	0	NE (NE, NE)	12	2.8 (2.0, 4.1)	0	NE (NE, NE)
S1-binding IgG level assay (U/mL)	1/Day 21	12	893.0 (588.2, 1355.7)	3	1.0 (1.0, 1.0)	12	635.8 (294.5, 1372.9)	3	1.1 (0.8, 1.4)
	2/1 Month	12	9676.2 (7407.6, 12639.5)	3	1.0 (1.0, 1.0)	12	8067.1 (4790.6, 13584.5)	2	1.3 (0.1, 26.9)
	2/6 Months	11	1476.1 (798.6, 2728.5)	0	NE (NE, NE)	12	949.7 (623.2, 1447.4)	0	NE (NE, NE)

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NE = not estimable;
NT50 = 50% neutralizing titer; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: The Dose 1 all-available population was used for time points after Dose 1 and before Dose 2 and the Dose 2 all-available population was used for time points after Dose 2.
Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay both before vaccination and at the given dose/sampling time point.
c. GMFRs and the corresponding 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.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:57)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adva s002 gmfr b2 aai p1

14.8. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		18-55 Years of Age				65-85 Years of Age			
		BNT162b2 (30 µg)		Placebo		BNT162b2 (30 µg)		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	15.792 (15.792, 15.792)	2	15.792 (15.792, 15.792)	11	15.792 (15.792, 15.792)	3	10.736 (2.041, 56.473)
	1/Day 21	12	0.051 (0.026, 0.101)	2	15.792 (15.792, 15.792)	11	0.048 (0.023, 0.101)	3	10.058 (1.444, 70.063)
	2/1 Month	11	0.030 (0.018, 0.050)	2	15.792 (15.792, 15.792)	11	0.031 (0.017, 0.058)	2	6.962 (0.000, 230230.605)
	2/6 Months	10	0.057 (0.045, 0.073)	0	NE (NE, NE)	11	0.052 (0.042, 0.063)	0	NE (NE, NE)

Abbreviations: GMR = geometric mean ratio; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NE = not estimable;
NT50 = 50% neutralizing titer; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: The Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2 and the Dose 2 evaluable population was used for time points after Dose 2.
Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate results for both the specified assays at the given dose/sampling time point.
c. GMRs and 2-sided CIs were calculated by exponentiating the mean differences in the logarithms of the assay 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: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:57)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adva s004 gm b2 eval p1

14.9. Summary of Geometric Mean Ratios – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		18-55 Years of Age				65-85 Years of Age			
		BNT162b2 (30 µg)		Placebo		BNT162b2 (30 µg)		Placebo	
Comparison	Dose/Sampling Time Point[a]	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])	n[b]	GMR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer) to S1-binding IgG level assay (U/mL)	1/Prevax	12	15.792 (15.792, 15.792)	3	15.792 (15.792, 15.792)	12	15.792 (15.792, 15.792)	3	10.736 (2.041, 56.473)
	1/Day 21	12	0.051 (0.026, 0.101)	3	15.792 (15.792, 15.792)	12	0.040 (0.018, 0.087)	3	10.058 (1.444, 70.063)
	2/1 Month	12	0.029 (0.019, 0.046)	3	15.792 (15.792, 15.792)	12	0.028 (0.016, 0.051)	2	6.962 (0.000, 230230.605)
	2/6 Months	11	0.056 (0.045, 0.070)	0	NE (NE, NE)	12	0.047 (0.036, 0.062)	0	NE (NE, NE)

Abbreviations: GMR = geometric mean ratio; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NE = not estimable;
NT50 = 50% neutralizing titer; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: The Dose 1 all-available population was used for time points after Dose 1 and before Dose 2 and the Dose 2 all-available population was used for time points after Dose 2.
Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate results for both the specified assays at the given dose/sampling time point.
c. GMRs and 2-sided CIs were calculated by exponentiating the mean differences in the logarithms of the assay 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: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:57)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adva s004 gm b2 aai p1

14.10. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		18-55 Years of Age				65-85 Years of Age			
		BNT162b2 (30 µg)		Placebo		BNT162b2 (30 µg)		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 21	12	6 (50.0) (21.1, 78.9)	2	0 (0.0) (0.0, 84.2)	11	1 (9.1) (0.2, 41.3)	3	0 (0.0) (0.0, 70.8)
	2/1 Month	11	11 (100.0) (71.5, 100.0)	2	0 (0.0) (0.0, 84.2)	11	9 (81.8) (48.2, 97.7)	2	0 (0.0) (0.0, 84.2)
	2/6 Months	10	6 (60.0) (26.2, 87.8)	0	0 (NE) (NE, NE)	11	3 (27.3) (6.0, 61.0)	0	0 (NE) (NE, NE)
S1-binding IgG level assay (U/mL)	1/Day 21	12	12 (100.0) (73.5, 100.0)	2	0 (0.0) (0.0, 84.2)	11	11 (100.0) (71.5, 100.0)	3	0 (0.0) (0.0, 70.8)
	2/1 Month	11	11 (100.0) (71.5, 100.0)	2	0 (0.0) (0.0, 84.2)	11	11 (100.0) (71.5, 100.0)	2	0 (0.0) (0.0, 84.2)
	2/6 Months	10	10 (100.0) (69.2, 100.0)	0	0 (NE) (NE, NE)	11	11 (100.0) (71.5, 100.0)	0	0 (NE) (NE, NE)

Abbreviations: IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NE = not estimable; NT50 = 50% neutralizing titer;
S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: The Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2 and the Dose 2 evaluable population was used for time points after Dose 2.
Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.
a. Protocol-specified timing for blood sample collection.
b. N = number of subjects with valid and determinate assay results for the specified assay both before vaccination and at the given dose/sampling time point. These values are the denominators for the percentage calculations.
c. n = Number of subjects with ≥4-fold rise from before vaccination for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
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(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adva s003 fr4 b2 eval p1

14.11. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – All-Available Immunogenicity Population

		Vaccine Group (as Randomized)							
		18-55 Years of Age				65-85 Years of Age			
		BNT162b2 (30 µg)		Placebo		BNT162b2 (30 µg)		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 21	12	6 (50.0) (21.1, 78.9)	3	0 (0.0) (0.0, 70.8)	12	1 (8.3) (0.2, 38.5)	3	0 (0.0) (0.0, 70.8)
	2/1 Month	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)	12	10 (83.3) (51.6, 97.9)	2	0 (0.0) (0.0, 84.2)
	2/6 Months	11	6 (54.5) (23.4, 83.3)	0	0 (NE) (NE, NE)	12	3 (25.0) (5.5, 57.2)	0	0 (NE) (NE, NE)
S1-binding IgG level assay (U/mL)	1/Day 21	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)
	2/1 Month	12	12 (100.0) (73.5, 100.0)	3	0 (0.0) (0.0, 70.8)	12	12 (100.0) (73.5, 100.0)	2	0 (0.0) (0.0, 84.2)
	2/6 Months	11	11 (100.0) (71.5, 100.0)	0	0 (NE) (NE, NE)	12	12 (100.0) (73.5, 100.0)	0	0 (NE) (NE, NE)

Abbreviations: IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NE = not estimable; NT50 = 50% neutralizing titer;
S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: The Dose 1 all-available population was used for time points after Dose 1 and before Dose 2 and the Dose 2 all-available population was used for time points after Dose 2.
Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.
a. Protocol-specified timing for blood sample collection.
b. N = number of subjects with valid and determinate assay results for the specified assay both before vaccination and at the given dose/sampling time point. These values are the denominators for the percentage calculations.
c. n = Number of subjects with ≥4-fold rise from before vaccination for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:57)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adva s003 fr4 b2 aai p1

Adverse Events

14.12. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Unblinding Date – Phase 1 – BNT162b2 (30 µg)/Placebo – Safety Population

	Vaccine Group (as Administered)			
	18-55 Years of Age		65-85 Years of Age	
Adverse Event	BNT162b2 (30 µg) (N^a=12) n^b (%)	Placebo (N^a=3) n^b (%)	BNT162b2 (30 µg) (N^a=12) n^b (%)	Placebo (N^a=3) n^b (%)
Any event	6 (50.0)	0	3 (25.0)	0
Related[c]	3 (25.0)	0	0	0
Severe	2 (16.7)	0	1 (8.3)	0
Life-threatening	0	0	0	0
Any serious adverse event	1 (8.3)	0	0	0
Related[c]	0	0	0	0
Severe	1 (8.3)	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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (06:50)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s091_b2_p1

14.13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 1 – BNT162b2 (30 µg)/Placebo – Safety Population

	Vaccine Group (as Administered)							
	18-55 Years of Age				65-85 Years of Age			
	BNT162b2 (30 µg) (N^a=12)		Placebo (N^a=3)		BNT162b2 (30 µg) (N^a=12)		Placebo (N^a=3)	
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 event	6 (50.0)	(21.1, 78.9)	0	(0.0, 70.8)	3 (25.0)	(5.5, 57.2)	0	(0.0, 70.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)	0	(0.0, 26.5)	0	(0.0, 70.8)
Lymphadenopathy	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)	0	(0.0, 26.5)	0	(0.0, 70.8)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)	0	(0.0, 26.5)	0	(0.0, 70.8)
Injection site pain	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)	0	(0.0, 26.5)	0	(0.0, 70.8)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)	0	(0.0, 26.5)	0	(0.0, 70.8)
Fall	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)	0	(0.0, 26.5)	0	(0.0, 70.8)
Tendon injury	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)	0	(0.0, 26.5)	0	(0.0, 70.8)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Muscle spasms	0	(0.0, 26.5)	0	(0.0, 70.8)	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Pain in extremity	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)	0	(0.0, 26.5)	0	(0.0, 70.8)
NERVOUS SYSTEM DISORDERS	3 (25.0)	(5.5, 57.2)	0	(0.0, 70.8)	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Dizziness	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)	0	(0.0, 26.5)	0	(0.0, 70.8)
Migraine	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)	0	(0.0, 26.5)	0	(0.0, 70.8)
Neuritis	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)	0	(0.0, 26.5)	0	(0.0, 70.8)
Sciatica	0	(0.0, 26.5)	0	(0.0, 70.8)	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
VASCULAR DISORDERS	0	(0.0, 26.5)	0	(0.0, 70.8)	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)
Hypertension	0	(0.0, 26.5)	0	(0.0, 70.8)	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)

14.13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 1 – BNT162b2 (30 µg)/Placebo – Safety Population

	Vaccine Group (as Administered)			
	18-55 Years of Age		65-85 Years of Age	
	BNT162b2 (30 µg) (N^a=12)	Placebo (N^a=3)	BNT162b2 (30 µg) (N^a=12)	Placebo (N^a=3)
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)

Note: MedDRA (v23.1) 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 category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (06:49)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 1md2 soc b2 p1

14.14. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 1 – BNT162b2 (30 µg)/Placebo – Safety Population

	Vaccine Group (as Administered)							
	18-55 Years of Age				65-85 Years of Age			
	BNT162b2 (30 µg) (N[a]=12)		Placebo (N[a]=3)		BNT162b2 (30 µg) (N[a]=12)		Placebo (N[a]=3)	
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 event	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)	0	(0.0, 26.5)	0	(0.0, 70.8)
NERVOUS SYSTEM DISORDERS	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)	0	(0.0, 26.5)	0	(0.0, 70.8)
Neuritis	1 (8.3)	(0.2, 38.5)	0	(0.0, 70.8)	0	(0.0, 26.5)	0	(0.0, 70.8)

Note: MedDRA (v23.1) 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 category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (06:51)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_6md2_sae_b2_p1

Phase 2/3

Conduct of Study

14.15. Disposition of All Randomized Subjects, by Age Group – Phase 2/3 Subjects ≥16 Years of Age Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=13104) n[b] (%)	Placebo (N[a]=13132) n[b] (%)	Total (N[a]=26236) n[b] (%)
Randomized	13104 (100.0)	13132 (100.0)	26236 (100.0)
Not vaccinated	31 (0.2)	32 (0.2)	63 (0.2)
Original blinded placebo-controlled follow-up period			
Vaccinated	13073 (99.8)	13100 (99.8)	26173 (99.8)
Dose 1	13073 (99.8)	13100 (99.8)	26173 (99.8)
Dose 2	12802 (97.7)	12825 (97.7)	25627 (97.7)
Discontinued from original blinded placebo-controlled vaccination period[c]	278 (2.1)	388 (3.0)	666 (2.5)
Reason for discontinuation			
Lost to follow-up	132 (1.0)	128 (1.0)	260 (1.0)
Withdrawal by subject	81 (0.6)	117 (0.9)	198 (0.8)
No longer meets eligibility criteria	23 (0.2)	94 (0.7)	117 (0.4)
Adverse event	15 (0.1)	12 (0.1)	27 (0.1)
Pregnancy	6 (0.0)	6 (0.0)	12 (0.0)
Protocol deviation	2 (0.0)	6 (0.0)	8 (0.0)
Physician decision	3 (0.0)	4 (0.0)	7 (0.0)
Medication error without associated adverse event	2 (0.0)	1 (0.0)	3 (0.0)
Death	0	2 (0.0)	2 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	13 (0.1)	18 (0.1)	31 (0.1)
Unblinded before 1-month post–Dose 2 visit	175 (1.3)	182 (1.4)	357 (1.4)
Completed 1-month post–Dose 2 visit	12586 (96.0)	12555 (95.6)	25141 (95.8)
Withdrawn from the study	259 (2.0)	349 (2.7)	608 (2.3)
Withdrawn after Dose 1 and before Dose 2	138 (1.1)	155 (1.2)	293 (1.1)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	85 (0.6)	104 (0.8)	189 (0.7)
Withdrawn after 1-month post–Dose 2 visit	36 (0.3)	90 (0.7)	126 (0.5)
Reason for withdrawal from the study			
Lost to follow-up	150 (1.1)	160 (1.2)	310 (1.2)
Withdrawal by subject	88 (0.7)	147 (1.1)	235 (0.9)
Protocol deviation	3 (0.0)	20 (0.2)	23 (0.1)
Adverse event	6 (0.0)	3 (0.0)	9 (0.0)

14.15. Disposition of All Randomized Subjects, by Age Group – Phase 2/3 Subjects ≥16 Years of Age Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=13104) n[b] (%)	Placebo (N[a]=13132) n[b] (%)	Total (N[a]=26236) n[b] (%)
Death	3 (0.0)	5 (0.0)	8 (0.0)
Physician decision	2 (0.0)	3 (0.0)	5 (0.0)
No longer meets eligibility criteria	1 (0.0)	2 (0.0)	3 (0.0)
Pregnancy	0	1 (0.0)	1 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	4 (0.0)	8 (0.1)	12 (0.0)
Open-label follow-up period			
Originally randomized to BNT162b2	11858 (90.5)		
Received Dose 2/unplanned dose	61 (0.5)		
Completed 1-month post–Dose 2 visit	141 (1.1)		
Completed 6-month post–Dose 2 visit	3341 (25.5)		
Withdrawn from the study	58 (0.4)		
Withdrawn before 6-month post–Dose 2 visit	56 (0.4)		
Withdrawn after 6-month post–Dose 2 visit	2 (0.0)		
Reason for withdrawal from the study			
Withdrawal by subject	32 (0.2)		
Protocol deviation	17 (0.1)		
Lost to follow-up	3 (0.0)		
Physician decision	2 (0.0)		
Adverse event	1 (0.0)		
No longer meets eligibility criteria	1 (0.0)		
Other	2 (0.0)		
Originally randomized to placebo		12299 (93.7)	
Withdrawn from the study after unblinding and before Dose 3		284 (2.2)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		11405 (86.8)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		8586 (65.4)	
Discontinued from open-label vaccination period[d]		16 (0.1)	
Reason for discontinuation from open-label vaccination period			
Withdrawal by subject		5 (0.0)	
Pregnancy		4 (0.0)	
Adverse event		3 (0.0)	
Protocol deviation		3 (0.0)	
Lost to follow-up		1 (0.0)	

14.15. Disposition of All Randomized Subjects, by Age Group – Phase 2/3 Subjects ≥16 Years of Age Age Group: 16-55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=13104) n[b] (%)	Placebo (N[a]=13132) n[b] (%)	Total (N[a]=26236) n[b] (%)
Completed 1-month post–Dose 4 visit		3424 (26.1)	
Withdrawn from the study		8 (0.1)	
Withdrawn after Dose 3 and before Dose 4		6 (0.0)	
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit		2 (0.0)	
Withdrawn after 1-month post–Dose 4 visit		0	
Reason for withdrawal from the study			
Withdrawal by subject		7 (0.1)	
Protocol deviation		1 (0.0)	

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, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 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.
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 is defined as the time period from Dose 1 to 1 month post–Dose 2.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 27MAR2021 (16:41)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adds s002 age p3 rand

14.16. Disposition of All Randomized Subjects, by Age Group – Phase 2/3 Subjects ≥16 Years of Age Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=8981) n[b] (%)	Placebo (N[a]=8948) n[b] (%)	Total (N[a]=17929) n[b] (%)
Randomized	8981 (100.0)	8948 (100.0)	17929 (100.0)
Not vaccinated	24 (0.3)	18 (0.2)	42 (0.2)
Original blinded placebo-controlled follow-up period			
Vaccinated	8957 (99.7)	8930 (99.8)	17887 (99.8)
Dose 1	8957 (99.7)	8930 (99.8)	17887 (99.8)
Dose 2	8873 (98.8)	8825 (98.6)	17698 (98.7)
Discontinued from original blinded placebo-controlled vaccination period[c]	74 (0.8)	140 (1.6)	214 (1.2)
Reason for discontinuation			
Withdrawal by subject	28 (0.3)	64 (0.7)	92 (0.5)
Lost to follow-up	19 (0.2)	25 (0.3)	44 (0.2)
No longer meets eligibility criteria	3 (0.0)	26 (0.3)	29 (0.2)
Adverse event	12 (0.1)	14 (0.2)	26 (0.1)
Physician decision	2 (0.0)	4 (0.0)	6 (0.0)
Death	3 (0.0)	2 (0.0)	5 (0.0)
Protocol deviation	1 (0.0)	2 (0.0)	3 (0.0)
Medication error without associated adverse event	1 (0.0)	1 (0.0)	2 (0.0)
Other	5 (0.1)	2 (0.0)	7 (0.0)
Unblinded before 1-month post–Dose 2 visit	78 (0.9)	58 (0.6)	136 (0.8)
Completed 1-month post–Dose 2 visit	8796 (97.9)	8738 (97.7)	17534 (97.8)
Withdrawn from the study	84 (0.9)	135 (1.5)	219 (1.2)
Withdrawn after Dose 1 and before Dose 2	38 (0.4)	56 (0.6)	94 (0.5)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	15 (0.2)	35 (0.4)	50 (0.3)
Withdrawn after 1-month post–Dose 2 visit	31 (0.3)	44 (0.5)	75 (0.4)
Reason for withdrawal from the study			
Withdrawal by subject	34 (0.4)	79 (0.9)	113 (0.6)
Lost to follow-up	24 (0.3)	31 (0.3)	55 (0.3)
Death	13 (0.1)	10 (0.1)	23 (0.1)
Protocol deviation	8 (0.1)	4 (0.0)	12 (0.1)
Adverse event	3 (0.0)	5 (0.1)	8 (0.0)
Physician decision	1 (0.0)	3 (0.0)	4 (0.0)
No longer meets eligibility criteria	0	2 (0.0)	2 (0.0)
Other	1 (0.0)	1 (0.0)	2 (0.0)
Open-label follow-up period			

14.16. Disposition of All Randomized Subjects, by Age Group – Phase 2/3 Subjects ≥16 Years of Age Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=8981) n[b] (%)	Placebo (N[a]=8948) n[b] (%)	Total (N[a]=17929) n[b] (%)
Originally randomized to BNT162b2	8546 (95.2)		
Received Dose 2/unplanned dose	26 (0.3)		
Completed 1-month post–Dose 2 visit	69 (0.8)		
Completed 6-month post–Dose 2 visit	3073 (34.2)		
Withdrawn from the study	47 (0.5)		
Withdrawn before 6-month post–Dose 2 visit	47 (0.5)		
Withdrawn after 6-month post–Dose 2 visit	0		
Reason for withdrawal from the study			
Withdrawal by subject	24 (0.3)		
Protocol deviation	18 (0.2)		
Death	3 (0.0)		
Lost to follow-up	1 (0.0)		
Other	1 (0.0)		
Originally randomized to placebo		8649 (96.7)	
Withdrawn from the study after unblinding and before Dose 3		213 (2.4)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		8207 (91.7)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		7400 (82.7)	
Discontinued from open-label vaccination period[d]		8 (0.1)	
Reason for discontinuation from open-label vaccination period			
Protocol deviation		3 (0.0)	
Adverse event		2 (0.0)	
Death		2 (0.0)	
Lost to follow-up		1 (0.0)	
Completed 1-month post–Dose 4 visit		3785 (42.3)	
Withdrawn from the study		6 (0.1)	
Withdrawn after Dose 3 and before Dose 4		5 (0.1)	
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit		0	
Withdrawn after 1-month post–Dose 4 visit		1 (0.0)	
Reason for withdrawal from the study			
Death		2 (0.0)	
Protocol deviation		2 (0.0)	
Adverse event		1 (0.0)	
Lost to follow-up		1 (0.0)	

14.16. Disposition of All Randomized Subjects, by Age Group – Phase 2/3 Subjects ≥16 Years of Age Age Group: >55 Years

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=8981) n^b (%)	Placebo (N^a=8948) n^b (%)	Total (N^a=17929) n^b (%)

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, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 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.
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 is defined as the time period from Dose 1 to 1 month post–Dose 2.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 27MAR2021 (16:41)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adds s002 age p3 rand

14.17. Disposition of All Randomized Subjects, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=689) n[b] (%)	Placebo (N[a]=719) n[b] (%)	Total (N[a]=1408) n[b] (%)
Randomized	689 (100.0)	719 (100.0)	1408 (100.0)
Not vaccinated	1 (0.1)	2 (0.3)	3 (0.2)
Original blinded placebo-controlled follow-up period			
Vaccinated	688 (99.9)	717 (99.7)	1405 (99.8)
Dose 1	688 (99.9)	717 (99.7)	1405 (99.8)
Dose 2	650 (94.3)	685 (95.3)	1335 (94.8)
Discontinued from original blinded placebo-controlled vaccination period[c]	32 (4.6)	39 (5.4)	71 (5.0)
Reason for discontinuation			
Lost to follow-up	14 (2.0)	11 (1.5)	25 (1.8)
Withdrawal by subject	10 (1.5)	10 (1.4)	20 (1.4)
No longer meets eligibility criteria	6 (0.9)	13 (1.8)	19 (1.3)
Physician decision	0	2 (0.3)	2 (0.1)
Pregnancy	1 (0.1)	1 (0.1)	2 (0.1)
Death	1 (0.1)	0	1 (0.1)
Medication error without associated adverse event	0	1 (0.1)	1 (0.1)
Other	0	1 (0.1)	1 (0.1)
Unblinded before 1-month post–Dose 2 visit	4 (0.6)	5 (0.7)	9 (0.6)
Completed 1-month post–Dose 2 visit	641 (93.0)	674 (93.7)	1315 (93.4)
Withdrawn from the study	30 (4.4)	24 (3.3)	54 (3.8)
Withdrawn after Dose 1 and before Dose 2	19 (2.8)	17 (2.4)	36 (2.6)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	7 (1.0)	6 (0.8)	13 (0.9)
Withdrawn after 1-month post–Dose 2 visit	4 (0.6)	1 (0.1)	5 (0.4)
Reason for withdrawal from the study			
Lost to follow-up	16 (2.3)	11 (1.5)	27 (1.9)
Withdrawal by subject	11 (1.6)	10 (1.4)	21 (1.5)
Physician decision	0	3 (0.4)	3 (0.2)
Death	2 (0.3)	0	2 (0.1)
Other	1 (0.1)	0	1 (0.1)
Open-label follow-up period			
Originally randomized to BNT162b2	600 (87.1)		
Received Dose 2/unplanned dose	12 (1.7)		
Completed 1-month post–Dose 2 visit	4 (0.6)		

14.17. Disposition of All Randomized Subjects, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=689) n[b] (%)	Placebo (N[a]=719) n[b] (%)	Total (N[a]=1408) n[b] (%)
Completed 6-month post–Dose 2 visit	147 (21.3)		
Withdrawn from the study	2 (0.3)		
Withdrawn before 6-month post–Dose 2 visit	2 (0.3)		
Withdrawn after 6-month post–Dose 2 visit	0		
Reason for withdrawal from the study			
Protocol deviation	1 (0.1)		
Withdrawal by subject	1 (0.1)		
Originally randomized to placebo		648 (90.1)	
Withdrawn from the study after unblinding and before Dose 3		11 (1.5)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		590 (82.1)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		451 (62.7)	
Discontinued from open-label vaccination period[d]		1 (0.1)	
Reason for discontinuation from open-label vaccination period			
Pregnancy		1 (0.1)	
Completed 1-month post–Dose 4 visit		111 (15.4)	
Withdrawn from the study		0	

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
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, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 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.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
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 is defined as the time period from Dose 1 to 1 month post–Dose 2.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 27MAR2021 (16:41)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adds s002 bs p3 rand

14.18. Disposition of All Randomized Subjects, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=21202) n[b] (%)	Placebo (N[a]=21202) n[b] (%)	Total (N[a]=42404) n[b] (%)
Randomized	21202 (100.0)	21202 (100.0)	42404 (100.0)
Not vaccinated	12 (0.1)	14 (0.1)	26 (0.1)
Original blinded placebo-controlled follow-up period			
Vaccinated	21190 (99.9)	21188 (99.9)	42378 (99.9)
Dose 1	21190 (99.9)	21188 (99.9)	42378 (99.9)
Dose 2	20877 (98.5)	20840 (98.3)	41717 (98.4)
Discontinued from original blinded placebo-controlled vaccination period[c]	315 (1.5)	488 (2.3)	803 (1.9)
Reason for discontinuation			
Lost to follow-up	135 (0.6)	141 (0.7)	276 (0.7)
Withdrawal by subject	97 (0.5)	171 (0.8)	268 (0.6)
No longer meets eligibility criteria	20 (0.1)	107 (0.5)	127 (0.3)
Adverse event	27 (0.1)	26 (0.1)	53 (0.1)
Physician decision	5 (0.0)	6 (0.0)	11 (0.0)
Protocol deviation	3 (0.0)	8 (0.0)	11 (0.0)
Pregnancy	5 (0.0)	5 (0.0)	10 (0.0)
Death	2 (0.0)	4 (0.0)	6 (0.0)
Medication error without associated adverse event	3 (0.0)	1 (0.0)	4 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	17 (0.1)	19 (0.1)	36 (0.1)
Unblinded before 1-month post–Dose 2 visit	247 (1.2)	234 (1.1)	481 (1.1)
Completed 1-month post–Dose 2 visit	20595 (97.1)	20496 (96.7)	41091 (96.9)
Withdrawn from the study	308 (1.5)	459 (2.2)	767 (1.8)
Withdrawn after Dose 1 and before Dose 2	153 (0.7)	194 (0.9)	347 (0.8)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	93 (0.4)	132 (0.6)	225 (0.5)
Withdrawn after 1-month post–Dose 2 visit	62 (0.3)	133 (0.6)	195 (0.5)
Reason for withdrawal from the study			
Lost to follow-up	155 (0.7)	179 (0.8)	334 (0.8)
Withdrawal by subject	109 (0.5)	216 (1.0)	325 (0.8)
Protocol deviation	11 (0.1)	24 (0.1)	35 (0.1)
Death	14 (0.1)	15 (0.1)	29 (0.1)
Adverse event	9 (0.0)	8 (0.0)	17 (0.0)
Physician decision	3 (0.0)	3 (0.0)	6 (0.0)
No longer meets eligibility criteria	1 (0.0)	4 (0.0)	5 (0.0)

14.18. Disposition of All Randomized Subjects, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=21202) n[b] (%)	Placebo (N[a]=21202) n[b] (%)	Total (N[a]=42404) n[b] (%)
Pregnancy	0	1 (0.0)	1 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	4 (0.0)	9 (0.0)	13 (0.0)
Open-label follow-up period			
Originally randomized to BNT162b2	19663 (92.7)		
Received Dose 2/unplanned dose	75 (0.4)		
Completed 1-month post–Dose 2 visit	205 (1.0)		
Completed 6-month post–Dose 2 visit	6243 (29.4)		
Withdrawn from the study	103 (0.5)		
Withdrawn before 6-month post–Dose 2 visit	101 (0.5)		
Withdrawn after 6-month post–Dose 2 visit	2 (0.0)		
Reason for withdrawal from the study			
Withdrawal by subject	55 (0.3)		
Protocol deviation	34 (0.2)		
Lost to follow-up	4 (0.0)		
Death	3 (0.0)		
Physician decision	2 (0.0)		
Adverse event	1 (0.0)		
No longer meets eligibility criteria	1 (0.0)		
Other	3 (0.0)		
Originally randomized to placebo		20182 (95.2)	
Withdrawn from the study after unblinding and before Dose 3		485 (2.3)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		18910 (89.2)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		15441 (72.8)	
Discontinued from open-label vaccination period[d]		23 (0.1)	
Reason for discontinuation from open-label vaccination period			
Protocol deviation		6 (0.0)	
Adverse event		5 (0.0)	
Withdrawal by subject		5 (0.0)	
Pregnancy		3 (0.0)	
Death		2 (0.0)	
Lost to follow-up		2 (0.0)	
Completed 1-month post–Dose 4 visit		7065 (33.3)	

14.18. Disposition of All Randomized Subjects, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=21202) n[b] (%)	Placebo (N[a]=21202) n[b] (%)	Total (N[a]=42404) n[b] (%)
Withdrawn from the study		14 (0.1)	
Withdrawn after Dose 3 and before Dose 4		11 (0.1)	
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit		2 (0.0)	
Withdrawn after 1-month post–Dose 4 visit		1 (0.0)	
Reason for withdrawal from the study			
Withdrawal by subject		7 (0.0)	
Protocol deviation		3 (0.0)	
Death		2 (0.0)	
Adverse event		1 (0.0)	
Lost to follow-up		1 (0.0)	

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
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, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 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.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
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 is defined as the time period from Dose 1 to 1 month post–Dose 2.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 27MAR2021 (16:41)
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14.19. Disposition of All Randomized Subjects, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age Ethnicity: Hispanic/Latino

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=5715) n[b] (%)	Placebo (N[a]=5710) n[b] (%)	Total (N[a]=11425) n[b] (%)
Randomized	5715 (100.0)	5710 (100.0)	11425 (100.0)
Not vaccinated	10 (0.2)	13 (0.2)	23 (0.2)
Original blinded placebo-controlled follow-up period			
Vaccinated	5705 (99.8)	5697 (99.8)	11402 (99.8)
Dose 1	5705 (99.8)	5697 (99.8)	11402 (99.8)
Dose 2	5544 (97.0)	5548 (97.2)	11092 (97.1)
Discontinued from original blinded placebo-controlled vaccination period[c]	124 (2.2)	201 (3.5)	325 (2.8)
Reason for discontinuation			
Withdrawal by subject	48 (0.8)	85 (1.5)	133 (1.2)
Lost to follow-up	47 (0.8)	48 (0.8)	95 (0.8)
No longer meets eligibility criteria	13 (0.2)	60 (1.1)	73 (0.6)
Adverse event	7 (0.1)	1 (0.0)	8 (0.1)
Physician decision	1 (0.0)	2 (0.0)	3 (0.0)
Pregnancy	2 (0.0)	1 (0.0)	3 (0.0)
Protocol deviation	1 (0.0)	2 (0.0)	3 (0.0)
Death	1 (0.0)	1 (0.0)	2 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	3 (0.1)	1 (0.0)	4 (0.0)
Unblinded before 1-month post–Dose 2 visit	72 (1.3)	19 (0.3)	91 (0.8)
Completed 1-month post–Dose 2 visit	5487 (96.0)	5482 (96.0)	10969 (96.0)
Withdrawn from the study	123 (2.2)	187 (3.3)	310 (2.7)
Withdrawn after Dose 1 and before Dose 2	63 (1.1)	86 (1.5)	149 (1.3)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	34 (0.6)	49 (0.9)	83 (0.7)
Withdrawn after 1-month post–Dose 2 visit	26 (0.5)	52 (0.9)	78 (0.7)
Reason for withdrawal from the study			
Withdrawal by subject	55 (1.0)	98 (1.7)	153 (1.3)
Lost to follow-up	54 (0.9)	67 (1.2)	121 (1.1)
Protocol deviation	8 (0.1)	15 (0.3)	23 (0.2)
Death	2 (0.0)	5 (0.1)	7 (0.1)
Adverse event	3 (0.1)	0	3 (0.0)
Physician decision	0	1 (0.0)	1 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	0	1 (0.0)	1 (0.0)

14.19. Disposition of All Randomized Subjects, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age Ethnicity: Hispanic/Latino

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=5715) n[b] (%)	Placebo (N[a]=5710) n[b] (%)	Total (N[a]=11425) n[b] (%)
Open-label follow-up period			
Originally randomized to BNT162b2	5214 (91.2)		
Received Dose 2/unplanned dose	45 (0.8)		
Completed 1-month post–Dose 2 visit	41 (0.7)		
Completed 6-month post–Dose 2 visit	1196 (20.9)		
Withdrawn from the study	17 (0.3)		
Withdrawn before 6-month post–Dose 2 visit	16 (0.3)		
Withdrawn after 6-month post–Dose 2 visit	1 (0.0)		
Reason for withdrawal from the study			
Protocol deviation	8 (0.1)		
Withdrawal by subject	8 (0.1)		
Lost to follow-up	1 (0.0)		
Originally randomized to placebo		5342 (93.6)	
Withdrawn from the study after unblinding and before Dose 3		83 (1.5)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		5003 (87.6)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		3132 (54.9)	
Discontinued from open-label vaccination period[d]		2 (0.0)	
Reason for discontinuation from open-label vaccination period			
Protocol deviation		1 (0.0)	
Withdrawal by subject		1 (0.0)	
Completed 1-month post–Dose 4 visit		908 (15.9)	
Withdrawn from the study		2 (0.0)	
Withdrawn after Dose 3 and before Dose 4		1 (0.0)	
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit		1 (0.0)	
Withdrawn after 1-month post–Dose 4 visit		0	
Reason for withdrawal from the study			
Withdrawal by subject		2 (0.0)	

14.19. Disposition of All Randomized Subjects, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age Ethnicity: Hispanic/Latino

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=5715) n^b (%)	Placebo (N^a=5710) n^b (%)	Total (N^a=11425) n^b (%)

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, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 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.
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 is defined as the time period from Dose 1 to 1 month post–Dose 2.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 27MAR2021 (16:41)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adds s002 eth p3 rand

14.20. Disposition of All Randomized Subjects, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=16259) n[b] (%)	Placebo (N[a]=16256) n[b] (%)	Total (N[a]=32515) n[b] (%)
Randomized	16259 (100.0)	16256 (100.0)	32515 (100.0)
Not vaccinated	45 (0.3)	37 (0.2)	82 (0.3)
Original blinded placebo-controlled follow-up period			
Vaccinated	16214 (99.7)	16219 (99.8)	32433 (99.7)
Dose 1	16214 (99.7)	16219 (99.8)	32433 (99.7)
Dose 2	16021 (98.5)	15989 (98.4)	32010 (98.4)
Discontinued from original blinded placebo-controlled vaccination period[c]	227 (1.4)	326 (2.0)	553 (1.7)
Reason for discontinuation			
Lost to follow-up	104 (0.6)	105 (0.6)	209 (0.6)
Withdrawal by subject	60 (0.4)	96 (0.6)	156 (0.5)
No longer meets eligibility criteria	13 (0.1)	59 (0.4)	72 (0.2)
Adverse event	20 (0.1)	25 (0.2)	45 (0.1)
Physician decision	4 (0.0)	6 (0.0)	10 (0.0)
Pregnancy	4 (0.0)	5 (0.0)	9 (0.0)
Protocol deviation	2 (0.0)	6 (0.0)	8 (0.0)
Death	2 (0.0)	3 (0.0)	5 (0.0)
Medication error without associated adverse event	3 (0.0)	2 (0.0)	5 (0.0)
Other	15 (0.1)	19 (0.1)	34 (0.1)
Unblinded before 1-month post–Dose 2 visit	181 (1.1)	221 (1.4)	402 (1.2)
Completed 1-month post–Dose 2 visit	15785 (97.1)	15698 (96.6)	31483 (96.8)
Withdrawn from the study	219 (1.3)	297 (1.8)	516 (1.6)
Withdrawn after Dose 1 and before Dose 2	112 (0.7)	125 (0.8)	237 (0.7)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	66 (0.4)	90 (0.6)	156 (0.5)
Withdrawn after 1-month post–Dose 2 visit	41 (0.3)	82 (0.5)	123 (0.4)
Reason for withdrawal from the study			
Lost to follow-up	120 (0.7)	124 (0.8)	244 (0.8)
Withdrawal by subject	66 (0.4)	128 (0.8)	194 (0.6)
Death	14 (0.1)	10 (0.1)	24 (0.1)
Adverse event	6 (0.0)	8 (0.0)	14 (0.0)
Protocol deviation	3 (0.0)	9 (0.1)	12 (0.0)
Physician decision	3 (0.0)	5 (0.0)	8 (0.0)
No longer meets eligibility criteria	1 (0.0)	4 (0.0)	5 (0.0)
Pregnancy	0	1 (0.0)	1 (0.0)

14.20. Disposition of All Randomized Subjects, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=16259) n[b] (%)	Placebo (N[a]=16256) n[b] (%)	Total (N[a]=32515) n[b] (%)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Other	5 (0.0)	8 (0.0)	13 (0.0)
Open-label follow-up period			
Originally randomized to BNT162b2	15083 (92.8)		
Received Dose 2/unplanned dose	42 (0.3)		
Completed 1-month post–Dose 2 visit	169 (1.0)		
Completed 6-month post–Dose 2 visit	5175 (31.8)		
Withdrawn from the study	88 (0.5)		
Withdrawn before 6-month post–Dose 2 visit	87 (0.5)		
Withdrawn after 6-month post–Dose 2 visit	1 (0.0)		
Reason for withdrawal from the study			
Withdrawal by subject	48 (0.3)		
Protocol deviation	27 (0.2)		
Death	3 (0.0)		
Lost to follow-up	3 (0.0)		
Physician decision	2 (0.0)		
Adverse event	1 (0.0)		
No longer meets eligibility criteria	1 (0.0)		
Other	3 (0.0)		
Originally randomized to placebo		15492 (95.3)	
Withdrawn from the study after unblinding and before Dose 3		411 (2.5)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		14499 (89.2)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		12765 (78.5)	
Discontinued from open-label vaccination period[d]		22 (0.1)	
Reason for discontinuation from open-label vaccination period			
Adverse event		5 (0.0)	
Protocol deviation		5 (0.0)	
Pregnancy		4 (0.0)	
Withdrawal by subject		4 (0.0)	
Death		2 (0.0)	
Lost to follow-up		2 (0.0)	
Completed 1-month post–Dose 4 visit		6249 (38.4)	
Withdrawn from the study		12 (0.1)	
Withdrawn after Dose 3 and before Dose 4		10 (0.1)	

14.20. Disposition of All Randomized Subjects, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=16259) n[b] (%)	Placebo (N[a]=16256) n[b] (%)	Total (N[a]=32515) n[b] (%)
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit		1 (0.0)	
Withdrawn after 1-month post–Dose 4 visit		1 (0.0)	
Reason for withdrawal from the study			
Withdrawal by subject		5 (0.0)	
Protocol deviation		3 (0.0)	
Death		2 (0.0)	
Adverse event		1 (0.0)	
Lost to follow-up		1 (0.0)	

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, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 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.
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 is defined as the time period from Dose 1 to 1 month post–Dose 2.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).
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(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adds s002 eth p3 rand

14.21. Disposition of All Randomized Subjects, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age Ethnicity: Not Reported

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=111) n[b] (%)	Placebo (N[a]=114) n[b] (%)	Total (N[a]=225) n[b] (%)
Randomized	111 (100.0)	114 (100.0)	225 (100.0)
Not vaccinated	0	0	0
Original blinded placebo-controlled follow-up period			
Vaccinated	111 (100.0)	114 (100.0)	225 (100.0)
Dose 1	111 (100.0)	114 (100.0)	225 (100.0)
Dose 2	110 (99.1)	113 (99.1)	223 (99.1)
Discontinued from original blinded placebo-controlled vaccination period[c]	1 (0.9)	1 (0.9)	2 (0.9)
Reason for discontinuation			
Withdrawal by subject	1 (0.9)	0	1 (0.4)
No longer meets eligibility criteria	0	1 (0.9)	1 (0.4)
Unblinded before 1-month post–Dose 2 visit	0	0	0
Completed 1-month post–Dose 2 visit	110 (99.1)	113 (99.1)	223 (99.1)
Withdrawn from the study	1 (0.9)	0	1 (0.4)
Withdrawn after Dose 1 and before Dose 2	1 (0.9)	0	1 (0.4)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	0	0	0
Withdrawn after 1-month post–Dose 2 visit	0	0	0
Reason for withdrawal from the study			
Withdrawal by subject	1 (0.9)	0	1 (0.4)
Open-label follow-up period			
Originally randomized to BNT162b2	107 (96.4)		
Received Dose 2/unplanned dose	0		
Completed 1-month post–Dose 2 visit	0		
Completed 6-month post–Dose 2 visit	43 (38.7)		
Withdrawn from the study	0		
Originally randomized to placebo		114 (100.0)	
Withdrawn from the study after unblinding and before Dose 3		3 (2.6)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		110 (96.5)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		89 (78.1)	
Discontinued from open-label vaccination period[d]		0	
Completed 1-month post–Dose 4 visit		52 (45.6)	
Withdrawn from the study		0	

14.21. Disposition of All Randomized Subjects, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age Ethnicity: Not Reported

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=111) n^b (%)	Placebo (N^a=114) n^b (%)	Total (N^a=225) n^b (%)

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, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 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.
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 is defined as the time period from Dose 1 to 1 month post–Dose 2.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 27MAR2021 (16:41)
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14.22. Disposition of All Randomized Subjects, by Race – Phase 2/3 Subjects ≥16 Years of Age Race: White

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=18106) n[b] (%)	Placebo (N[a]=18105) n[b] (%)	Total (N[a]=36211) n[b] (%)
Randomized	18106 (100.0)	18105 (100.0)	36211 (100.0)
Not vaccinated	45 (0.2)	36 (0.2)	81 (0.2)
Original blinded placebo-controlled follow-up period			
Vaccinated	18061 (99.8)	18069 (99.8)	36130 (99.8)
Dose 1	18061 (99.8)	18069 (99.8)	36130 (99.8)
Dose 2	17782 (98.2)	17784 (98.2)	35566 (98.2)
Discontinued from original blinded placebo-controlled vaccination period[c]	260 (1.4)	409 (2.3)	669 (1.8)
Reason for discontinuation			
Withdrawal by subject	83 (0.5)	143 (0.8)	226 (0.6)
Lost to follow-up	104 (0.6)	105 (0.6)	209 (0.6)
No longer meets eligibility criteria	21 (0.1)	110 (0.6)	131 (0.4)
Adverse event	26 (0.1)	18 (0.1)	44 (0.1)
Protocol deviation	3 (0.0)	7 (0.0)	10 (0.0)
Death	3 (0.0)	4 (0.0)	7 (0.0)
Physician decision	1 (0.0)	6 (0.0)	7 (0.0)
Pregnancy	3 (0.0)	3 (0.0)	6 (0.0)
Medication error without associated adverse event	2 (0.0)	2 (0.0)	4 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	13 (0.1)	11 (0.1)	24 (0.1)
Unblinded before 1-month post–Dose 2 visit	184 (1.0)	159 (0.9)	343 (0.9)
Completed 1-month post–Dose 2 visit	17573 (97.1)	17524 (96.8)	35097 (96.9)
Withdrawn from the study	257 (1.4)	379 (2.1)	636 (1.8)
Withdrawn after Dose 1 and before Dose 2	126 (0.7)	151 (0.8)	277 (0.8)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	76 (0.4)	115 (0.6)	191 (0.5)
Withdrawn after 1-month post–Dose 2 visit	55 (0.3)	113 (0.6)	168 (0.5)
Reason for withdrawal from the study			
Withdrawal by subject	95 (0.5)	183 (1.0)	278 (0.8)
Lost to follow-up	122 (0.7)	138 (0.8)	260 (0.7)
Protocol deviation	10 (0.1)	22 (0.1)	32 (0.1)
Death	13 (0.1)	14 (0.1)	27 (0.1)
Adverse event	8 (0.0)	8 (0.0)	16 (0.0)
Physician decision	2 (0.0)	4 (0.0)	6 (0.0)
No longer meets eligibility criteria	0	4 (0.0)	4 (0.0)

14.22. Disposition of All Randomized Subjects, by Race – Phase 2/3 Subjects ≥16 Years of Age Race: White

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=18106) n[b] (%)	Placebo (N[a]=18105) n[b] (%)	Total (N[a]=36211) n[b] (%)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	5 (0.0)	6 (0.0)	11 (0.0)
Open-label follow-up period			
Originally randomized to BNT162b2	16931 (93.5)		
Received Dose 2/unplanned dose	73 (0.4)		
Completed 1-month post–Dose 2 visit	153 (0.8)		
Completed 6-month post–Dose 2 visit	5420 (29.9)		
Withdrawn from the study	81 (0.4)		
Withdrawn before 6-month post–Dose 2 visit	79 (0.4)		
Withdrawn after 6-month post–Dose 2 visit	2 (0.0)		
Reason for withdrawal from the study			
Withdrawal by subject	41 (0.2)		
Protocol deviation	29 (0.2)		
Death	3 (0.0)		
Lost to follow-up	2 (0.0)		
Physician decision	2 (0.0)		
Adverse event	1 (0.0)		
No longer meets eligibility criteria	1 (0.0)		
Other	2 (0.0)		
Originally randomized to placebo		17332 (95.7)	
Withdrawn from the study after unblinding and before Dose 3		405 (2.2)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		16300 (90.0)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		13243 (73.1)	
Discontinued from open-label vaccination period[d]		18 (0.1)	
Reason for discontinuation from open-label vaccination period			
Protocol deviation		6 (0.0)	
Adverse event		5 (0.0)	
Withdrawal by subject		4 (0.0)	
Death		2 (0.0)	
Lost to follow-up		1 (0.0)	
Completed 1-month post–Dose 4 visit		6264 (34.6)	
Withdrawn from the study		12 (0.1)	
Withdrawn after Dose 3 and before Dose 4		9 (0.0)	

14.22. Disposition of All Randomized Subjects, by Race – Phase 2/3 Subjects ≥16 Years of Age Race: White

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=18106) n[b] (%)	Placebo (N[a]=18105) n[b] (%)	Total (N[a]=36211) n[b] (%)
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit		2 (0.0)	
Withdrawn after 1-month post–Dose 4 visit		1 (0.0)	
Reason for withdrawal from the study			
Withdrawal by subject		6 (0.0)	
Protocol deviation		3 (0.0)	
Death		2 (0.0)	
Adverse event		1 (0.0)	

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, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 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.
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 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 is defined as the time period from Dose 1 to 1 month post–Dose 2.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 27MAR2021 (16:41)
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./nda2 unblinded/C4591001 BLA/adds s002 race p3 rand

14.23. Disposition of All Randomized Subjects, by Race – Phase 2/3 Subjects ≥16 Years of Age Race: Black or African American

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=2106) n[b] (%)	Placebo (N[a]=2126) n[b] (%)	Total (N[a]=4232) n[b] (%)
Randomized	2106 (100.0)	2126 (100.0)	4232 (100.0)
Not vaccinated	6 (0.3)	7 (0.3)	13 (0.3)
Original blinded placebo-controlled follow-up period			
Vaccinated	2100 (99.7)	2119 (99.7)	4219 (99.7)
Dose 1	2100 (99.7)	2119 (99.7)	4219 (99.7)
Dose 2	2050 (97.3)	2057 (96.8)	4107 (97.0)
Discontinued from original blinded placebo-controlled vaccination period[c]	68 (3.2)	82 (3.9)	150 (3.5)
Reason for discontinuation			
Lost to follow-up	34 (1.6)	38 (1.8)	72 (1.7)
Withdrawal by subject	19 (0.9)	24 (1.1)	43 (1.0)
Adverse event	1 (0.0)	7 (0.3)	8 (0.2)
No longer meets eligibility criteria	4 (0.2)	4 (0.2)	8 (0.2)
Physician decision	3 (0.1)	2 (0.1)	5 (0.1)
Pregnancy	2 (0.1)	3 (0.1)	5 (0.1)
Protocol deviation	0	1 (0.0)	1 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Other	4 (0.2)	3 (0.1)	7 (0.2)
Unblinded before 1-month post–Dose 2 visit	14 (0.7)	7 (0.3)	21 (0.5)
Completed 1-month post–Dose 2 visit	2019 (95.9)	2032 (95.6)	4051 (95.7)
Withdrawn from the study	64 (3.0)	75 (3.5)	139 (3.3)
Withdrawn after Dose 1 and before Dose 2	39 (1.9)	46 (2.2)	85 (2.0)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	16 (0.8)	16 (0.8)	32 (0.8)
Withdrawn after 1-month post–Dose 2 visit	9 (0.4)	13 (0.6)	22 (0.5)
Reason for withdrawal from the study			
Lost to follow-up	38 (1.8)	41 (1.9)	79 (1.9)
Withdrawal by subject	20 (0.9)	27 (1.3)	47 (1.1)
Death	2 (0.1)	1 (0.0)	3 (0.1)
Physician decision	1 (0.0)	2 (0.1)	3 (0.1)
Protocol deviation	1 (0.0)	1 (0.0)	2 (0.0)
Adverse event	1 (0.0)	0	1 (0.0)
No longer meets eligibility criteria	1 (0.0)	0	1 (0.0)
Other	0	3 (0.1)	3 (0.1)
Open-label follow-up period			

14.23. Disposition of All Randomized Subjects, by Race – Phase 2/3 Subjects ≥16 Years of Age Race: Black or African American

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=2106) n[b] (%)	Placebo (N[a]=2126) n[b] (%)	Total (N[a]=4232) n[b] (%)
Originally randomized to BNT162b2	1755 (83.3)		
Received Dose 2/unplanned dose	2 (0.1)		
Completed 1-month post–Dose 2 visit	9 (0.4)		
Completed 6-month post–Dose 2 visit	529 (25.1)		
Withdrawn from the study	13 (0.6)		
Withdrawn before 6-month post–Dose 2 visit	13 (0.6)		
Withdrawn after 6-month post–Dose 2 visit	0		
Reason for withdrawal from the study			
Withdrawal by subject	8 (0.4)		
Protocol deviation	3 (0.1)		
Lost to follow-up	2 (0.1)		
Originally randomized to placebo		1845 (86.8)	
Withdrawn from the study after unblinding and before Dose 3		45 (2.1)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		1636 (77.0)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		1273 (59.9)	
Discontinued from open-label vaccination period[d]		2 (0.1)	
Reason for discontinuation from open-label vaccination period			
Lost to follow-up		1 (0.0)	
Pregnancy		1 (0.0)	
Completed 1-month post–Dose 4 visit		314 (14.8)	
Withdrawn from the study		1 (0.0)	
Withdrawn after Dose 3 and before Dose 4		1 (0.0)	
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit		0	
Withdrawn after 1-month post–Dose 4 visit		0	
Reason for withdrawal from the study			
Lost to follow-up		1 (0.0)	

14.23. Disposition of All Randomized Subjects, by Race – Phase 2/3 Subjects ≥16 Years of Age Race: Black or African American

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=2106) n[b] (%)	Placebo (N[a]=2126) n[b] (%)	Total (N[a]=4232) n[b] (%)

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, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 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.
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 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 is defined as the time period from Dose 1 to 1 month post–Dose 2.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).
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14.24. Disposition of All Randomized Subjects, by Race – Phase 2/3 Subjects ≥16 Years of Age Race: All Others

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1873) n[b] (%)	Placebo (N[a]=1849) n[b] (%)	Total (N[a]=3722) n[b] (%)
Randomized	1873 (100.0)	1849 (100.0)	3722 (100.0)
Not vaccinated	4 (0.2)	7 (0.4)	11 (0.3)
Original blinded placebo-controlled follow-up period			
Vaccinated	1869 (99.8)	1842 (99.6)	3711 (99.7)
Dose 1	1869 (99.8)	1842 (99.6)	3711 (99.7)
Dose 2	1843 (98.4)	1809 (97.8)	3652 (98.1)
Discontinued from original blinded placebo-controlled vaccination period[c]	24 (1.3)	37 (2.0)	61 (1.6)
Reason for discontinuation			
Lost to follow-up	13 (0.7)	10 (0.5)	23 (0.6)
Withdrawal by subject	7 (0.4)	14 (0.8)	21 (0.6)
No longer meets eligibility criteria	1 (0.1)	6 (0.3)	7 (0.2)
Adverse event	0	1 (0.1)	1 (0.0)
Physician decision	1 (0.1)	0	1 (0.0)
Pregnancy	1 (0.1)	0	1 (0.0)
Other	1 (0.1)	6 (0.3)	7 (0.2)
Unblinded before 1-month post–Dose 2 visit	55 (2.9)	74 (4.0)	129 (3.5)
Completed 1-month post–Dose 2 visit	1790 (95.6)	1737 (93.9)	3527 (94.8)
Withdrawn from the study	22 (1.2)	30 (1.6)	52 (1.4)
Withdrawn after Dose 1 and before Dose 2	11 (0.6)	14 (0.8)	25 (0.7)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	8 (0.4)	8 (0.4)	16 (0.4)
Withdrawn after 1-month post–Dose 2 visit	3 (0.2)	8 (0.4)	11 (0.3)
Reason for withdrawal from the study			
Lost to follow-up	14 (0.7)	12 (0.6)	26 (0.7)
Withdrawal by subject	7 (0.4)	16 (0.9)	23 (0.6)
Death	1 (0.1)	0	1 (0.0)
Pregnancy	0	1 (0.1)	1 (0.0)
Protocol deviation	0	1 (0.1)	1 (0.0)
Open-label follow-up period			
Originally randomized to BNT162b2	1718 (91.7)		
Received Dose 2/unplanned dose	12 (0.6)		
Completed 1-month post–Dose 2 visit	48 (2.6)		
Completed 6-month post–Dose 2 visit	465 (24.8)		
Withdrawn from the study	11 (0.6)		

14.24. Disposition of All Randomized Subjects, by Race – Phase 2/3 Subjects ≥16 Years of Age Race: All Others

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1873) n[b] (%)	Placebo (N[a]=1849) n[b] (%)	Total (N[a]=3722) n[b] (%)
Withdrawn before 6-month post–Dose 2 visit	11 (0.6)		
Withdrawn after 6-month post–Dose 2 visit	0		
Reason for withdrawal from the study			
Withdrawal by subject	7 (0.4)		
Protocol deviation	3 (0.2)		
Other	1 (0.1)		
Originally randomized to placebo		1771 (95.8)	
Withdrawn from the study after unblinding and before Dose 3		47 (2.5)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		1676 (90.6)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		1470 (79.5)	
Discontinued from open-label vaccination period[d]		4 (0.2)	
Reason for discontinuation from open-label vaccination period			
Pregnancy		3 (0.2)	
Withdrawal by subject		1 (0.1)	
Completed 1-month post–Dose 4 visit		631 (34.1)	
Withdrawn from the study		1 (0.1)	
Withdrawn after Dose 3 and before Dose 4		1 (0.1)	
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit		0	
Withdrawn after 1-month post–Dose 4 visit		0	
Reason for withdrawal from the study			
Withdrawal by subject		1 (0.1)	

14.24. Disposition of All Randomized Subjects, by Race – Phase 2/3 Subjects ≥16 Years of Age Race: All Others

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1873) n[b] (%)	Placebo (N[a]=1849) n[b] (%)	Total (N[a]=3722) n[b] (%)

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, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 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.
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 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 is defined as the time period from Dose 1 to 1 month post–Dose 2.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).
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14.25. Disposition of All Randomized Subjects, by Sex – Phase 2/3 Subjects ≥16 Years of Age Sex: Male

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=11357) n[b] (%)	Placebo (N[a]=11127) n[b] (%)	Total (N[a]=22484) n[b] (%)
Randomized	11357 (100.0)	11127 (100.0)	22484 (100.0)
Not vaccinated	30 (0.3)	27 (0.2)	57 (0.3)
Original blinded placebo-controlled follow-up period			
Vaccinated	11327 (99.7)	11100 (99.8)	22427 (99.7)
Dose 1	11327 (99.7)	11100 (99.8)	22427 (99.7)
Dose 2	11134 (98.0)	10908 (98.0)	22042 (98.0)
Discontinued from original blinded placebo-controlled vaccination period[c]	212 (1.9)	294 (2.6)	506 (2.3)
Reason for discontinuation			
Lost to follow-up	105 (0.9)	98 (0.9)	203 (0.9)
Withdrawal by subject	63 (0.6)	101 (0.9)	164 (0.7)
No longer meets eligibility criteria	18 (0.2)	56 (0.5)	74 (0.3)
Adverse event	7 (0.1)	14 (0.1)	21 (0.1)
Physician decision	4 (0.0)	4 (0.0)	8 (0.0)
Protocol deviation	1 (0.0)	6 (0.1)	7 (0.0)
Death	3 (0.0)	2 (0.0)	5 (0.0)
Medication error without associated adverse event	1 (0.0)	1 (0.0)	2 (0.0)
Other	10 (0.1)	12 (0.1)	22 (0.1)
Unblinded before 1-month post–Dose 2 visit	113 (1.0)	113 (1.0)	226 (1.0)
Completed 1-month post–Dose 2 visit	10980 (96.7)	10711 (96.3)	21691 (96.5)
Withdrawn from the study	221 (1.9)	276 (2.5)	497 (2.2)
Withdrawn after Dose 1 and before Dose 2	108 (1.0)	115 (1.0)	223 (1.0)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	68 (0.6)	95 (0.9)	163 (0.7)
Withdrawn after 1-month post–Dose 2 visit	45 (0.4)	66 (0.6)	111 (0.5)
Reason for withdrawal from the study			
Lost to follow-up	120 (1.1)	119 (1.1)	239 (1.1)
Withdrawal by subject	73 (0.6)	119 (1.1)	192 (0.9)
Protocol deviation	7 (0.1)	12 (0.1)	19 (0.1)
Death	10 (0.1)	8 (0.1)	18 (0.1)
Adverse event	3 (0.0)	6 (0.1)	9 (0.0)
Physician decision	3 (0.0)	4 (0.0)	7 (0.0)
No longer meets eligibility criteria	0	3 (0.0)	3 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Other	4 (0.0)	5 (0.0)	9 (0.0)

14.25. Disposition of All Randomized Subjects, by Sex – Phase 2/3 Subjects ≥16 Years of Age Sex: Male

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=11357) n[b] (%)	Placebo (N[a]=11127) n[b] (%)	Total (N[a]=22484) n[b] (%)
Open-label follow-up period			
Originally randomized to BNT162b2	10407 (91.6)		
Received Dose 2/unplanned dose	40 (0.4)		
Completed 1-month post–Dose 2 visit	90 (0.8)		
Completed 6-month post–Dose 2 visit	3156 (27.8)		
Withdrawn from the study	56 (0.5)		
Withdrawn before 6-month post–Dose 2 visit	54 (0.5)		
Withdrawn after 6-month post–Dose 2 visit	2 (0.0)		
Reason for withdrawal from the study			
Withdrawal by subject	30 (0.3)		
Protocol deviation	19 (0.2)		
Lost to follow-up	3 (0.0)		
Death	2 (0.0)		
Adverse event	1 (0.0)		
Physician decision	1 (0.0)		
Originally randomized to placebo		10497 (94.3)	
Withdrawn from the study after unblinding and before Dose 3		251 (2.3)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		9842 (88.5)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		7959 (71.5)	
Discontinued from open-label vaccination period[d]		10 (0.1)	
Reason for discontinuation from open-label vaccination period			
Adverse event		2 (0.0)	
Death		2 (0.0)	
Lost to follow-up		2 (0.0)	
Protocol deviation		2 (0.0)	
Withdrawal by subject		2 (0.0)	
Completed 1-month post–Dose 4 visit		3455 (31.1)	
Withdrawn from the study		9 (0.1)	
Withdrawn after Dose 3 and before Dose 4		7 (0.1)	
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit		1 (0.0)	
Withdrawn after 1-month post–Dose 4 visit		1 (0.0)	
Reason for withdrawal from the study			
Withdrawal by subject		3 (0.0)	

14.25. Disposition of All Randomized Subjects, by Sex – Phase 2/3 Subjects ≥16 Years of Age Sex: Male

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=11357) n[b] (%)	Placebo (N[a]=11127) n[b] (%)	Total (N[a]=22484) n[b] (%)
Death		2 (0.0)	
Protocol deviation		2 (0.0)	
Adverse event		1 (0.0)	
Lost to follow-up		1 (0.0)	

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, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 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.
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 is defined as the time period from Dose 1 to 1 month post–Dose 2.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).
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14.26. Disposition of All Randomized Subjects, by Sex – Phase 2/3 Subjects ≥16 Years of Age Sex: Female

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=10728) n[b] (%)	Placebo (N[a]=10953) n[b] (%)	Total (N[a]=21681) n[b] (%)
Randomized	10728 (100.0)	10953 (100.0)	21681 (100.0)
Not vaccinated	25 (0.2)	23 (0.2)	48 (0.2)
Original blinded placebo-controlled follow-up period			
Vaccinated	10703 (99.8)	10930 (99.8)	21633 (99.8)
Dose 1	10703 (99.8)	10930 (99.8)	21633 (99.8)
Dose 2	10541 (98.3)	10742 (98.1)	21283 (98.2)
Discontinued from original blinded placebo-controlled vaccination period[c]	140 (1.3)	234 (2.1)	374 (1.7)
Reason for discontinuation			
Withdrawal by subject	46 (0.4)	80 (0.7)	126 (0.6)
Lost to follow-up	46 (0.4)	55 (0.5)	101 (0.5)
No longer meets eligibility criteria	8 (0.1)	64 (0.6)	72 (0.3)
Adverse event	20 (0.2)	12 (0.1)	32 (0.1)
Pregnancy	6 (0.1)	6 (0.1)	12 (0.1)
Physician decision	1 (0.0)	4 (0.0)	5 (0.0)
Protocol deviation	2 (0.0)	2 (0.0)	4 (0.0)
Medication error without associated adverse event	2 (0.0)	1 (0.0)	3 (0.0)
Death	0	2 (0.0)	2 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	8 (0.1)	8 (0.1)	16 (0.1)
Unblinded before 1-month post–Dose 2 visit	140 (1.3)	127 (1.2)	267 (1.2)
Completed 1-month post–Dose 2 visit	10402 (97.0)	10582 (96.6)	20984 (96.8)
Withdrawn from the study	122 (1.1)	208 (1.9)	330 (1.5)
Withdrawn after Dose 1 and before Dose 2	68 (0.6)	96 (0.9)	164 (0.8)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	32 (0.3)	44 (0.4)	76 (0.4)
Withdrawn after 1-month post–Dose 2 visit	22 (0.2)	68 (0.6)	90 (0.4)
Reason for withdrawal from the study			
Withdrawal by subject	49 (0.5)	107 (1.0)	156 (0.7)
Lost to follow-up	54 (0.5)	72 (0.7)	126 (0.6)
Protocol deviation	4 (0.0)	12 (0.1)	16 (0.1)
Death	6 (0.1)	7 (0.1)	13 (0.1)
Adverse event	6 (0.1)	2 (0.0)	8 (0.0)
Physician decision	0	2 (0.0)	2 (0.0)
No longer meets eligibility criteria	1 (0.0)	1 (0.0)	2 (0.0)

14.26. Disposition of All Randomized Subjects, by Sex – Phase 2/3 Subjects ≥16 Years of Age Sex: Female

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=10728) n[b] (%)	Placebo (N[a]=10953) n[b] (%)	Total (N[a]=21681) n[b] (%)
Pregnancy	0	1 (0.0)	1 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	1 (0.0)	4 (0.0)	5 (0.0)
Open-label follow-up period			
Originally randomized to BNT162b2	9997 (93.2)		
Received Dose 2/unplanned dose	47 (0.4)		
Completed 1-month post–Dose 2 visit	120 (1.1)		
Completed 6-month post–Dose 2 visit	3258 (30.4)		
Withdrawn from the study	49 (0.5)		
Withdrawn before 6-month post–Dose 2 visit	49 (0.5)		
Withdrawn after 6-month post–Dose 2 visit	0		
Reason for withdrawal from the study			
Withdrawal by subject	26 (0.2)		
Protocol deviation	16 (0.1)		
Death	1 (0.0)		
Lost to follow-up	1 (0.0)		
Physician decision	1 (0.0)		
No longer meets eligibility criteria	1 (0.0)		
Other	3 (0.0)		
Originally randomized to placebo		10451 (95.4)	
Withdrawn from the study after unblinding and before Dose 3		246 (2.2)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		9770 (89.2)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		8027 (73.3)	
Discontinued from open-label vaccination period[d]		14 (0.1)	
Reason for discontinuation from open-label vaccination period			
Pregnancy		4 (0.0)	
Protocol deviation		4 (0.0)	
Adverse event		3 (0.0)	
Withdrawal by subject		3 (0.0)	
Completed 1-month post–Dose 4 visit		3754 (34.3)	
Withdrawn from the study		5 (0.0)	
Withdrawn after Dose 3 and before Dose 4		4 (0.0)	
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit		1 (0.0)	

14.26. Disposition of All Randomized Subjects, by Sex – Phase 2/3 Subjects ≥16 Years of Age Sex: Female

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=10728) n[b] (%)	Placebo (N[a]=10953) n[b] (%)	Total (N[a]=21681) n[b] (%)
Withdrawn after 1-month post–Dose 4 visit		0	
Reason for withdrawal from the study			
Withdrawal by subject		4 (0.0)	
Protocol deviation		1 (0.0)	

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, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 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.
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 is defined as the time period from Dose 1 to 1 month post–Dose 2.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 27MAR2021 (16:41)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adds_s002_sex_p3_rand

14.27. Follow-up Time After Dose 2, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Placebo (N[a]=13095) n[b] (%)	Total (N[a]=26164) n[b] (%)
Subjects (%) with length of follow-up of:			
Original blinded placebo-controlled follow-up period			
<2 Months	917 (7.0)	962 (7.3)	1879 (7.2)
≥2 Months to <4 months	4448 (34.0)	4726 (36.1)	9174 (35.1)
≥4 Months to <6 months	6343 (48.5)	6327 (48.3)	12670 (48.4)
≥6 Months	1361 (10.4)	1080 (8.2)	2441 (9.3)
Total exposure from Dose 2 to cutoff date			
<2 Months	305 (2.3)		
≥2 Months to <4 months	552 (4.2)		
≥4 Months to <6 months	5546 (42.4)		
≥6 Months	6666 (51.0)		

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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_fu_d2_age_p3_saf

14.28. Follow-up Time After Dose 2, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=8957) n[b] (%)	Placebo (N[a]=8926) n[b] (%)	Total (N[a]=17883) n[b] (%)
Subjects (%) with length of follow-up of:			
Original blinded placebo-controlled follow-up period			
<2 Months	334 (3.7)	369 (4.1)	703 (3.9)
≥2 Months to <4 months	3296 (36.8)	3344 (37.5)	6640 (37.1)
≥4 Months to <6 months	4910 (54.8)	4989 (55.9)	9899 (55.4)
≥6 Months	417 (4.7)	224 (2.5)	641 (3.6)
Total exposure from Dose 2 to cutoff date			
<2 Months	85 (0.9)		
≥2 Months to <4 months	127 (1.4)		
≥4 Months to <6 months	3405 (38.0)		
≥6 Months	5340 (59.6)		

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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adsl fu d2 age p3 saf

14.29. Follow-up Time After Dose 1 of BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=19611) n[b] (%)
Subjects (%) with length of follow-up of:	
Open-label follow-up period	
<1 Month	4934 (25.2)
≥1 Month to <2 months	9323 (47.5)
≥2 Months to <3 months	4145 (21.1)
≥3 Months	1209 (6.2)

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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_fu_d1_p3_saf

14.30. Safety Population, by Age Group – Phase 2/3 Subjects ≥16 Years of Age

Age Group		Vaccine Group (as Administered) BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
16-55 Years	Randomized[b]			26236
	Vaccinated	13073	13099	26173 (99.8)
	Safety population	13069	13095	26165 (99.7)
	HIV-positive	74	69	143 (0.5)
	Indeterminate vaccine[c]			1 (0.0)
	Excluded from safety population			71 (0.3)
	Reason for exclusion			
	Subject did not receive study vaccine			63 (0.2)
	Unreliable data due to lack of PI oversight			8 (0.0)
>55 Years	Randomized[b]			17929
	Vaccinated	8959	8926	17887 (99.8)
	Safety population	8957	8926	17885 (99.8)
	HIV-positive	26	31	57 (0.3)
	Indeterminate vaccine[c]			2 (0.0)
	Excluded from safety population			44 (0.2)
	Reason for exclusion			
	Subject did not receive study vaccine			42 (0.2)
	Unreliable data due to lack of PI oversight			2 (0.0)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
c. "Indeterminate vaccine" refers to subjects whose vaccine group (as administered) could not be determined. These subjects were not included in the safety analysis but their safety data is listed separately.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:42)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_s003_pop_age_p3

14.31. Safety Population, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age

Baseline SARS-CoV-2 Status		Vaccine Group (as Administered) BNT162b2 (30 µg) n[a]	Vaccine Group (as Administered) Placebo n[a]	Total n[a] (%)
Positive	Randomized[b]			1408
	Vaccinated	689	716	1405 (99.8)
	Safety population	689	716	1405 (99.8)
	HIV-positive	15	11	26 (1.8)
	Excluded from safety population			3 (0.2)
	Reason for exclusion			
	Subject did not receive study vaccine			3 (0.2)
Negative	Randomized[b]			42404
	Vaccinated	21191	21184	42378 (99.9)
	Safety population	21185	21180	42368 (99.9)
	HIV-positive	83	88	171 (0.4)
	Indeterminate vaccine[c]			3 (0.0)
	Excluded from safety population			36 (0.1)
	Reason for exclusion			
	Subject did not receive study vaccine			26 (0.1)
	Unreliable data due to lack of PI oversight			10 (0.0)
Missing	Randomized[b]			353
	Vaccinated	152	125	277 (78.5)
	Safety population	152	125	277 (78.5)
	HIV-positive	2	1	3 (0.8)
	Excluded from safety population			76 (21.5)
	Reason for exclusion			
	Subject did not receive study vaccine			76 (21.5)

14.31. Safety Population, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age

Baseline SARS-CoV-2 Status	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative
N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
c. "Indeterminate vaccine" refers to subjects whose vaccine group (as administered) could not be determined. These subjects were not included in the safety analysis but their safety data is listed separately.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:42)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_s003_pop_base_p7

14.32. Safety Population, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age

Ethnicity		Vaccine Group (as Administered) BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
Hispanic/ Latino	Randomized[b]			11425
	Vaccinated	5706	5696	11402 (99.8)
	Safety population	5704	5695	11399 (99.8)
	HIV-positive	20	12	32 (0.3)
	Excluded from safety population			26 (0.2)
	Reason for exclusion			
	Subject did not receive study vaccine			23 (0.2)
	Unreliable data due to lack of PI oversight			3 (0.0)
Non-Hispanic/ non-Latino	Randomized[b]			32515
	Vaccinated	16215	16215	32433 (99.7)
	Safety population	16211	16212	32426 (99.7)
	HIV-positive	80	87	167 (0.5)
	Indeterminate vaccine[c]			3 (0.0)
	Excluded from safety population			89 (0.3)
	Reason for exclusion			
	Subject did not receive study vaccine			82 (0.3)
	Unreliable data due to lack of PI oversight			7 (0.0)
Not reported	Randomized[b]			225
	Vaccinated	111	114	225 (100.0)
	Safety population	111	114	225 (100.0)
	HIV-positive	0	1	1 (0.4)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
c. "Indeterminate vaccine" refers to subjects whose vaccine group (as administered) could not be determined. These subjects were not included in the safety analysis but their safety data is listed separately.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:42)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_s003_pop_eth_p6

14.33. Safety Population, by Race – Phase 2/3 Subjects ≥16 Years of Age

Race		Vaccine Group (as Administered) BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
White	Randomized[b]			36211
	Vaccinated	18061	18067	36130 (99.8)
	Safety population	18056	18064	36122 (99.8)
	HIV-positive	44	37	81 (0.2)
	Indeterminate vaccine[c]			2 (0.0)
	Excluded from safety population			89 (0.2)
	Reason for exclusion			
	Subject did not receive study vaccine			81 (0.2)
	Unreliable data due to lack of PI oversight			8 (0.0)
Black or African American	Randomized[b]			4232
	Vaccinated	2099	2119	4219 (99.7)
	Safety population	2098	2118	4217 (99.6)
	HIV-positive	52	57	109 (2.6)
	Indeterminate vaccine[c]			1 (0.0)
	Excluded from safety population			15 (0.4)
	Reason for exclusion			
	Subject did not receive study vaccine			13 (0.3)
	Unreliable data due to lack of PI oversight			2 (0.0)
All others	Randomized[b]			3722
	Vaccinated	1872	1839	3711 (99.7)
	Safety population	1872	1839	3711 (99.7)
	HIV-positive	4	6	10 (0.3)
	Excluded from safety population			11 (0.3)
	Reason for exclusion			
	Subject did not receive study vaccine			11 (0.3)

14.33. Safety Population, by Race – Phase 2/3 Subjects ≥16 Years of Age

Race	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
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 with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
c. "Indeterminate vaccine" refers to subjects whose vaccine group (as administered) could not be determined. These subjects were not included in the safety analysis but their safety data is listed separately.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:42)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_s003_pop_race_p5

14.34. Safety Population, by Sex – Phase 2/3 Subjects ≥16 Years of Age

Sex		Vaccine Group (as Administered)		
		BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
Male	Randomized[b]			22484
	Vaccinated	11327	11100	22427 (99.7)
	Safety population	11322	11098	22420 (99.7)
	HIV-positive	69	66	135 (0.6)
	Excluded from safety population			64 (0.3)
	Reason for exclusion			
	Subject did not receive study vaccine			57 (0.3)
	Unreliable data due to lack of PI oversight			7 (0.0)
Female	Randomized[b]			21681
	Vaccinated	10705	10925	21633 (99.8)
	Safety population	10704	10923	21630 (99.8)
	HIV-positive	31	34	65 (0.3)
	Indeterminate vaccine[c]			3 (0.0)
	Excluded from safety population			51 (0.2)
	Reason for exclusion			
	Subject did not receive study vaccine			48 (0.2)
	Unreliable data due to lack of PI oversight			3 (0.0)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
c. "Indeterminate vaccine" refers to subjects whose vaccine group (as administered) could not be determined. These subjects were not included in the safety analysis but their safety data is listed separately.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:42)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_s003_pop_sex_p4

14.35. Demographic Characteristics, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Placebo (N[a]=13095) n[b] (%)	Total (N[a]=26164) n[b] (%)
Sex			
Male	6640 (50.8)	6412 (49.0)	13052 (49.9)
Female	6429 (49.2)	6683 (51.0)	13112 (50.1)
Race			
White	10221 (78.2)	10251 (78.3)	20472 (78.2)
Black or African American	1429 (10.9)	1436 (11.0)	2865 (11.0)
American Indian or Alaska Native	165 (1.3)	153 (1.2)	318 (1.2)
Asian	703 (5.4)	712 (5.4)	1415 (5.4)
Native Hawaiian or other Pacific Islander	43 (0.3)	21 (0.2)	64 (0.2)
Multiracial	437 (3.3)	438 (3.3)	875 (3.3)
Not reported	71 (0.5)	84 (0.6)	155 (0.6)
Racial designation			
Japanese	39 (0.3)	41 (0.3)	80 (0.3)
Ethnicity			
Hispanic/Latino	4047 (31.0)	4023 (30.7)	8070 (30.8)
Non-Hispanic/non-Latino	8967 (68.6)	9011 (68.8)	17978 (68.7)
Not reported	55 (0.4)	61 (0.5)	116 (0.4)
Country			
Argentina	1975 (15.1)	1973 (15.1)	3948 (15.1)
Brazil	1191 (9.1)	1189 (9.1)	2380 (9.1)
Germany	134 (1.0)	139 (1.1)	273 (1.0)
South Africa	328 (2.5)	330 (2.5)	658 (2.5)
Turkey	190 (1.5)	197 (1.5)	387 (1.5)
USA	9251 (70.8)	9267 (70.8)	18518 (70.8)
Age at vaccination (years)			
Mean (SD)	39.0 (10.76)	38.7 (10.75)	38.9 (10.76)
Median	40.0	40.0	40.0
Min, max	(16, 55)	(16, 55)	(16, 55)
Baseline SARS-CoV-2 status			
Positive[c]	517 (4.0)	541 (4.1)	1058 (4.0)
Negative[d]	12466 (95.4)	12485 (95.3)	24951 (95.4)
Missing	86 (0.7)	69 (0.5)	155 (0.6)
Body mass index (BMI)			

14.35. Demographic Characteristics, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=13069) n^b (%)	Placebo (N^a=13095) n^b (%)	Total (N^a=26164) n^b (%)
Underweight (<18.5 kg/m^2)	199 (1.5)	224 (1.7)	423 (1.6)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	4208 (32.2)	4268 (32.6)	8476 (32.4)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	4258 (32.6)	4178 (31.9)	8436 (32.2)
Obese (≥30.0 kg/m^2)	4401 (33.7)	4421 (33.8)	8822 (33.7)
Missing	3 (0.0)	4 (0.0)	7 (0.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (15:19)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adsl s005 demo age p3 safl

14.36. Demographic Characteristics, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=8957) n[b] (%)	Placebo (N[a]=8926) n[b] (%)	Total (N[a]=17883) n[b] (%)
Sex			
Male	4682 (52.3)	4686 (52.5)	9368 (52.4)
Female	4275 (47.7)	4240 (47.5)	8515 (47.6)
Race			
White	7835 (87.5)	7813 (87.5)	15648 (87.5)
Black or African American	669 (7.5)	682 (7.6)	1351 (7.6)
American Indian or Alaska Native	56 (0.6)	64 (0.7)	120 (0.7)
Asian	249 (2.8)	230 (2.6)	479 (2.7)
Native Hawaiian or other Pacific Islander	15 (0.2)	11 (0.1)	26 (0.1)
Multiracial	113 (1.3)	95 (1.1)	208 (1.2)
Not reported	20 (0.2)	31 (0.3)	51 (0.3)
Racial designation			
Japanese	39 (0.4)	37 (0.4)	76 (0.4)
Ethnicity			
Hispanic/Latino	1657 (18.5)	1672 (18.7)	3329 (18.6)
Non-Hispanic/non-Latino	7244 (80.9)	7201 (80.7)	14445 (80.8)
Not reported	56 (0.6)	53 (0.6)	109 (0.6)
Country			
Argentina	908 (10.1)	908 (10.2)	1816 (10.2)
Brazil	261 (2.9)	259 (2.9)	520 (2.9)
Germany	115 (1.3)	111 (1.2)	226 (1.3)
South Africa	73 (0.8)	69 (0.8)	142 (0.8)
Turkey	59 (0.7)	52 (0.6)	111 (0.6)
USA	7541 (84.2)	7527 (84.3)	15068 (84.3)
Age at vaccination (years)			
Mean (SD)	65.5 (6.52)	65.4 (6.51)	65.5 (6.51)
Median	65.0	65.0	65.0
Min, max	(56, 89)	(56, 91)	(56, 91)
Baseline SARS-CoV-2 status			
Positive[c]	172 (1.9)	175 (2.0)	347 (1.9)
Negative[d]	8719 (97.3)	8695 (97.4)	17414 (97.4)
Missing	66 (0.7)	56 (0.6)	122 (0.7)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	72 (0.8)	80 (0.9)	152 (0.8)

14.36. Demographic Characteristics, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=8957) n[b] (%)	Placebo (N[a]=8926) n[b] (%)	Total (N[a]=17883) n[b] (%)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	2327 (26.0)	2256 (25.3)	4583 (25.6)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	3412 (38.1)	3380 (37.9)	6792 (38.0)
Obese (≥30.0 kg/m^2)	3142 (35.1)	3208 (35.9)	6350 (35.5)
Missing	4 (0.0)	2 (0.0)	6 (0.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (15:19)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adsl s005 demo age p3 safl

14.37. Demographic Characteristics, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=689) n[b] (%)	Placebo (N[a]=716) n[b] (%)	Total (N[a]=1405) n[b] (%)
Sex			
Male	342 (49.6)	333 (46.5)	675 (48.0)
Female	347 (50.4)	383 (53.5)	730 (52.0)
Race			
White	411 (59.7)	400 (55.9)	811 (57.7)
Black or African American	205 (29.8)	238 (33.2)	443 (31.5)
American Indian or Alaska Native	11 (1.6)	5 (0.7)	16 (1.1)
Asian	15 (2.2)	18 (2.5)	33 (2.3)
Native Hawaiian or other Pacific Islander	3 (0.4)	0	3 (0.2)
Multiracial	40 (5.8)	51 (7.1)	91 (6.5)
Not reported	4 (0.6)	4 (0.6)	8 (0.6)
Racial designation			
Japanese	1 (0.1)	5 (0.7)	6 (0.4)
Ethnicity			
Hispanic/Latino	229 (33.2)	244 (34.1)	473 (33.7)
Non-Hispanic/non-Latino	459 (66.6)	471 (65.8)	930 (66.2)
Not reported	1 (0.1)	1 (0.1)	2 (0.1)
Country			
Argentina	52 (7.5)	81 (11.3)	133 (9.5)
Brazil	107 (15.5)	103 (14.4)	210 (14.9)
Germany	2 (0.3)	0	2 (0.1)
South Africa	74 (10.7)	91 (12.7)	165 (11.7)
Turkey	9 (1.3)	9 (1.3)	18 (1.3)
USA	445 (64.6)	432 (60.3)	877 (62.4)
Age group (at vaccination)			
16-55 Years	517 (75.0)	541 (75.6)	1058 (75.3)
>55 Years	172 (25.0)	175 (24.4)	347 (24.7)
Age at vaccination (years)			
Mean (SD)	43.8 (15.61)	43.5 (15.01)	43.6 (15.30)
Median	42.0	43.0	43.0
Min, max	(16, 82)	(16, 82)	(16, 82)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	3 (0.4)	9 (1.3)	12 (0.9)

14.37. Demographic Characteristics, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=689) n[b] (%)	Placebo (N[a]=716) n[b] (%)	Total (N[a]=1405) n[b] (%)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	158 (22.9)	174 (24.3)	332 (23.6)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	241 (35.0)	237 (33.1)	478 (34.0)
Obese (≥30.0 kg/m^2)	286 (41.5)	296 (41.3)	582 (41.4)
Missing	1 (0.1)	0	1 (0.1)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of 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.
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14.38. Demographic Characteristics, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=21185) n[b] (%)	Placebo (N[a]=21180) n[b] (%)	Total (N[a]=42365) n[b] (%)
Sex			
Male	10903 (51.5)	10699 (50.5)	21602 (51.0)
Female	10282 (48.5)	10481 (49.5)	20763 (49.0)
Race			
White	17530 (82.7)	17573 (83.0)	35103 (82.9)
Black or African American	1865 (8.8)	1860 (8.8)	3725 (8.8)
American Indian or Alaska Native	208 (1.0)	211 (1.0)	419 (1.0)
Asian	931 (4.4)	919 (4.3)	1850 (4.4)
Native Hawaiian or other Pacific Islander	55 (0.3)	31 (0.1)	86 (0.2)
Multiracial	509 (2.4)	477 (2.3)	986 (2.3)
Not reported	87 (0.4)	109 (0.5)	196 (0.5)
Racial designation			
Japanese	76 (0.4)	73 (0.3)	149 (0.4)
Ethnicity			
Hispanic/Latino	5453 (25.7)	5428 (25.6)	10881 (25.7)
Non-Hispanic/non-Latino	15625 (73.8)	15641 (73.8)	31266 (73.8)
Not reported	107 (0.5)	111 (0.5)	218 (0.5)
Country			
Argentina	2824 (13.3)	2794 (13.2)	5618 (13.3)
Brazil	1342 (6.3)	1342 (6.3)	2684 (6.3)
Germany	247 (1.2)	250 (1.2)	497 (1.2)
South Africa	321 (1.5)	306 (1.4)	627 (1.5)
Turkey	240 (1.1)	240 (1.1)	480 (1.1)
USA	16211 (76.5)	16248 (76.7)	32459 (76.6)
Age group (at vaccination)			
16-55 Years	12466 (58.8)	12485 (58.9)	24951 (58.9)
>55 Years	8719 (41.2)	8695 (41.1)	17414 (41.1)
Age at vaccination (years)			
Mean (SD)	49.9 (15.96)	49.8 (16.04)	49.8 (16.00)
Median	51.0	51.0	51.0
Min, max	(16, 89)	(16, 91)	(16, 91)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	268 (1.3)	294 (1.4)	562 (1.3)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	6324 (29.9)	6318 (29.8)	12642 (29.8)

14.38. Demographic Characteristics, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=21185) n[b] (%)	Placebo (N[a]=21180) n[b] (%)	Total (N[a]=42365) n[b] (%)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	7389 (34.9)	7284 (34.4)	14673 (34.6)
Obese (≥30.0 kg/m^2)	7198 (34.0)	7279 (34.4)	14477 (34.2)
Missing	6 (0.0)	5 (0.0)	11 (0.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of 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.
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14.39. Demographic Characteristics, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=5704) n[b] (%)	Placebo (N[a]=5695) n[b] (%)	Total (N[a]=11399) n[b] (%)
Sex			
Male	3131 (54.9)	3000 (52.7)	6131 (53.8)
Female	2573 (45.1)	2695 (47.3)	5268 (46.2)
Race			
White	5347 (93.7)	5330 (93.6)	10677 (93.7)
Black or African American	130 (2.3)	126 (2.2)	256 (2.2)
American Indian or Alaska Native	31 (0.5)	37 (0.6)	68 (0.6)
Asian	74 (1.3)	70 (1.2)	144 (1.3)
Native Hawaiian or other Pacific Islander	11 (0.2)	4 (0.1)	15 (0.1)
Multiracial	52 (0.9)	52 (0.9)	104 (0.9)
Not reported	59 (1.0)	76 (1.3)	135 (1.2)
Racial designation			
Japanese	34 (0.6)	32 (0.6)	66 (0.6)
Country			
Argentina	2843 (49.8)	2856 (50.1)	5699 (50.0)
Brazil	663 (11.6)	661 (11.6)	1324 (11.6)
Germany	0	1 (0.0)	1 (0.0)
South Africa	2 (0.0)	1 (0.0)	3 (0.0)
Turkey	0	0	0
USA	2196 (38.5)	2176 (38.2)	4372 (38.4)
Age group (at vaccination)			
16-55 Years	4047 (71.0)	4023 (70.6)	8070 (70.8)
>55 Years	1657 (29.0)	1672 (29.4)	3329 (29.2)
Age at vaccination (years)			
Mean (SD)	45.8 (15.01)	45.9 (14.86)	45.9 (14.93)
Median	46.0	46.0	46.0
Min, max	(16, 89)	(16, 84)	(16, 89)
Baseline SARS-CoV-2 status			
Positive[c]	229 (4.0)	244 (4.3)	473 (4.1)
Negative[d]	5453 (95.6)	5428 (95.3)	10881 (95.5)
Missing	22 (0.4)	23 (0.4)	45 (0.4)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	60 (1.1)	67 (1.2)	127 (1.1)

14.39. Demographic Characteristics, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=5704) n[b] (%)	Placebo (N[a]=5695) n[b] (%)	Total (N[a]=11399) n[b] (%)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	1631 (28.6)	1652 (29.0)	3283 (28.8)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	2094 (36.7)	2004 (35.2)	4098 (36.0)
Obese (≥30.0 kg/m^2)	1918 (33.6)	1971 (34.6)	3889 (34.1)
Missing	1 (0.0)	1 (0.0)	2 (0.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
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14.40. Demographic Characteristics, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=16211) n[b] (%)	Placebo (N[a]=16212) n[b] (%)	Total (N[a]=32423) n[b] (%)
Sex			
Male	8136 (50.2)	8035 (49.6)	16171 (49.9)
Female	8075 (49.8)	8177 (50.4)	16252 (50.1)
Race			
White	12634 (77.9)	12659 (78.1)	25293 (78.0)
Black or African American	1942 (12.0)	1972 (12.2)	3914 (12.1)
American Indian or Alaska Native	190 (1.2)	180 (1.1)	370 (1.1)
Asian	873 (5.4)	865 (5.3)	1738 (5.4)
Native Hawaiian or other Pacific Islander	47 (0.3)	28 (0.2)	75 (0.2)
Multiracial	496 (3.1)	478 (2.9)	974 (3.0)
Not reported	29 (0.2)	30 (0.2)	59 (0.2)
Racial designation			
Japanese	44 (0.3)	46 (0.3)	90 (0.3)
Country			
Argentina	37 (0.2)	24 (0.1)	61 (0.2)
Brazil	789 (4.9)	786 (4.8)	1575 (4.9)
Germany	249 (1.5)	248 (1.5)	497 (1.5)
South Africa	399 (2.5)	398 (2.5)	797 (2.5)
Turkey	249 (1.5)	249 (1.5)	498 (1.5)
USA	14488 (89.4)	14507 (89.5)	28995 (89.4)
Age group (at vaccination)			
16-55 Years	8967 (55.3)	9011 (55.6)	17978 (55.4)
>55 Years	7244 (44.7)	7201 (44.4)	14445 (44.6)
Age at vaccination (years)			
Mean (SD)	51.1 (16.10)	50.8 (16.25)	51.0 (16.18)
Median	53.0	53.0	53.0
Min, max	(16, 89)	(16, 91)	(16, 91)
Baseline SARS-CoV-2 status			
Positive[c]	459 (2.8)	471 (2.9)	930 (2.9)
Negative[d]	15625 (96.4)	15641 (96.5)	31266 (96.4)
Missing	127 (0.8)	100 (0.6)	227 (0.7)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	211 (1.3)	236 (1.5)	447 (1.4)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	4877 (30.1)	4840 (29.9)	9717 (30.0)

14.40. Demographic Characteristics, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=16211) n^b (%)	Placebo (N^a=16212) n^b (%)	Total (N^a=32423) n^b (%)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	5535 (34.1)	5516 (34.0)	11051 (34.1)
Obese (≥30.0 kg/m^2)	5582 (34.4)	5615 (34.6)	11197 (34.5)
Missing	6 (0.0)	5 (0.0)	11 (0.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
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14.41. Demographic Characteristics, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Not Reported

	BNT162b2 (30 µg) (N[a]=111) n[b] (%)	Placebo (N[a]=114) n[b] (%)	Total (N[a]=225) n[b] (%)
Sex			
Male	55 (49.5)	63 (55.3)	118 (52.4)
Female	56 (50.5)	51 (44.7)	107 (47.6)
Race			
White	75 (67.6)	75 (65.8)	150 (66.7)
Black or African American	26 (23.4)	20 (17.5)	46 (20.4)
American Indian or Alaska Native	0	0	0
Asian	5 (4.5)	7 (6.1)	12 (5.3)
Native Hawaiian or other Pacific Islander	0	0	0
Multiracial	2 (1.8)	3 (2.6)	5 (2.2)
Not reported	3 (2.7)	9 (7.9)	12 (5.3)
Country			
Argentina	3 (2.7)	1 (0.9)	4 (1.8)
Brazil	0	1 (0.9)	1 (0.4)
Germany	0	1 (0.9)	1 (0.4)
South Africa	0	0	0
Turkey	0	0	0
USA	108 (97.3)	111 (97.4)	219 (97.3)
Age group (at vaccination)			
16-55 Years	55 (49.5)	61 (53.5)	116 (51.6)
>55 Years	56 (50.5)	53 (46.5)	109 (48.4)
Age at vaccination (years)			
Mean (SD)	54.0 (13.72)	52.7 (17.20)	53.3 (15.56)
Median	56.0	54.5	55.0
Min, max	(20, 81)	(16, 84)	(16, 84)
Baseline SARS-CoV-2 status			
Positive[c]	1 (0.9)	1 (0.9)	2 (0.9)
Negative[d]	107 (96.4)	111 (97.4)	218 (96.9)
Missing	3 (2.7)	2 (1.8)	5 (2.2)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	0	1 (0.9)	1 (0.4)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	27 (24.3)	32 (28.1)	59 (26.2)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	41 (36.9)	38 (33.3)	79 (35.1)
Obese (≥30.0 kg/m^2)	43 (38.7)	43 (37.7)	86 (38.2)
Missing	0	0	0

14.41. Demographic Characteristics, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Not Reported

	BNT162b2 (30 µg) (N[a]=111) n[b] (%)	Placebo (N[a]=114) n[b] (%)	Total (N[a]=225) n[b] (%)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
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14.42. Demographic Characteristics, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18056) n[b] (%)	Placebo (N[a]=18064) n[b] (%)	Total (N[a]=36120) n[b] (%)
Sex			
Male	9291 (51.5)	9107 (50.4)	18398 (50.9)
Female	8765 (48.5)	8957 (49.6)	17722 (49.1)
Ethnicity			
Hispanic/Latino	5347 (29.6)	5330 (29.5)	10677 (29.6)
Non-Hispanic/non-Latino	12634 (70.0)	12659 (70.1)	25293 (70.0)
Not reported	75 (0.4)	75 (0.4)	150 (0.4)
Country			
Argentina	2858 (15.8)	2860 (15.8)	5718 (15.8)
Brazil	814 (4.5)	808 (4.5)	1622 (4.5)
Germany	248 (1.4)	246 (1.4)	494 (1.4)
South Africa	100 (0.6)	96 (0.5)	196 (0.5)
Turkey	249 (1.4)	248 (1.4)	497 (1.4)
USA	13787 (76.4)	13806 (76.4)	27593 (76.4)
Age group (at vaccination)			
16-55 Years	10221 (56.6)	10251 (56.7)	20472 (56.7)
>55 Years	7835 (43.4)	7813 (43.3)	15648 (43.3)
Age at vaccination (years)			
Mean (SD)	50.7 (16.07)	50.5 (16.17)	50.6 (16.12)
Median	52.0	52.0	52.0
Min, max	(16, 89)	(16, 91)	(16, 91)
Baseline SARS-CoV-2 status			
Positive[c]	411 (2.3)	400 (2.2)	811 (2.2)
Negative[d]	17530 (97.1)	17573 (97.3)	35103 (97.2)
Missing	115 (0.6)	91 (0.5)	206 (0.6)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	215 (1.2)	224 (1.2)	439 (1.2)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	5382 (29.8)	5326 (29.5)	10708 (29.6)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	6417 (35.5)	6341 (35.1)	12758 (35.3)
Obese (≥30.0 kg/m^2)	6037 (33.4)	6168 (34.1)	12205 (33.8)
Missing	5 (0.0)	5 (0.0)	10 (0.0)

14.42. Demographic Characteristics, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18056) n[b] (%)	Placebo (N[a]=18064) n[b] (%)	Total (N[a]=36120) n[b] (%)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
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14.43. Demographic Characteristics, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=2098) n[b] (%)	Placebo (N[a]=2118) n[b] (%)	Total (N[a]=4216) n[b] (%)
Sex			
Male	1058 (50.4)	1041 (49.2)	2099 (49.8)
Female	1040 (49.6)	1077 (50.8)	2117 (50.2)
Ethnicity			
Hispanic/Latino	130 (6.2)	126 (5.9)	256 (6.1)
Non-Hispanic/non-Latino	1942 (92.6)	1972 (93.1)	3914 (92.8)
Not reported	26 (1.2)	20 (0.9)	46 (1.1)
Country			
Argentina	5 (0.2)	4 (0.2)	9 (0.2)
Brazil	239 (11.4)	245 (11.6)	484 (11.5)
Germany	0	1 (0.0)	1 (0.0)
South Africa	223 (10.6)	232 (11.0)	455 (10.8)
Turkey	0	0	0
USA	1631 (77.7)	1636 (77.2)	3267 (77.5)
Age group (at vaccination)			
16-55 Years	1429 (68.1)	1436 (67.8)	2865 (68.0)
>55 Years	669 (31.9)	682 (32.2)	1351 (32.0)
Age at vaccination (years)			
Mean (SD)	46.7 (14.57)	46.6 (14.62)	46.6 (14.59)
Median	48.0	46.0	47.0
Min, max	(16, 83)	(16, 84)	(16, 84)
Baseline SARS-CoV-2 status			
Positive[c]	205 (9.8)	238 (11.2)	443 (10.5)
Negative[d]	1865 (88.9)	1860 (87.8)	3725 (88.4)
Missing	28 (1.3)	20 (0.9)	48 (1.1)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	22 (1.0)	34 (1.6)	56 (1.3)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	473 (22.5)	473 (22.3)	946 (22.4)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	607 (28.9)	592 (28.0)	1199 (28.4)
Obese (≥30.0 kg/m^2)	994 (47.4)	1018 (48.1)	2012 (47.7)
Missing	2 (0.1)	1 (0.0)	3 (0.1)

14.43. Demographic Characteristics, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=2098) n^b (%)	Placebo (N^a=2118) n^b (%)	Total (N^a=4216) n^b (%)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
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14.44. Demographic Characteristics, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: All Others

	BNT162b2 (30 µg) (N[a]=1872) n[b] (%)	Placebo (N[a]=1839) n[b] (%)	Total (N[a]=3711) n[b] (%)
Sex			
Male	973 (52.0)	950 (51.7)	1923 (51.8)
Female	899 (48.0)	889 (48.3)	1788 (48.2)
Racial designation			
Japanese	78 (4.2)	78 (4.2)	156 (4.2)
Ethnicity			
Hispanic/Latino	227 (12.1)	239 (13.0)	466 (12.6)
Non-Hispanic/non-Latino	1635 (87.3)	1581 (86.0)	3216 (86.7)
Not reported	10 (0.5)	19 (1.0)	29 (0.8)
Country			
Argentina	20 (1.1)	17 (0.9)	37 (1.0)
Brazil	399 (21.3)	395 (21.5)	794 (21.4)
Germany	1 (0.1)	3 (0.2)	4 (0.1)
South Africa	78 (4.2)	71 (3.9)	149 (4.0)
Turkey	0	1 (0.1)	1 (0.0)
USA	1374 (73.4)	1352 (73.5)	2726 (73.5)
Age group (at vaccination)			
16-55 Years	1419 (75.8)	1408 (76.6)	2827 (76.2)
>55 Years	453 (24.2)	431 (23.4)	884 (23.8)
Age at vaccination (years)			
Mean (SD)	44.2 (15.13)	43.8 (14.79)	44.0 (14.96)
Median	44.0	43.0	44.0
Min, max	(16, 86)	(16, 91)	(16, 91)
Baseline SARS-CoV-2 status			
Positive[c]	73 (3.9)	78 (4.2)	151 (4.1)
Negative[d]	1790 (95.6)	1747 (95.0)	3537 (95.3)
Missing	9 (0.5)	14 (0.8)	23 (0.6)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	34 (1.8)	46 (2.5)	80 (2.2)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	680 (36.3)	725 (39.4)	1405 (37.9)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	646 (34.5)	625 (34.0)	1271 (34.2)
Obese (≥30.0 kg/m^2)	512 (27.4)	443 (24.1)	955 (25.7)
Missing	0	0	0

14.44. Demographic Characteristics, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: All Others

	BNT162b2 (30 µg) (N[a]=1872) n[b] (%)	Placebo (N[a]=1839) n[b] (%)	Total (N[a]=3711) n[b] (%)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
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14.45. Demographic Characteristics, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=11322) n[b] (%)	Placebo (N[a]=11098) n[b] (%)	Total (N[a]=22420) n[b] (%)
Race			
White	9291 (82.1)	9107 (82.1)	18398 (82.1)
Black or African American	1058 (9.3)	1041 (9.4)	2099 (9.4)
American Indian or Alaska Native	96 (0.8)	102 (0.9)	198 (0.9)
Asian	539 (4.8)	519 (4.7)	1058 (4.7)
Native Hawaiian or other Pacific Islander	27 (0.2)	20 (0.2)	47 (0.2)
Multiracial	255 (2.3)	239 (2.2)	494 (2.2)
Not reported	56 (0.5)	70 (0.6)	126 (0.6)
Racial designation			
Japanese	47 (0.4)	38 (0.3)	85 (0.4)
Ethnicity			
Hispanic/Latino	3131 (27.7)	3000 (27.0)	6131 (27.3)
Non-Hispanic/non-Latino	8136 (71.9)	8035 (72.4)	16171 (72.1)
Not reported	55 (0.5)	63 (0.6)	118 (0.5)
Country			
Argentina	1589 (14.0)	1531 (13.8)	3120 (13.9)
Brazil	687 (6.1)	684 (6.2)	1371 (6.1)
Germany	132 (1.2)	134 (1.2)	266 (1.2)
South Africa	181 (1.6)	168 (1.5)	349 (1.6)
Turkey	170 (1.5)	158 (1.4)	328 (1.5)
USA	8563 (75.6)	8423 (75.9)	16986 (75.8)
Age group (at vaccination)			
16-55 Years	6640 (58.6)	6412 (57.8)	13052 (58.2)
>55 Years	4682 (41.4)	4686 (42.2)	9368 (41.8)
Age at vaccination (years)			
Mean (SD)	50.0 (16.06)	50.3 (16.21)	50.2 (16.14)
Median	51.0	52.0	51.0
Min, max	(16, 89)	(16, 91)	(16, 91)
Baseline SARS-CoV-2 status			
Positive[c]	342 (3.0)	333 (3.0)	675 (3.0)
Negative[d]	10903 (96.3)	10699 (96.4)	21602 (96.4)
Missing	77 (0.7)	66 (0.6)	143 (0.6)
Body mass index (BMI)			

14.45. Demographic Characteristics, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=11322) n[b] (%)	Placebo (N[a]=11098) n[b] (%)	Total (N[a]=22420) n[b] (%)
Underweight (<18.5 kg/m^2)	87 (0.8)	101 (0.9)	188 (0.8)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	2810 (24.8)	2722 (24.5)	5532 (24.7)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	4525 (40.0)	4403 (39.7)	8928 (39.8)
Obese (≥30.0 kg/m^2)	3898 (34.4)	3867 (34.8)	7765 (34.6)
Missing	2 (0.0)	5 (0.0)	7 (0.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
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14.46. Demographic Characteristics, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=10704) n[b] (%)	Placebo (N[a]=10923) n[b] (%)	Total (N[a]=21627) n[b] (%)
Race			
White	8765 (81.9)	8957 (82.0)	17722 (81.9)
Black or African American	1040 (9.7)	1077 (9.9)	2117 (9.8)
American Indian or Alaska Native	125 (1.2)	115 (1.1)	240 (1.1)
Asian	413 (3.9)	423 (3.9)	836 (3.9)
Native Hawaiian or other Pacific Islander	31 (0.3)	12 (0.1)	43 (0.2)
Multiracial	295 (2.8)	294 (2.7)	589 (2.7)
Not reported	35 (0.3)	45 (0.4)	80 (0.4)
Racial designation			
Japanese	31 (0.3)	40 (0.4)	71 (0.3)
Ethnicity			
Hispanic/Latino	2573 (24.0)	2695 (24.7)	5268 (24.4)
Non-Hispanic/non-Latino	8075 (75.4)	8177 (74.9)	16252 (75.1)
Not reported	56 (0.5)	51 (0.5)	107 (0.5)
Country			
Argentina	1294 (12.1)	1350 (12.4)	2644 (12.2)
Brazil	765 (7.1)	764 (7.0)	1529 (7.1)
Germany	117 (1.1)	116 (1.1)	233 (1.1)
South Africa	220 (2.1)	231 (2.1)	451 (2.1)
Turkey	79 (0.7)	91 (0.8)	170 (0.8)
USA	8229 (76.9)	8371 (76.6)	16600 (76.8)
Age group (at vaccination)			
16-55 Years	6429 (60.1)	6683 (61.2)	13112 (60.6)
>55 Years	4275 (39.9)	4240 (38.8)	8515 (39.4)
Age at vaccination (years)			
Mean (SD)	49.4 (15.90)	48.8 (15.86)	49.1 (15.88)
Median	51.0	50.0	50.0
Min, max	(16, 89)	(16, 91)	(16, 91)
Baseline SARS-CoV-2 status			
Positive[c]	347 (3.2)	383 (3.5)	730 (3.4)
Negative[d]	10282 (96.1)	10481 (96.0)	20763 (96.0)
Missing	75 (0.7)	59 (0.5)	134 (0.6)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	184 (1.7)	203 (1.9)	387 (1.8)

14.46. Demographic Characteristics, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=10704) n[b] (%)	Placebo (N[a]=10923) n[b] (%)	Total (N[a]=21627) n[b] (%)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	3725 (34.8)	3802 (34.8)	7527 (34.8)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	3145 (29.4)	3155 (28.9)	6300 (29.1)
Obese (≥30.0 kg/m^2)	3645 (34.1)	3762 (34.4)	7407 (34.2)
Missing	5 (0.0)	1 (0.0)	6 (0.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
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14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Any medical history	17984 (81.6)	18113 (82.3)
Blood and lymphatic system disorders	341 (1.5)	355 (1.6)
Activated protein C resistance	1 (0.0)	0
Anaemia	203 (0.9)	220 (1.0)
Anaemia macrocytic	2 (0.0)	0
Anaemia of pregnancy	0	1 (0.0)
Anaemia vitamin B12 deficiency	2 (0.0)	0
Antiphospholipid syndrome	4 (0.0)	5 (0.0)
Blood loss anaemia	1 (0.0)	1 (0.0)
Coagulopathy	2 (0.0)	3 (0.0)
Eosinophilia	1 (0.0)	0
Haemolytic anaemia	0	3 (0.0)
Haemolytic uraemic syndrome	1 (0.0)	0
Hypercoagulation	4 (0.0)	2 (0.0)
Hypersplenism	1 (0.0)	0
Hypochromic anaemia	1 (0.0)	0
Immune thrombocytopenia	6 (0.0)	10 (0.0)
Increased tendency to bruise	2 (0.0)	2 (0.0)
Iron deficiency anaemia	55 (0.2)	61 (0.3)
Leukocytosis	3 (0.0)	0
Leukopenia	5 (0.0)	6 (0.0)
Lymphadenitis	0	1 (0.0)
Lymphadenopathy	10 (0.0)	9 (0.0)
Lymphatic disorder	1 (0.0)	0
Lymphocytosis	0	1 (0.0)
Lymphoid tissue hyperplasia	1 (0.0)	0
Macrocytosis	1 (0.0)	2 (0.0)
Mast cell activation syndrome	1 (0.0)	0
Mastocytosis	2 (0.0)	0
Microcytic anaemia	1 (0.0)	1 (0.0)
Microcytosis	0	1 (0.0)
Monoclonal B-cell lymphocytosis	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Neutropenia	1 (0.0)	5 (0.0)
Normocytic anaemia	1 (0.0)	1 (0.0)
Pancytopenia	0	2 (0.0)
Pernicious anaemia	7 (0.0)	2 (0.0)
Polycythaemia	7 (0.0)	4 (0.0)
Pseudolymphoma	0	1 (0.0)
Spherocytic anaemia	0	1 (0.0)
Splenic lesion	1 (0.0)	0
Splenomegaly	1 (0.0)	2 (0.0)
Thrombocytopenia	18 (0.1)	17 (0.1)
Thrombocytosis	3 (0.0)	2 (0.0)
Thrombotic thrombocytopenic purpura	0	1 (0.0)
Thymic cyst	1 (0.0)	0
Cardiac disorders	1283 (5.8)	1246 (5.7)
Acute cardiac event	0	1 (0.0)
Acute coronary syndrome	0	2 (0.0)
Acute myocardial infarction	42 (0.2)	23 (0.1)
Adams-Stokes syndrome	1 (0.0)	0
Angina pectoris	49 (0.2)	43 (0.2)
Angina unstable	2 (0.0)	3 (0.0)
Aortic valve disease	2 (0.0)	2 (0.0)
Aortic valve incompetence	12 (0.1)	13 (0.1)
Aortic valve prolapse	1 (0.0)	0
Aortic valve sclerosis	1 (0.0)	0
Aortic valve stenosis	9 (0.0)	9 (0.0)
Arrhythmia	76 (0.3)	82 (0.4)
Arrhythmia supraventricular	1 (0.0)	2 (0.0)
Arteriosclerosis coronary artery	22 (0.1)	24 (0.1)
Arteriospasm coronary	2 (0.0)	4 (0.0)
Atrial fibrillation	249 (1.1)	241 (1.1)
Atrial flutter	17 (0.1)	18 (0.1)
Atrial tachycardia	9 (0.0)	3 (0.0)
Atrioventricular block	3 (0.0)	5 (0.0)
Atrioventricular block complete	3 (0.0)	5 (0.0)
Atrioventricular block first degree	5 (0.0)	5 (0.0)
Atrioventricular block second degree	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Bifascicular block	0	1 (0.0)
Bradyarrhythmia	0	1 (0.0)
Bradycardia	24 (0.1)	25 (0.1)
Bradycardia neonatal	0	1 (0.0)
Bundle branch block	0	2 (0.0)
Bundle branch block left	12 (0.1)	11 (0.0)
Bundle branch block right	11 (0.0)	16 (0.1)
Cardiac amyloidosis	1 (0.0)	0
Cardiac aneurysm	0	2 (0.0)
Cardiac arrest	2 (0.0)	2 (0.0)
Cardiac disorder	7 (0.0)	7 (0.0)
Cardiac failure	14 (0.1)	8 (0.0)
Cardiac failure acute	1 (0.0)	1 (0.0)
Cardiac failure chronic	5 (0.0)	3 (0.0)
Cardiac failure congestive	60 (0.3)	54 (0.2)
Cardiac flutter	0	2 (0.0)
Cardiac septal hypertrophy	1 (0.0)	0
Cardiac valve disease	3 (0.0)	1 (0.0)
Cardiac ventricular thrombosis	1 (0.0)	0
Cardio-respiratory arrest	0	1 (0.0)
Cardiomegaly	3 (0.0)	3 (0.0)
Cardiomyopathy	19 (0.1)	14 (0.1)
Cardiomyopathy alcoholic	0	1 (0.0)
Cardiovascular disorder	5 (0.0)	8 (0.0)
Chronic left ventricular failure	1 (0.0)	2 (0.0)
Congestive cardiomyopathy	3 (0.0)	3 (0.0)
Coronary artery aneurysm	0	1 (0.0)
Coronary artery disease	295 (1.3)	310 (1.4)
Coronary artery dissection	2 (0.0)	0
Coronary artery insufficiency	2 (0.0)	5 (0.0)
Coronary artery occlusion	21 (0.1)	12 (0.1)
Coronary artery stenosis	2 (0.0)	2 (0.0)
Diastolic dysfunction	0	3 (0.0)
Extrasystoles	4 (0.0)	1 (0.0)
Heart valve incompetence	2 (0.0)	1 (0.0)
Hypertensive heart disease	0	4 (0.0)
Ischaemic cardiomyopathy	2 (0.0)	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Left ventricular dysfunction	0	1 (0.0)
Left ventricular failure	1 (0.0)	8 (0.0)
Left ventricular hypertrophy	8 (0.0)	7 (0.0)
Long QT syndrome	1 (0.0)	0
Microvascular coronary artery disease	1 (0.0)	0
Mitral valve disease	6 (0.0)	2 (0.0)
Mitral valve incompetence	22 (0.1)	18 (0.1)
Mitral valve prolapse	74 (0.3)	53 (0.2)
Mitral valve stenosis	3 (0.0)	0
Myocardial infarction	161 (0.7)	183 (0.8)
Myocardial ischaemia	6 (0.0)	6 (0.0)
Myocarditis	2 (0.0)	0
Palpitations	59 (0.3)	51 (0.2)
Pericardial effusion	1 (0.0)	1 (0.0)
Pericarditis	5 (0.0)	5 (0.0)
Postural orthostatic tachycardia syndrome	5 (0.0)	2 (0.0)
Prinzmetal angina	1 (0.0)	2 (0.0)
Pulmonary valve incompetence	1 (0.0)	1 (0.0)
Pulmonary valve stenosis	2 (0.0)	2 (0.0)
Rheumatic heart disease	1 (0.0)	0
Right atrial enlargement	0	1 (0.0)
Right ventricular failure	1 (0.0)	0
Silent myocardial infarction	1 (0.0)	0
Sinus arrhythmia	6 (0.0)	4 (0.0)
Sinus bradycardia	4 (0.0)	8 (0.0)
Sinus node dysfunction	10 (0.0)	3 (0.0)
Sinus tachycardia	10 (0.0)	13 (0.1)
Stress cardiomyopathy	3 (0.0)	2 (0.0)
Supraventricular extrasystoles	9 (0.0)	9 (0.0)
Supraventricular tachycardia	64 (0.3)	47 (0.2)
Tachyarrhythmia	3 (0.0)	1 (0.0)
Tachycardia	33 (0.1)	37 (0.2)
Tachycardia paroxysmal	3 (0.0)	3 (0.0)
Tricuspid valve disease	1 (0.0)	1 (0.0)
Tricuspid valve incompetence	1 (0.0)	3 (0.0)
Ventricular arrhythmia	1 (0.0)	1 (0.0)
Ventricular enlargement	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Ventricular extrasystoles	49 (0.2)	53 (0.2)
Ventricular fibrillation	2 (0.0)	1 (0.0)
Ventricular tachycardia	9 (0.0)	7 (0.0)
Wolff-Parkinson-White syndrome	9 (0.0)	13 (0.1)
Congenital, familial and genetic disorders	413 (1.9)	416 (1.9)
Acrocephalosyndactyly	1 (0.0)	0
Adrenogenital syndrome	1 (0.0)	0
Albinism	1 (0.0)	0
Alpha-1 antitrypsin deficiency	3 (0.0)	0
Amniotic band syndrome	1 (0.0)	0
Anal atresia	1 (0.0)	0
Aniridia	0	1 (0.0)
Ankyloglossia congenital	0	1 (0.0)
Anomalous pulmonary venous connection	1 (0.0)	1 (0.0)
Anomaly of external ear congenital	0	1 (0.0)
Antithrombin III deficiency	0	2 (0.0)
Arnold-Chiari malformation	7 (0.0)	4 (0.0)
Arterial tortuosity syndrome	1 (0.0)	0
Arteriovenous malformation	6 (0.0)	1 (0.0)
Asplenia	1 (0.0)	0
Asymptomatic gene carrier	1 (0.0)	0
Ataxia telangiectasia	0	1 (0.0)
Atrial septal defect	9 (0.0)	16 (0.1)
BRCA1 gene mutation	0	1 (0.0)
BRCA2 gene mutation	0	2 (0.0)
Benign familial pemphigus	1 (0.0)	0
Bicuspid aortic valve	13 (0.1)	4 (0.0)
Bicuspid pulmonary valve	0	1 (0.0)
Blindness congenital	2 (0.0)	0
Brachymetatarsia	0	1 (0.0)
Branchial cyst	1 (0.0)	0
Breast malformation	1 (0.0)	0
Cancer gene carrier	1 (0.0)	3 (0.0)
Carpus curvus	0	1 (0.0)
Cataract congenital	3 (0.0)	1 (0.0)
Cerebral palsy	2 (0.0)	10 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Cerebrovascular arteriovenous malformation	0	4 (0.0)
Checkpoint kinase 2 gene mutation	1 (0.0)	0
Chediak-Higashi syndrome	1 (0.0)	0
Cleft lip	0	2 (0.0)
Cleft palate	4 (0.0)	4 (0.0)
Coarctation of the aorta	1 (0.0)	1 (0.0)
Colour blindness	2 (0.0)	1 (0.0)
Congenital absence of vertebra	1 (0.0)	0
Congenital anomaly	1 (0.0)	1 (0.0)
Congenital aortic anomaly	0	1 (0.0)
Congenital aortic stenosis	2 (0.0)	1 (0.0)
Congenital benign neoplasm	0	1 (0.0)
Congenital cerebrovascular anomaly	1 (0.0)	1 (0.0)
Congenital coronary artery malformation	0	1 (0.0)
Congenital cystic kidney disease	11 (0.0)	4 (0.0)
Congenital cystic lung	2 (0.0)	0
Congenital ectodermal dysplasia	0	1 (0.0)
Congenital eye disorder	1 (0.0)	1 (0.0)
Congenital flat feet	3 (0.0)	0
Congenital foot malformation	0	2 (0.0)
Congenital hand malformation	0	1 (0.0)
Congenital hearing disorder	2 (0.0)	0
Congenital heart valve disorder	0	2 (0.0)
Congenital hydronephrosis	0	1 (0.0)
Congenital hypothyroidism	1 (0.0)	1 (0.0)
Congenital intestinal malformation	0	2 (0.0)
Congenital jaw malformation	4 (0.0)	2 (0.0)
Congenital joint malformation	2 (0.0)	1 (0.0)
Congenital lymphoedema	0	2 (0.0)
Congenital multiplex arthrogryposis	2 (0.0)	0
Congenital musculoskeletal anomaly	2 (0.0)	1 (0.0)
Congenital myopathy	0	1 (0.0)
Congenital myopia	1 (0.0)	0
Congenital neoplasm	0	1 (0.0)
Congenital osteodystrophy	1 (0.0)	0
Congenital pulmonary valve disorder	1 (0.0)	0
Congenital renal disorder	1 (0.0)	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Congenital scoliosis	1 (0.0)	0
Congenital skin disorder	0	1 (0.0)
Congenital small intestinal atresia	0	1 (0.0)
Congenital spinal cord anomaly	1 (0.0)	0
Congenital spinal stenosis	2 (0.0)	0
Congenital spondylolisthesis	1 (0.0)	0
Congenital toxoplasmosis	1 (0.0)	0
Congenital ureteric anomaly	0	1 (0.0)
Congenital urethral anomaly	0	1 (0.0)
Congenital uterine anomaly	1 (0.0)	3 (0.0)
Congenital vas deferens absence	1 (0.0)	0
Corneal dystrophy	13 (0.1)	9 (0.0)
Cornelia de Lange syndrome	0	1 (0.0)
Craniosynostosis	0	1 (0.0)
Cryptorchism	3 (0.0)	4 (0.0)
Cystic fibrosis	0	2 (0.0)
Deafness congenital	2 (0.0)	2 (0.0)
Dermoid cyst	1 (0.0)	1 (0.0)
Developmental glaucoma	0	1 (0.0)
Developmental hip dysplasia	4 (0.0)	10 (0.0)
Dextrocardia	0	1 (0.0)
Diverticulitis Meckel's	1 (0.0)	0
Dolichocolon	2 (0.0)	1 (0.0)
Dopa-responsive dystonia	1 (0.0)	0
Duodenal atresia	1 (0.0)	0
Dysmorphism	1 (0.0)	1 (0.0)
Dysplastic naevus syndrome	1 (0.0)	0
Eagle Barrett syndrome	1 (0.0)	0
Ear malformation	2 (0.0)	0
Ectopic kidney	1 (0.0)	0
Ectrodactyly	1 (0.0)	0
Ehlers-Danlos syndrome	13 (0.1)	8 (0.0)
Factor II deficiency	0	1 (0.0)
Factor II mutation	2 (0.0)	1 (0.0)
Factor V Leiden carrier	3 (0.0)	4 (0.0)
Factor V Leiden mutation	16 (0.1)	21 (0.1)
Factor V deficiency	4 (0.0)	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Factor VII deficiency	0	2 (0.0)
Factor VIII deficiency	1 (0.0)	1 (0.0)
Factor XI deficiency	2 (0.0)	2 (0.0)
Factor XII deficiency	1 (0.0)	2 (0.0)
Factor XIII deficiency	1 (0.0)	0
Fallot's tetralogy	2 (0.0)	2 (0.0)
Familial hypertriglyceridaemia	1 (0.0)	0
Familial mediterranean fever	2 (0.0)	2 (0.0)
Familial polycythaemia	1 (0.0)	0
Familial tremor	4 (0.0)	3 (0.0)
Femoral anteversion	1 (0.0)	0
Gallbladder anomaly congenital	0	1 (0.0)
Gastrointestinal arteriovenous malformation	0	1 (0.0)
Gaucher's disease	0	1 (0.0)
Gene mutation	2 (0.0)	1 (0.0)
Gilbert's syndrome	13 (0.1)	10 (0.0)
Glucose-6-phosphate dehydrogenase deficiency	2 (0.0)	7 (0.0)
Haemangioma congenital	1 (0.0)	0
Haemoglobin C trait	0	1 (0.0)
Haemoglobinopathy	3 (0.0)	3 (0.0)
Haemophilia	0	1 (0.0)
Hamartoma	0	1 (0.0)
Heart disease congenital	4 (0.0)	3 (0.0)
Hepato-lenticular degeneration	0	1 (0.0)
Hereditary haemochromatosis	2 (0.0)	2 (0.0)
Hereditary motor and sensory neuropathy	2 (0.0)	1 (0.0)
Hereditary non-polyposis colorectal cancer syndrome	0	2 (0.0)
Hereditary pancreatitis	0	1 (0.0)
Hereditary spherocytosis	3 (0.0)	1 (0.0)
Heterotaxia	1 (0.0)	0
Hydrocele	9 (0.0)	4 (0.0)
Hypertrophic cardiomyopathy	2 (0.0)	6 (0.0)
Hypochondroplasia	0	1 (0.0)
Hypophosphatasia	1 (0.0)	0
Hypospadias	1 (0.0)	1 (0.0)
Ichthyosis	2 (0.0)	1 (0.0)
Imperforate hymen	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Intestinal malrotation	0	1 (0.0)
Intracranial lipoma	0	1 (0.0)
Keratosis follicular	2 (0.0)	0
Kidney malformation	0	1 (0.0)
Klinefelter's syndrome	2 (0.0)	0
Klippel-Feil syndrome	2 (0.0)	2 (0.0)
Kyphosis congenital	1 (0.0)	0
Leptin receptor deficiency	0	1 (0.0)
Limb malformation	0	2 (0.0)
Limb reduction defect	1 (0.0)	1 (0.0)
Malformation venous	0	1 (0.0)
Marfan's syndrome	2 (0.0)	1 (0.0)
Methylenetetrahydrofolate reductase gene mutation	0	5 (0.0)
Micrognathia	0	2 (0.0)
Microphthalmos	1 (0.0)	0
Morton's syndrome	0	1 (0.0)
Muscular dystrophy	1 (0.0)	0
Myocardial bridging	0	1 (0.0)
Myoclonic dystonia	0	1 (0.0)
Myotonia congenita	0	1 (0.0)
Myotonic dystrophy	0	1 (0.0)
Naevus flammeus	1 (0.0)	0
Neurofibromatosis	6 (0.0)	6 (0.0)
Non-compaction cardiomyopathy	1 (0.0)	0
Oesophageal cyst	0	1 (0.0)
Olfacto genital dysplasia	0	1 (0.0)
Osteogenesis imperfecta	0	1 (0.0)
Otospondylomegaepiphyseal dysplasia	1 (0.0)	0
PTEN gene mutation	0	1 (0.0)
Pancreas divisum	1 (0.0)	0
Patent ductus arteriosus	0	3 (0.0)
Pectus carinatum	0	1 (0.0)
Pectus excavatum	4 (0.0)	3 (0.0)
Pelvic kidney	0	1 (0.0)
Phenylketonuria	0	1 (0.0)
Phimosis	3 (0.0)	6 (0.0)
Poland's syndrome	2 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Polycystic liver disease	2 (0.0)	1 (0.0)
Polydactyly	0	1 (0.0)
Porokeratosis	1 (0.0)	1 (0.0)
Porphyria	1 (0.0)	0
Primary familial brain calcification	0	1 (0.0)
Protein C deficiency	0	1 (0.0)
Protein S deficiency	4 (0.0)	2 (0.0)
Pseudoxanthoma elasticum	1 (0.0)	0
Pulmonary hypoplasia	1 (0.0)	0
Pulmonary malformation	1 (0.0)	0
Pyloric stenosis	3 (0.0)	11 (0.0)
Renal aplasia	4 (0.0)	3 (0.0)
Renal dysplasia	1 (0.0)	0
Renal fusion anomaly	2 (0.0)	1 (0.0)
Renal hypoplasia	0	1 (0.0)
Retinal anomaly congenital	1 (0.0)	0
Retinitis pigmentosa	1 (0.0)	2 (0.0)
Schizencephaly	0	1 (0.0)
Schmid Fraccaro syndrome	1 (0.0)	0
Scimitar syndrome	0	1 (0.0)
Sebaceous naevus	0	1 (0.0)
Sickle cell anaemia	1 (0.0)	1 (0.0)
Sickle cell trait	5 (0.0)	8 (0.0)
Spina bifida	2 (0.0)	4 (0.0)
Spina bifida occulta	0	2 (0.0)
Spine malformation	1 (0.0)	2 (0.0)
Stargardt's disease	1 (0.0)	4 (0.0)
Supernumerary nipple	1 (0.0)	0
Syndactyly	1 (0.0)	1 (0.0)
Syringomyelia	1 (0.0)	0
Talipes	4 (0.0)	4 (0.0)
Thalassaemia	11 (0.0)	8 (0.0)
Thalassaemia alpha	1 (0.0)	3 (0.0)
Thalassaemia beta	3 (0.0)	8 (0.0)
Thalassaemia minor	10 (0.0)	11 (0.0)
Thyroglossal cyst	1 (0.0)	2 (0.0)
Tourette's disorder	5 (0.0)	3 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Tracheo-oesophageal fistula	1 (0.0)	0
Transitional vertebrae	1 (0.0)	0
Tuberous sclerosis complex	1 (0.0)	2 (0.0)
Type II hyperlipidaemia	0	1 (0.0)
Type IIa hyperlipidaemia	16 (0.1)	14 (0.1)
Type V hyperlipidaemia	43 (0.2)	26 (0.1)
Umbilical malformation	0	1 (0.0)
Urethral valves	2 (0.0)	0
VACTERL syndrome	0	1 (0.0)
Venous angioma of brain	1 (0.0)	0
Ventricular septal defect	2 (0.0)	9 (0.0)
Vitello-intestinal duct remnant	3 (0.0)	1 (0.0)
Von Willebrand's disease	3 (0.0)	4 (0.0)
Wolff-Parkinson-White syndrome congenital	1 (0.0)	0
Ear and labyrinth disorders	641 (2.9)	648 (2.9)
Auditory disorder	5 (0.0)	8 (0.0)
Aural polyp	0	1 (0.0)
Cerumen impaction	7 (0.0)	7 (0.0)
Conductive deafness	1 (0.0)	1 (0.0)
Deafness	102 (0.5)	103 (0.5)
Deafness bilateral	110 (0.5)	128 (0.6)
Deafness neurosensory	22 (0.1)	14 (0.1)
Deafness transitory	1 (0.0)	0
Deafness unilateral	55 (0.2)	63 (0.3)
Ear congestion	1 (0.0)	0
Ear deformity acquired	1 (0.0)	0
Ear disorder	2 (0.0)	3 (0.0)
Ear pain	1 (0.0)	7 (0.0)
Ear pruritus	1 (0.0)	1 (0.0)
Endolymphatic hydrops	0	3 (0.0)
Eustachian tube dysfunction	4 (0.0)	6 (0.0)
Eustachian tube patulous	1 (0.0)	0
Eustachian tube stenosis	0	1 (0.0)
Excessive cerumen production	1 (0.0)	1 (0.0)
Exostosis of external ear canal	2 (0.0)	1 (0.0)
Hyperacusis	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Hypoacusis	51 (0.2)	61 (0.3)
Inner ear disorder	2 (0.0)	0
Meniere's disease	44 (0.2)	30 (0.1)
Middle ear effusion	1 (0.0)	0
Mixed deafness	1 (0.0)	1 (0.0)
Motion sickness	6 (0.0)	3 (0.0)
Otosclerosis	8 (0.0)	8 (0.0)
Presbyacusis	6 (0.0)	1 (0.0)
Sudden hearing loss	2 (0.0)	1 (0.0)
Superior semicircular canal dehiscence	1 (0.0)	0
Tinnitus	152 (0.7)	145 (0.7)
Tympanic membrane perforation	13 (0.1)	9 (0.0)
Tympanic membrane scarring	1 (0.0)	0
Vertigo	90 (0.4)	104 (0.5)
Vertigo positional	14 (0.1)	13 (0.1)
Vestibular disorder	1 (0.0)	3 (0.0)
Endocrine disorders	2099 (9.5)	2169 (9.8)
Acromegaly	0	1 (0.0)
Addison's disease	1 (0.0)	1 (0.0)
Adrenal cyst	1 (0.0)	0
Adrenal disorder	0	1 (0.0)
Adrenal insufficiency	2 (0.0)	0
Adrenal mass	1 (0.0)	2 (0.0)
Androgen deficiency	5 (0.0)	6 (0.0)
Anovulatory cycle	1 (0.0)	1 (0.0)
Autoimmune hypothyroidism	2 (0.0)	2 (0.0)
Autoimmune thyroiditis	73 (0.3)	58 (0.3)
Basedow's disease	28 (0.1)	23 (0.1)
Diabetes insipidus	0	3 (0.0)
Empty sella syndrome	1 (0.0)	0
Endocrine disorder	1 (0.0)	1 (0.0)
Goitre	45 (0.2)	62 (0.3)
Gonadotrophin deficiency	1 (0.0)	1 (0.0)
Growth hormone deficiency	2 (0.0)	2 (0.0)
Hyperaldosteronism	1 (0.0)	5 (0.0)
Hyperandrogenism	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Hypergonadism	2 (0.0)	1 (0.0)
Hyperparathyroidism	20 (0.1)	9 (0.0)
Hyperparathyroidism primary	1 (0.0)	2 (0.0)
Hyperplasia adrenal	1 (0.0)	0
Hyperprolactinaemia	5 (0.0)	2 (0.0)
Hyperthyroidism	93 (0.4)	88 (0.4)
Hypogonadism	81 (0.4)	77 (0.3)
Hypogonadism male	14 (0.1)	7 (0.0)
Hypoparathyroidism	4 (0.0)	3 (0.0)
Hypopituitarism	1 (0.0)	0
Hypoprogesteronism	1 (0.0)	0
Hypothalamo-pituitary disorder	0	1 (0.0)
Hypothyroidism	1736 (7.9)	1811 (8.2)
Immune-mediated thyroiditis	0	1 (0.0)
Oestrogen deficiency	6 (0.0)	7 (0.0)
Parathyroid disorder	2 (0.0)	1 (0.0)
Pituitary enlargement	1 (0.0)	0
Pituitary-dependent Cushing's syndrome	1 (0.0)	0
Primary hypogonadism	1 (0.0)	1 (0.0)
Secondary hypogonadism	2 (0.0)	1 (0.0)
Secondary hypothyroidism	0	1 (0.0)
Testicular failure	6 (0.0)	5 (0.0)
Thyroid atrophy	0	1 (0.0)
Thyroid calcification	1 (0.0)	0
Thyroid cyst	10 (0.0)	7 (0.0)
Thyroid disorder	12 (0.1)	5 (0.0)
Thyroid mass	48 (0.2)	61 (0.3)
Thyroid stimulating hormone deficiency	0	1 (0.0)
Thyroiditis	5 (0.0)	3 (0.0)
Thyroiditis subacute	0	2 (0.0)
Toxic nodular goitre	0	2 (0.0)
Eye disorders	2300 (10.4)	2298 (10.4)
Age-related macular degeneration	3 (0.0)	3 (0.0)
Amaurosis	1 (0.0)	1 (0.0)
Amaurosis fugax	1 (0.0)	0
Amblyopia	16 (0.1)	17 (0.1)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Amblyopia strabismic	0	1 (0.0)
Angle closure glaucoma	5 (0.0)	2 (0.0)
Anisometropia	2 (0.0)	1 (0.0)
Arcus lipoides	1 (0.0)	0
Asthenopia	0	1 (0.0)
Astigmatism	73 (0.3)	80 (0.4)
Binocular eye movement disorder	1 (0.0)	0
Blepharitis	7 (0.0)	3 (0.0)
Blepharospasm	2 (0.0)	2 (0.0)
Blindness	5 (0.0)	1 (0.0)
Blindness unilateral	26 (0.1)	14 (0.1)
Borderline glaucoma	5 (0.0)	4 (0.0)
Cataract	509 (2.3)	513 (2.3)
Cataract cortical	0	2 (0.0)
Cataract diabetic	1 (0.0)	0
Cataract nuclear	7 (0.0)	6 (0.0)
Central vision loss	0	1 (0.0)
Chalazion	3 (0.0)	2 (0.0)
Chorioretinopathy	10 (0.0)	2 (0.0)
Cogan's syndrome	0	1 (0.0)
Conjunctival haemorrhage	1 (0.0)	1 (0.0)
Conjunctivitis allergic	15 (0.1)	13 (0.1)
Conjunctivochalasis	0	1 (0.0)
Corneal degeneration	1 (0.0)	1 (0.0)
Corneal disorder	1 (0.0)	2 (0.0)
Corneal epithelium defect	0	1 (0.0)
Corneal oedema	1 (0.0)	0
Corneal opacity	2 (0.0)	0
Corneal scar	2 (0.0)	1 (0.0)
Dacryostenosis acquired	3 (0.0)	5 (0.0)
Dermatochalasis	6 (0.0)	0
Diabetic eye disease	1 (0.0)	0
Diabetic retinopathy	15 (0.1)	13 (0.1)
Diplopia	1 (0.0)	3 (0.0)
Dry age-related macular degeneration	8 (0.0)	1 (0.0)
Dry eye	123 (0.6)	110 (0.5)
Endocrine ophthalmopathy	0	2 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Entropion	1 (0.0)	1 (0.0)
Exfoliation glaucoma	0	1 (0.0)
Exfoliation syndrome	0	1 (0.0)
Exophthalmos	0	1 (0.0)
Extraocular muscle disorder	0	1 (0.0)
Extraocular muscle paresis	0	1 (0.0)
Eye allergy	1 (0.0)	3 (0.0)
Eye disorder	2 (0.0)	5 (0.0)
Eye haemorrhage	1 (0.0)	1 (0.0)
Eye inflammation	2 (0.0)	1 (0.0)
Eye irritation	1 (0.0)	2 (0.0)
Eye movement disorder	1 (0.0)	1 (0.0)
Eye pruritus	2 (0.0)	1 (0.0)
Eye swelling	1 (0.0)	1 (0.0)
Eyelid cyst	1 (0.0)	2 (0.0)
Eyelid ptosis	21 (0.1)	9 (0.0)
Fuchs' syndrome	0	1 (0.0)
Giant papillary conjunctivitis	0	1 (0.0)
Glaucoma	231 (1.0)	234 (1.1)
Heterophoria	0	1 (0.0)
Holmes-Adie pupil	1 (0.0)	0
Hyalosis asteroid	0	1 (0.0)
Hypermetropia	270 (1.2)	256 (1.2)
Idiopathic orbital inflammation	1 (0.0)	0
Iridocorneal endothelial syndrome	1 (0.0)	0
Iridocyclitis	0	2 (0.0)
Iridodialysis	0	1 (0.0)
Iris disorder	1 (0.0)	1 (0.0)
Iritis	3 (0.0)	6 (0.0)
Keratitis	3 (0.0)	1 (0.0)
Keratoconus	9 (0.0)	10 (0.0)
Lacrimal disorder	0	1 (0.0)
Lenticular opacities	1 (0.0)	0
Macular degeneration	54 (0.2)	48 (0.2)
Macular fibrosis	5 (0.0)	9 (0.0)
Macular hole	1 (0.0)	5 (0.0)
Macular oedema	3 (0.0)	2 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Macular scar	0	1 (0.0)
Macular telangiectasia	1 (0.0)	0
Maculopathy	6 (0.0)	4 (0.0)
Meibomian gland dysfunction	3 (0.0)	1 (0.0)
Mydriasis	2 (0.0)	1 (0.0)
Myopia	825 (3.7)	840 (3.8)
Myopic chorioretinal degeneration	2 (0.0)	2 (0.0)
Narrow anterior chamber angle	0	1 (0.0)
Necrotising retinitis	1 (0.0)	0
Neovascular age-related macular degeneration	4 (0.0)	0
Non-proliferative retinopathy	0	1 (0.0)
Normal tension glaucoma	1 (0.0)	3 (0.0)
Ocular discomfort	1 (0.0)	1 (0.0)
Ocular fistula	0	1 (0.0)
Ocular hypertension	4 (0.0)	9 (0.0)
Ocular ischaemic syndrome	0	1 (0.0)
Ocular pemphigoid	1 (0.0)	0
Ocular rosacea	2 (0.0)	1 (0.0)
Ocular vascular disorder	2 (0.0)	2 (0.0)
Open angle glaucoma	7 (0.0)	8 (0.0)
Optic atrophy	1 (0.0)	1 (0.0)
Optic disc drusen	1 (0.0)	0
Optic ischaemic neuropathy	1 (0.0)	3 (0.0)
Optic nerve cupping	0	1 (0.0)
Optic neuropathy	1 (0.0)	1 (0.0)
Oscillopsia	0	2 (0.0)
Photophobia	1 (0.0)	1 (0.0)
Pigment dispersion syndrome	1 (0.0)	0
Pigmentary glaucoma	1 (0.0)	0
Pinguecula	1 (0.0)	0
Posterior capsule opacification	1 (0.0)	0
Presbyopia	290 (1.3)	297 (1.3)
Pterygium	8 (0.0)	5 (0.0)
Punctate keratitis	2 (0.0)	0
Pupils unequal	0	2 (0.0)
Refraction disorder	3 (0.0)	5 (0.0)
Refractive amblyopia	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Retinal artery occlusion	1 (0.0)	1 (0.0)
Retinal artery thrombosis	1 (0.0)	0
Retinal degeneration	4 (0.0)	2 (0.0)
Retinal detachment	40 (0.2)	36 (0.2)
Retinal disorder	4 (0.0)	3 (0.0)
Retinal drusen	1 (0.0)	0
Retinal dystrophy	0	1 (0.0)
Retinal haemorrhage	1 (0.0)	0
Retinal oedema	0	1 (0.0)
Retinal scar	2 (0.0)	1 (0.0)
Retinal tear	11 (0.0)	12 (0.1)
Retinal vascular disorder	1 (0.0)	1 (0.0)
Retinal vein occlusion	3 (0.0)	3 (0.0)
Retinal vein thrombosis	0	1 (0.0)
Retinopathy	2 (0.0)	1 (0.0)
Retinopathy proliferative	2 (0.0)	1 (0.0)
Retinoschisis	0	1 (0.0)
Scintillating scotoma	0	1 (0.0)
Strabismus	29 (0.1)	33 (0.1)
Subretinal fluid	1 (0.0)	0
Ulcerative keratitis	0	1 (0.0)
Uveitis	4 (0.0)	5 (0.0)
Vision blurred	6 (0.0)	3 (0.0)
Visual acuity reduced	115 (0.5)	131 (0.6)
Visual impairment	27 (0.1)	40 (0.2)
Vitreous degeneration	2 (0.0)	2 (0.0)
Vitreous detachment	9 (0.0)	8 (0.0)
Vitreous disorder	0	1 (0.0)
Vitreous floaters	4 (0.0)	3 (0.0)
Vitreous haemorrhage	1 (0.0)	3 (0.0)
Gastrointestinal disorders	3901 (17.7)	3857 (17.5)
Abdominal adhesions	3 (0.0)	2 (0.0)
Abdominal discomfort	0	4 (0.0)
Abdominal distension	6 (0.0)	9 (0.0)
Abdominal fat apron	1 (0.0)	0
Abdominal hernia	62 (0.3)	60 (0.3)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Abdominal mass	1 (0.0)	1 (0.0)
Abdominal migraine	2 (0.0)	1 (0.0)
Abdominal pain	23 (0.1)	19 (0.1)
Abdominal pain lower	3 (0.0)	2 (0.0)
Abdominal pain upper	14 (0.1)	7 (0.0)
Abdominal tenderness	1 (0.0)	0
Abdominal wall mass	1 (0.0)	0
Acquired oesophageal web	4 (0.0)	2 (0.0)
Anal fissure	6 (0.0)	11 (0.0)
Anal fistula	5 (0.0)	9 (0.0)
Anal haemorrhage	0	1 (0.0)
Anal incontinence	1 (0.0)	3 (0.0)
Anal prolapse	0	1 (0.0)
Anal skin tags	1 (0.0)	0
Angular cheilitis	1 (0.0)	0
Anogenital dysplasia	1 (0.0)	2 (0.0)
Aphthous ulcer	8 (0.0)	4 (0.0)
Appendiceal mucocoele	0	1 (0.0)
Appendicitis noninfective	1 (0.0)	1 (0.0)
Appendix disorder	1 (0.0)	1 (0.0)
Barrett's oesophagus	43 (0.2)	43 (0.2)
Bile acid malabsorption	1 (0.0)	2 (0.0)
Cannabinoid hyperemesis syndrome	0	1 (0.0)
Chronic gastritis	13 (0.1)	19 (0.1)
Coeliac artery stenosis	0	1 (0.0)
Coeliac disease	45 (0.2)	49 (0.2)
Colitis	10 (0.0)	10 (0.0)
Colitis ischaemic	1 (0.0)	5 (0.0)
Colitis microscopic	8 (0.0)	7 (0.0)
Colitis ulcerative	24 (0.1)	28 (0.1)
Constipation	217 (1.0)	216 (1.0)
Crohn's disease	17 (0.1)	16 (0.1)
Cyclic vomiting syndrome	1 (0.0)	0
Defaecation disorder	1 (0.0)	0
Dental caries	11 (0.0)	16 (0.1)
Dental plaque	1 (0.0)	0
Diaphragmatic hernia	3 (0.0)	2 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Diarrhoea	61 (0.3)	60 (0.3)
Diverticular perforation	1 (0.0)	0
Diverticulum	122 (0.6)	104 (0.5)
Diverticulum intestinal	24 (0.1)	30 (0.1)
Diverticulum oesophageal	0	2 (0.0)
Dry mouth	8 (0.0)	7 (0.0)
Dumping syndrome	0	1 (0.0)
Duodenal stenosis	0	1 (0.0)
Duodenal ulcer	7 (0.0)	10 (0.0)
Duodenogastric reflux	5 (0.0)	9 (0.0)
Dyspepsia	346 (1.6)	318 (1.4)
Dysphagia	12 (0.1)	11 (0.0)
Encapsulating peritoneal sclerosis	0	1 (0.0)
Enlarged uvula	0	1 (0.0)
Enteritis	1 (0.0)	0
Enterovesical fistula	2 (0.0)	2 (0.0)
Eosinophilic oesophagitis	10 (0.0)	10 (0.0)
Epigastric discomfort	1 (0.0)	0
Epiploic appendagitis	0	1 (0.0)
Erosive oesophagitis	1 (0.0)	0
Eructation	0	1 (0.0)
Faeces hard	0	1 (0.0)
Faeces soft	2 (0.0)	1 (0.0)
Femoral hernia	2 (0.0)	4 (0.0)
Flatulence	3 (0.0)	3 (0.0)
Food poisoning	1 (0.0)	5 (0.0)
Functional gastrointestinal disorder	1 (0.0)	0
Gastric disorder	3 (0.0)	2 (0.0)
Gastric fistula	0	1 (0.0)
Gastric haemorrhage	1 (0.0)	1 (0.0)
Gastric ileus	1 (0.0)	0
Gastric mucosal lesion	1 (0.0)	0
Gastric polyps	0	1 (0.0)
Gastric ulcer	40 (0.2)	53 (0.2)
Gastric ulcer haemorrhage	1 (0.0)	0
Gastric ulcer perforation	1 (0.0)	1 (0.0)
Gastritis	80 (0.4)	75 (0.3)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Gastritis erosive	3 (0.0)	1 (0.0)
Gastroenteritis eosinophilic	1 (0.0)	0
Gastrointestinal disorder	7 (0.0)	4 (0.0)
Gastrointestinal fistula	0	1 (0.0)
Gastrointestinal haemorrhage	10 (0.0)	11 (0.0)
Gastrointestinal hypomotility	2 (0.0)	2 (0.0)
Gastrointestinal inflammation	0	2 (0.0)
Gastrointestinal necrosis	1 (0.0)	0
Gastrointestinal pain	4 (0.0)	2 (0.0)
Gastrointestinal perforation	2 (0.0)	1 (0.0)
Gastrointestinal polyp	1 (0.0)	2 (0.0)
Gastrointestinal scarring	0	1 (0.0)
Gastrointestinal ulcer	2 (0.0)	1 (0.0)
Gastrointestinal ulcer haemorrhage	2 (0.0)	0
Gastrooesophageal reflux disease	2111 (9.6)	2087 (9.5)
Gingival blister	0	1 (0.0)
Gingival discomfort	0	1 (0.0)
Gingival disorder	1 (0.0)	2 (0.0)
Gingival pain	0	1 (0.0)
Gingival recession	1 (0.0)	4 (0.0)
Haematochezia	2 (0.0)	4 (0.0)
Haemorrhoids	183 (0.8)	181 (0.8)
Haemorrhoids thrombosed	1 (0.0)	0
Hiatus hernia	108 (0.5)	134 (0.6)
Hyperaesthesia teeth	1 (0.0)	0
Hyperchlorhydria	1 (0.0)	0
Ileus	0	1 (0.0)
Impaired gastric emptying	17 (0.1)	14 (0.1)
Inflammatory bowel disease	2 (0.0)	5 (0.0)
Inguinal hernia	278 (1.3)	292 (1.3)
Internal hernia	1 (0.0)	0
Intestinal cyst	2 (0.0)	1 (0.0)
Intestinal obstruction	17 (0.1)	11 (0.0)
Intestinal perforation	3 (0.0)	3 (0.0)
Intestinal polyp	6 (0.0)	4 (0.0)
Intestinal prolapse	0	1 (0.0)
Intestinal pseudo-obstruction	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Intestinal strangulation	1 (0.0)	0
Intussusception	1 (0.0)	1 (0.0)
Irritable bowel syndrome	308 (1.4)	300 (1.4)
Large intestinal obstruction	3 (0.0)	1 (0.0)
Large intestinal stenosis	0	1 (0.0)
Large intestinal ulcer	1 (0.0)	0
Large intestine perforation	5 (0.0)	2 (0.0)
Large intestine polyp	112 (0.5)	106 (0.5)
Leukoplakia oral	1 (0.0)	1 (0.0)
Lip swelling	1 (0.0)	0
Lower gastrointestinal haemorrhage	1 (0.0)	1 (0.0)
Lumbar hernia	10 (0.0)	4 (0.0)
Lymphangiectasia intestinal	0	1 (0.0)
Malabsorption	3 (0.0)	2 (0.0)
Malocclusion	4 (0.0)	5 (0.0)
Mouth cyst	1 (0.0)	0
Mouth ulceration	5 (0.0)	5 (0.0)
Nausea	24 (0.1)	33 (0.1)
Necrotising colitis	1 (0.0)	0
Noninfective gingivitis	0	1 (0.0)
Noninfective sialoadenitis	2 (0.0)	0
Obstruction gastric	0	2 (0.0)
Obstructive pancreatitis	0	1 (0.0)
Odynophagia	1 (0.0)	0
Oesophageal achalasia	3 (0.0)	5 (0.0)
Oesophageal dilatation	1 (0.0)	0
Oesophageal disorder	1 (0.0)	1 (0.0)
Oesophageal fistula	1 (0.0)	0
Oesophageal haemorrhage	1 (0.0)	0
Oesophageal motility disorder	0	1 (0.0)
Oesophageal perforation	1 (0.0)	2 (0.0)
Oesophageal spasm	6 (0.0)	4 (0.0)
Oesophageal stenosis	9 (0.0)	5 (0.0)
Oesophageal ulcer	5 (0.0)	2 (0.0)
Oesophagitis	18 (0.1)	17 (0.1)
Oral disorder	0	1 (0.0)
Oral lichen planus	1 (0.0)	2 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Oral mucosal blistering	1 (0.0)	1 (0.0)
Pancreatic cyst	8 (0.0)	4 (0.0)
Pancreatic disorder	0	1 (0.0)
Pancreatic failure	1 (0.0)	5 (0.0)
Pancreatic mass	0	1 (0.0)
Pancreatic pseudocyst	1 (0.0)	0
Pancreatitis	28 (0.1)	18 (0.1)
Pancreatitis acute	5 (0.0)	2 (0.0)
Pancreatitis chronic	5 (0.0)	7 (0.0)
Pancreatitis necrotising	0	1 (0.0)
Pelvic floor dysfunction	4 (0.0)	1 (0.0)
Peptic ulcer	14 (0.1)	22 (0.1)
Peptic ulcer haemorrhage	0	1 (0.0)
Periodontal disease	2 (0.0)	3 (0.0)
Peritoneal cyst	0	1 (0.0)
Pharyngo-oesophageal diverticulum	2 (0.0)	0
Poor dental condition	0	1 (0.0)
Precancerous lesion of digestive tract	1 (0.0)	0
Proctalgia	0	2 (0.0)
Proctitis	0	1 (0.0)
Proctitis ulcerative	2 (0.0)	3 (0.0)
Rectal fissure	4 (0.0)	3 (0.0)
Rectal haemorrhage	8 (0.0)	7 (0.0)
Rectal polyp	1 (0.0)	1 (0.0)
Rectal prolapse	3 (0.0)	6 (0.0)
Rectal spasm	1 (0.0)	0
Reflux gastritis	1 (0.0)	1 (0.0)
Salivary gland calculus	1 (0.0)	1 (0.0)
Salivary gland cyst	3 (0.0)	0
Salivary gland disorder	0	1 (0.0)
Short-bowel syndrome	3 (0.0)	1 (0.0)
Small intestinal obstruction	14 (0.1)	3 (0.0)
Small intestinal perforation	1 (0.0)	1 (0.0)
Small intestinal stenosis	1 (0.0)	1 (0.0)
Small intestine ulcer	1 (0.0)	0
Spigelian hernia	1 (0.0)	0
Splenic artery aneurysm	0	3 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Steatorrhoea	1 (0.0)	0
Stomatitis	1 (0.0)	5 (0.0)
Superior mesenteric artery syndrome	0	1 (0.0)
Swollen tongue	1 (0.0)	1 (0.0)
Tongue coated	0	1 (0.0)
Tongue discomfort	0	1 (0.0)
Tongue geographic	0	1 (0.0)
Tooth disorder	2 (0.0)	0
Tooth impacted	35 (0.2)	28 (0.1)
Tooth loss	4 (0.0)	3 (0.0)
Toothache	6 (0.0)	12 (0.1)
Umbilical hernia	147 (0.7)	136 (0.6)
Upper gastrointestinal haemorrhage	1 (0.0)	0
Uvulitis	1 (0.0)	0
Varices oesophageal	2 (0.0)	2 (0.0)
Volvulus	2 (0.0)	5 (0.0)
Vomiting	6 (0.0)	6 (0.0)
General disorders and administration site conditions	480 (2.2)	458 (2.1)
Adverse drug reaction	16 (0.1)	15 (0.1)
Adverse food reaction	1 (0.0)	0
Application site vesicles	0	1 (0.0)
Asthenia	1 (0.0)	2 (0.0)
Atrophy	1 (0.0)	3 (0.0)
Axillary pain	0	1 (0.0)
Calcinosis	2 (0.0)	1 (0.0)
Chest discomfort	1 (0.0)	2 (0.0)
Chest pain	25 (0.1)	14 (0.1)
Chronic fatigue syndrome	5 (0.0)	3 (0.0)
Complication associated with device	0	1 (0.0)
Cyst	18 (0.1)	25 (0.1)
Cyst rupture	1 (0.0)	1 (0.0)
Device intolerance	0	1 (0.0)
Discomfort	0	2 (0.0)
Disease susceptibility	0	1 (0.0)
Drug intolerance	59 (0.3)	60 (0.3)
Dysplasia	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Face oedema	2 (0.0)	0
Facial pain	0	1 (0.0)
Fat tissue increased	1 (0.0)	1 (0.0)
Fatigue	31 (0.1)	34 (0.2)
Feeling abnormal	1 (0.0)	0
Fibrosis	0	1 (0.0)
Gait disturbance	6 (0.0)	1 (0.0)
Generalised oedema	1 (0.0)	1 (0.0)
Granuloma	0	1 (0.0)
Gravitational oedema	1 (0.0)	1 (0.0)
Hernia	42 (0.2)	40 (0.2)
Hyperplasia	4 (0.0)	1 (0.0)
Hyperthermia malignant	1 (0.0)	0
Inflammation	2 (0.0)	2 (0.0)
Inflammatory pain	1 (0.0)	0
Injection site erythema	0	1 (0.0)
Injection site swelling	1 (0.0)	1 (0.0)
Injury associated with device	1 (0.0)	0
Lithiasis	0	1 (0.0)
Localised oedema	1 (0.0)	1 (0.0)
Malaise	0	2 (0.0)
Medical device site scar	0	1 (0.0)
Necrosis	1 (0.0)	0
Nodule	0	1 (0.0)
Non-cardiac chest pain	1 (0.0)	2 (0.0)
Oedema	25 (0.1)	15 (0.1)
Oedema peripheral	132 (0.6)	122 (0.6)
Pain	75 (0.3)	84 (0.4)
Pelvic mass	1 (0.0)	1 (0.0)
Perforated ulcer	2 (0.0)	0
Peripheral swelling	12 (0.1)	12 (0.1)
Polyp	2 (0.0)	1 (0.0)
Pre-existing condition improved	1 (0.0)	0
Precancerous condition	5 (0.0)	3 (0.0)
Procedural failure	0	1 (0.0)
Pyrexia	2 (0.0)	1 (0.0)
Stenosis	2 (0.0)	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Surgical failure	0	2 (0.0)
Swelling face	1 (0.0)	0
Temperature intolerance	1 (0.0)	0
Therapeutic response unexpected	0	1 (0.0)
Therapy responder	0	1 (0.0)
Treatment noncompliance	1 (0.0)	2 (0.0)
Ulcer	4 (0.0)	1 (0.0)
Ulcer haemorrhage	1 (0.0)	1 (0.0)
Vaccination site reaction	0	1 (0.0)
Vaccination site swelling	2 (0.0)	0
Vascular stent occlusion	0	2 (0.0)
Xerosis	3 (0.0)	0
Hepatobiliary disorders	818 (3.7)	793 (3.6)
Bile duct stone	6 (0.0)	4 (0.0)
Biliary colic	8 (0.0)	1 (0.0)
Biliary cyst	0	2 (0.0)
Biliary dyskinesia	5 (0.0)	1 (0.0)
Biliary obstruction	0	1 (0.0)
Biliary polyp	0	1 (0.0)
Biliary tract disorder	4 (0.0)	1 (0.0)
Cholangitis sclerosing	2 (0.0)	0
Cholecystitis	144 (0.7)	173 (0.8)
Cholecystitis acute	2 (0.0)	6 (0.0)
Cholecystitis chronic	2 (0.0)	1 (0.0)
Cholelithiasis	453 (2.1)	431 (2.0)
Cholelithiasis obstructive	1 (0.0)	1 (0.0)
Cholestasis	2 (0.0)	2 (0.0)
Cirrhosis alcoholic	5 (0.0)	1 (0.0)
Drug-induced liver injury	1 (0.0)	1 (0.0)
Fatty liver alcoholic	1 (0.0)	0
Gallbladder cholesterolosis	1 (0.0)	0
Gallbladder disorder	64 (0.3)	58 (0.3)
Gallbladder enlargement	0	1 (0.0)
Gallbladder hypofunction	4 (0.0)	5 (0.0)
Gallbladder obstruction	1 (0.0)	1 (0.0)
Gallbladder oedema	2 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Gallbladder polyp	2 (0.0)	5 (0.0)
Gallbladder rupture	2 (0.0)	1 (0.0)
Hepatic artery stenosis	0	1 (0.0)
Hepatic atrophy	0	1 (0.0)
Hepatic cirrhosis	9 (0.0)	4 (0.0)
Hepatic cyst	4 (0.0)	9 (0.0)
Hepatic fibrosis	0	1 (0.0)
Hepatic function abnormal	0	1 (0.0)
Hepatic lesion	2 (0.0)	0
Hepatic mass	0	4 (0.0)
Hepatic steatosis	89 (0.4)	65 (0.3)
Hepatitis	0	4 (0.0)
Hepatitis alcoholic	0	1 (0.0)
Hepatobiliary disease	0	1 (0.0)
Hepatomegaly	5 (0.0)	1 (0.0)
Hepatorenal syndrome	0	1 (0.0)
Hyperbilirubinaemia	1 (0.0)	1 (0.0)
Jaundice	1 (0.0)	1 (0.0)
Liver disorder	1 (0.0)	6 (0.0)
Non-alcoholic steatohepatitis	15 (0.1)	8 (0.0)
Nonalcoholic fatty liver disease	12 (0.1)	14 (0.1)
Portal hypertension	1 (0.0)	0
Portal vein thrombosis	0	1 (0.0)
Primary biliary cholangitis	1 (0.0)	1 (0.0)
Immune system disorders	5987 (27.2)	5997 (27.2)
Allergic oedema	7 (0.0)	5 (0.0)
Allergic reaction to excipient	0	1 (0.0)
Allergy to animal	134 (0.6)	134 (0.6)
Allergy to arthropod bite	3 (0.0)	5 (0.0)
Allergy to arthropod sting	77 (0.3)	73 (0.3)
Allergy to chemicals	19 (0.1)	15 (0.1)
Allergy to metals	25 (0.1)	20 (0.1)
Allergy to plants	25 (0.1)	32 (0.1)
Allergy to silk	0	1 (0.0)
Allergy to surgical sutures	0	4 (0.0)
Allergy to synthetic fabric	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Allergy to vaccine	13 (0.1)	11 (0.0)
Allergy to venom	0	2 (0.0)
Amyloidosis	1 (0.0)	1 (0.0)
Anaphylactic reaction	14 (0.1)	21 (0.1)
Anaphylactic shock	1 (0.0)	0
Anti-neutrophil cytoplasmic antibody positive vasculitis	1 (0.0)	0
Atopy	2 (0.0)	3 (0.0)
Autoinflammatory disease	1 (0.0)	0
Cockroach allergy	1 (0.0)	1 (0.0)
Contrast media allergy	37 (0.2)	40 (0.2)
Contrast media reaction	1 (0.0)	1 (0.0)
Device allergy	1 (0.0)	0
Drug hypersensitivity	2811 (12.8)	2696 (12.2)
Dust allergy	32 (0.1)	48 (0.2)
Flour sensitivity	0	1 (0.0)
Food allergy	399 (1.8)	380 (1.7)
Hypersensitivity	225 (1.0)	210 (1.0)
Iodine allergy	48 (0.2)	57 (0.3)
Milk allergy	18 (0.1)	24 (0.1)
Mite allergy	25 (0.1)	25 (0.1)
Multiple allergies	22 (0.1)	26 (0.1)
Mycotic allergy	31 (0.1)	25 (0.1)
Oral allergy syndrome	1 (0.0)	1 (0.0)
Perennial allergy	32 (0.1)	37 (0.2)
Perfume sensitivity	2 (0.0)	5 (0.0)
Reaction to colouring	6 (0.0)	7 (0.0)
Reaction to food additive	9 (0.0)	10 (0.0)
Reaction to preservatives	2 (0.0)	2 (0.0)
Rubber sensitivity	125 (0.6)	130 (0.6)
Sarcoidosis	12 (0.1)	16 (0.1)
Seasonal allergy	3303 (15.0)	3390 (15.4)
Serum sickness	0	2 (0.0)
Smoke sensitivity	3 (0.0)	2 (0.0)
Sunscreen sensitivity	0	2 (0.0)
Infections and infestations	2443 (11.1)	2325 (10.6)
Abdominal infection	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Abscess limb	2 (0.0)	1 (0.0)
Abscess neck	2 (0.0)	0
Abscess soft tissue	0	1 (0.0)
Acarodermatitis	0	1 (0.0)
Actinomycosis	0	1 (0.0)
Acute hepatitis B	0	1 (0.0)
Acute pulmonary histoplasmosis	1 (0.0)	0
Acute sinusitis	2 (0.0)	6 (0.0)
Adenoiditis	16 (0.1)	13 (0.1)
American trypanosomiasis	2 (0.0)	1 (0.0)
Anal abscess	0	1 (0.0)
Anorectal human papilloma virus infection	0	1 (0.0)
Appendiceal abscess	1 (0.0)	0
Appendicitis	486 (2.2)	464 (2.1)
Appendicitis perforated	16 (0.1)	9 (0.0)
Arthritis bacterial	3 (0.0)	3 (0.0)
Arthritis infective	2 (0.0)	3 (0.0)
Asymptomatic HIV infection	1 (0.0)	1 (0.0)
Atypical pneumonia	2 (0.0)	0
Babesiosis	0	1 (0.0)
Bacterial allergy	0	1 (0.0)
Bacterial infection	1 (0.0)	0
Bacterial toxaemia	1 (0.0)	0
Bacterial tracheitis	1 (0.0)	0
Bacterial vaginosis	3 (0.0)	4 (0.0)
Bacterial vulvovaginitis	1 (0.0)	0
Bartonellosis	0	1 (0.0)
Beta haemolytic streptococcal infection	0	1 (0.0)
Body tinea	1 (0.0)	1 (0.0)
Bone abscess	1 (0.0)	0
Brain abscess	0	2 (0.0)
Breast abscess	2 (0.0)	0
Bronchitis	39 (0.2)	35 (0.2)
Bronchitis bacterial	1 (0.0)	0
Bronchopulmonary aspergillosis allergic	1 (0.0)	0
COVID-19	1 (0.0)	0
Candida infection	2 (0.0)	3 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Carbuncle	1 (0.0)	0
Cat scratch disease	3 (0.0)	3 (0.0)
Cellulitis	15 (0.1)	13 (0.1)
Cellulitis orbital	0	1 (0.0)
Central nervous system viral infection	0	1 (0.0)
Cervicitis human papilloma virus	2 (0.0)	2 (0.0)
Chikungunya virus infection	5 (0.0)	4 (0.0)
Chlamydial cervicitis	0	1 (0.0)
Chlamydial infection	14 (0.1)	13 (0.1)
Cholecystitis infective	2 (0.0)	1 (0.0)
Cholera	1 (0.0)	0
Chronic hepatitis B	1 (0.0)	0
Chronic hepatitis C	1 (0.0)	1 (0.0)
Chronic pulmonary histoplasmosis	0	1 (0.0)
Chronic sinusitis	74 (0.3)	75 (0.3)
Chronic tonsillitis	11 (0.0)	10 (0.0)
Clostridial infection	1 (0.0)	0
Clostridium difficile colitis	3 (0.0)	1 (0.0)
Clostridium difficile infection	9 (0.0)	5 (0.0)
Coccidioidomycosis	2 (0.0)	0
Conjunctivitis	5 (0.0)	4 (0.0)
Conjunctivitis viral	1 (0.0)	1 (0.0)
Croup infectious	0	1 (0.0)
Cyclosporidium infection	0	1 (0.0)
Cystitis	7 (0.0)	6 (0.0)
Cytomegalovirus hepatitis	0	1 (0.0)
Cytomegalovirus infection	1 (0.0)	2 (0.0)
Dengue fever	5 (0.0)	7 (0.0)
Dermatophytosis	0	1 (0.0)
Device related infection	3 (0.0)	0
Diverticulitis	104 (0.5)	92 (0.4)
Ear infection	37 (0.2)	33 (0.1)
Ear infection viral	1 (0.0)	0
Eczema infected	1 (0.0)	0
Eczema vaccinatum	0	1 (0.0)
Empyema	1 (0.0)	1 (0.0)
Encephalitis	4 (0.0)	2 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Encephalitis eastern equine	0	1 (0.0)
Encephalomyelitis	1 (0.0)	0
Endocarditis	1 (0.0)	2 (0.0)
Endometritis	0	1 (0.0)
Enterobiasis	1 (0.0)	0
Epidemic typhus	1 (0.0)	0
Epididymitis	3 (0.0)	1 (0.0)
Epiglottitis	0	1 (0.0)
Epstein-Barr virus infection	1 (0.0)	2 (0.0)
Erysipelas	0	2 (0.0)
Escherichia bacteraemia	0	1 (0.0)
Escherichia infection	2 (0.0)	2 (0.0)
Escherichia sepsis	0	1 (0.0)
Extradural abscess	0	1 (0.0)
Eye infection	0	1 (0.0)
Eye infection toxoplasmal	0	2 (0.0)
Eyelid infection	1 (0.0)	1 (0.0)
Folliculitis	6 (0.0)	8 (0.0)
Fracture infection	1 (0.0)	0
Fungal infection	13 (0.1)	2 (0.0)
Fungal skin infection	9 (0.0)	16 (0.1)
Furuncle	2 (0.0)	3 (0.0)
Gangrene	1 (0.0)	0
Gastroenteritis	4 (0.0)	6 (0.0)
Gastroenteritis norovirus	1 (0.0)	0
Gastroenteritis salmonella	0	1 (0.0)
Gastroenteritis viral	0	1 (0.0)
Gastrointestinal bacterial overgrowth	1 (0.0)	2 (0.0)
Gastrointestinal infection	0	2 (0.0)
Genital herpes	51 (0.2)	49 (0.2)
Genital herpes simplex	17 (0.1)	13 (0.1)
Genitourinary chlamydia infection	0	1 (0.0)
Giardiasis	1 (0.0)	0
Gingivitis	0	2 (0.0)
Gonorrhoea	3 (0.0)	3 (0.0)
Groin abscess	1 (0.0)	0
Groin infection	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
HIV infection	22 (0.1)	25 (0.1)
Hand-foot-and-mouth disease	0	1 (0.0)
Helicobacter gastritis	6 (0.0)	1 (0.0)
Helicobacter infection	8 (0.0)	13 (0.1)
Hepatitis A	43 (0.2)	33 (0.1)
Hepatitis B	15 (0.1)	13 (0.1)
Hepatitis C	34 (0.2)	42 (0.2)
Herpes dermatitis	1 (0.0)	2 (0.0)
Herpes ophthalmic	1 (0.0)	3 (0.0)
Herpes simplex	178 (0.8)	150 (0.7)
Herpes simplex meningitis	1 (0.0)	0
Herpes virus infection	18 (0.1)	19 (0.1)
Herpes zoster	118 (0.5)	116 (0.5)
Herpes zoster oticus	1 (0.0)	0
Histoplasmosis	6 (0.0)	0
Hordeolum	2 (0.0)	4 (0.0)
Human ehrlichiosis	0	1 (0.0)
Impetigo	1 (0.0)	2 (0.0)
Infected bite	1 (0.0)	0
Infected cyst	0	2 (0.0)
Infected dermal cyst	1 (0.0)	0
Infection	2 (0.0)	1 (0.0)
Infectious mononucleosis	9 (0.0)	7 (0.0)
Infective myositis	0	1 (0.0)
Infective tenosynovitis	1 (0.0)	0
Influenza	4 (0.0)	5 (0.0)
Joint abscess	0	2 (0.0)
Kidney infection	4 (0.0)	10 (0.0)
Labyrinthitis	11 (0.0)	9 (0.0)
Large intestine infection	0	2 (0.0)
Laryngitis	5 (0.0)	0
Latent tuberculosis	10 (0.0)	7 (0.0)
Liver abscess	0	1 (0.0)
Localised infection	5 (0.0)	3 (0.0)
Ludwig angina	1 (0.0)	0
Lung abscess	1 (0.0)	0
Lyme disease	9 (0.0)	22 (0.1)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Lymph gland infection	0	1 (0.0)
Lymph node abscess	1 (0.0)	0
Malaria	3 (0.0)	2 (0.0)
Mastitis	0	4 (0.0)
Mastoiditis	0	2 (0.0)
Measles	0	1 (0.0)
Mediastinitis	1 (0.0)	0
Meningitis	7 (0.0)	8 (0.0)
Meningitis aseptic	1 (0.0)	0
Meningitis herpes	0	1 (0.0)
Meningitis viral	4 (0.0)	3 (0.0)
Mycobacterium avium complex infection	1 (0.0)	1 (0.0)
Myiasis	0	1 (0.0)
Myocarditis infectious	0	1 (0.0)
Myringitis	1 (0.0)	1 (0.0)
Nasopharyngitis	2 (0.0)	2 (0.0)
Nocardiosis	1 (0.0)	0
Oesophageal candidiasis	1 (0.0)	0
Oesophagitis bacterial	1 (0.0)	0
Onychomycosis	61 (0.3)	69 (0.3)
Ophthalmic herpes simplex	0	2 (0.0)
Ophthalmic herpes zoster	2 (0.0)	3 (0.0)
Oral candidiasis	1 (0.0)	1 (0.0)
Oral herpes	104 (0.5)	121 (0.5)
Oral infection	1 (0.0)	0
Orchitis	0	1 (0.0)
Osteomyelitis	12 (0.1)	11 (0.0)
Otitis externa	2 (0.0)	4 (0.0)
Otitis externa fungal	0	1 (0.0)
Otitis media	8 (0.0)	14 (0.1)
Otitis media acute	1 (0.0)	1 (0.0)
Otitis media chronic	5 (0.0)	4 (0.0)
Otosalpingitis	1 (0.0)	0
Overgrowth bacterial	0	1 (0.0)
Papilloma viral infection	11 (0.0)	6 (0.0)
Parasite allergy	1 (0.0)	0
Paronychia	0	3 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Parotitis	0	1 (0.0)
Pelvic infection	0	1 (0.0)
Pelvic inflammatory disease	4 (0.0)	3 (0.0)
Periodontal destruction	1 (0.0)	0
Periodontitis	2 (0.0)	1 (0.0)
Perirectal abscess	1 (0.0)	2 (0.0)
Peritonitis	6 (0.0)	5 (0.0)
Peritonsillar abscess	2 (0.0)	1 (0.0)
Pertussis	2 (0.0)	3 (0.0)
Pharyngitis	7 (0.0)	4 (0.0)
Pharyngitis streptococcal	22 (0.1)	15 (0.1)
Pharyngotonsillitis	0	2 (0.0)
Pilonidal cyst	15 (0.1)	19 (0.1)
Plasmodium falciparum infection	1 (0.0)	0
Pleurisy viral	0	1 (0.0)
Pneumocystis jirovecii pneumonia	0	1 (0.0)
Pneumonia	97 (0.4)	83 (0.4)
Pneumonia adenoviral	0	1 (0.0)
Pneumonia bacterial	3 (0.0)	1 (0.0)
Pneumonia legionella	0	1 (0.0)
Pneumonia streptococcal	1 (0.0)	0
Pneumonia viral	1 (0.0)	1 (0.0)
Poliomyelitis	7 (0.0)	10 (0.0)
Post procedural infection	0	2 (0.0)
Post procedural sepsis	0	1 (0.0)
Post treatment Lyme disease syndrome	0	1 (0.0)
Postoperative abscess	1 (0.0)	0
Postoperative wound infection	0	1 (0.0)
Presumed ocular histoplasmosis syndrome	0	1 (0.0)
Prostate infection	1 (0.0)	0
Pseudomonal bacteraemia	0	1 (0.0)
Pulmonary mycosis	0	1 (0.0)
Pulmonary sepsis	0	1 (0.0)
Pulmonary tuberculosis	5 (0.0)	3 (0.0)
Pyelonephritis	3 (0.0)	5 (0.0)
Rectal abscess	1 (0.0)	1 (0.0)
Renal abscess	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Renal tuberculosis	0	1 (0.0)
Respiratory syncytial virus infection	1 (0.0)	1 (0.0)
Respiratory tract infection	1 (0.0)	0
Rhinitis	40 (0.2)	35 (0.2)
Rocky mountain spotted fever	2 (0.0)	1 (0.0)
Root canal infection	0	1 (0.0)
Rubella	0	1 (0.0)
Salmonellosis	0	1 (0.0)
Salpingitis	2 (0.0)	2 (0.0)
Scarlet fever	3 (0.0)	3 (0.0)
Scrotal infection	1 (0.0)	0
Sepsis	6 (0.0)	10 (0.0)
Sepsis syndrome	1 (0.0)	0
Septic arthritis staphylococcal	4 (0.0)	0
Septic shock	1 (0.0)	1 (0.0)
Sinobronchitis	0	1 (0.0)
Sinusitis	120 (0.5)	106 (0.5)
Sinusitis bacterial	2 (0.0)	0
Sinusitis fungal	2 (0.0)	1 (0.0)
Skin bacterial infection	2 (0.0)	0
Skin candida	0	1 (0.0)
Skin infection	0	3 (0.0)
Soft tissue infection	1 (0.0)	0
Staphylococcal bacteraemia	0	1 (0.0)
Staphylococcal infection	21 (0.1)	18 (0.1)
Staphylococcal skin infection	3 (0.0)	2 (0.0)
Streptococcal infection	7 (0.0)	1 (0.0)
Subacute endocarditis	1 (0.0)	0
Subcutaneous abscess	2 (0.0)	1 (0.0)
Syphilis	10 (0.0)	5 (0.0)
Tinea capitis	1 (0.0)	0
Tinea cruris	2 (0.0)	1 (0.0)
Tinea infection	1 (0.0)	1 (0.0)
Tinea pedis	13 (0.1)	5 (0.0)
Tinea versicolour	16 (0.1)	15 (0.1)
Tonsillitis	489 (2.2)	442 (2.0)
Tonsillitis streptococcal	1 (0.0)	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Tooth abscess	2 (0.0)	5 (0.0)
Tooth infection	2 (0.0)	5 (0.0)
Toxic shock syndrome	2 (0.0)	2 (0.0)
Trichomoniasis	2 (0.0)	0
Tropical ulcer	0	1 (0.0)
Tuberculosis	14 (0.1)	8 (0.0)
Tuberculous pleurisy	1 (0.0)	2 (0.0)
Tubo-ovarian abscess	0	1 (0.0)
Typhoid fever	1 (0.0)	1 (0.0)
Typhus	1 (0.0)	1 (0.0)
Upper respiratory tract infection	7 (0.0)	10 (0.0)
Urethritis	0	2 (0.0)
Urinary tract infection	124 (0.6)	116 (0.5)
Urinary tract infection bacterial	1 (0.0)	1 (0.0)
Urosepsis	1 (0.0)	1 (0.0)
Uterine infection	2 (0.0)	0
Vaginal infection	5 (0.0)	5 (0.0)
Vaginitis chlamydial	1 (0.0)	2 (0.0)
Vaginitis gardnerella	1 (0.0)	0
Varicella	13 (0.1)	7 (0.0)
Varicella zoster virus infection	1 (0.0)	0
Vestibular neuronitis	0	2 (0.0)
Viral cardiomyopathy	0	1 (0.0)
Viral infection	3 (0.0)	0
Viral myocarditis	0	1 (0.0)
Vulval abscess	1 (0.0)	0
Vulvitis	1 (0.0)	0
Vulvovaginal candidiasis	1 (0.0)	5 (0.0)
Vulvovaginal mycotic infection	4 (0.0)	4 (0.0)
West Nile viral infection	0	1 (0.0)
Injury, poisoning and procedural complications	1590 (7.2)	1596 (7.2)
Abdominal injury	4 (0.0)	1 (0.0)
Accident	4 (0.0)	2 (0.0)
Accident at work	0	1 (0.0)
Accidental poisoning	1 (0.0)	0
Acetabulum fracture	1 (0.0)	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Alcohol poisoning	0	1 (0.0)
Anaemia postoperative	0	1 (0.0)
Animal bite	3 (0.0)	2 (0.0)
Animal scratch	1 (0.0)	0
Ankle fracture	118 (0.5)	102 (0.5)
Arterial injury	1 (0.0)	3 (0.0)
Arthropod bite	8 (0.0)	5 (0.0)
Arthropod sting	2 (0.0)	1 (0.0)
Asbestosis	0	1 (0.0)
Avulsion fracture	0	2 (0.0)
Back injury	21 (0.1)	17 (0.1)
Bite	1 (0.0)	0
Bladder injury	1 (0.0)	1 (0.0)
Blindness traumatic	1 (0.0)	1 (0.0)
Brachial plexus injury	1 (0.0)	0
Burns second degree	2 (0.0)	0
Burns third degree	1 (0.0)	3 (0.0)
Bursa injury	0	1 (0.0)
Cardiac valve rupture	1 (0.0)	0
Cartilage injury	47 (0.2)	42 (0.2)
Cataract traumatic	0	2 (0.0)
Cervical vertebral fracture	17 (0.1)	11 (0.0)
Chemical poisoning	0	1 (0.0)
Chest injury	2 (0.0)	2 (0.0)
Clavicle fracture	30 (0.1)	45 (0.2)
Colon injury	0	1 (0.0)
Compression fracture	1 (0.0)	1 (0.0)
Concussion	25 (0.1)	14 (0.1)
Contusion	4 (0.0)	3 (0.0)
Corneal abrasion	0	2 (0.0)
Craniocerebral injury	13 (0.1)	11 (0.0)
Craniofacial fracture	0	1 (0.0)
Deafness traumatic	0	2 (0.0)
Decompression sickness	1 (0.0)	1 (0.0)
Dental restoration failure	1 (0.0)	0
Dermatitis artefacta	1 (0.0)	0
Dislocation of vertebra	2 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Donor site complication	0	1 (0.0)
Epicondylitis	18 (0.1)	16 (0.1)
Epiphyseal fracture	0	1 (0.0)
Exposure to communicable disease	3 (0.0)	3 (0.0)
Exposure to radiation	1 (0.0)	0
Eye injury	3 (0.0)	10 (0.0)
Eyeball avulsion	1 (0.0)	0
Eyelid contusion	1 (0.0)	0
Face injury	3 (0.0)	2 (0.0)
Facial bones fracture	38 (0.2)	45 (0.2)
Fall	14 (0.1)	10 (0.0)
Fascial rupture	2 (0.0)	0
Femoral neck fracture	0	2 (0.0)
Femur fracture	41 (0.2)	31 (0.1)
Fibula fracture	18 (0.1)	19 (0.1)
Flail chest	0	1 (0.0)
Foot fracture	74 (0.3)	70 (0.3)
Forearm fracture	11 (0.0)	11 (0.0)
Foreign body	3 (0.0)	1 (0.0)
Foreign body in ear	0	1 (0.0)
Foreign body in eye	0	2 (0.0)
Foreign body in gastrointestinal tract	1 (0.0)	0
Fracture	4 (0.0)	3 (0.0)
Fractured coccyx	2 (0.0)	4 (0.0)
Gastrointestinal injury	0	1 (0.0)
Gastrointestinal procedural complication	0	1 (0.0)
Glaucoma traumatic	1 (0.0)	0
Gun shot wound	11 (0.0)	17 (0.1)
Hand fracture	75 (0.3)	70 (0.3)
Head injury	13 (0.1)	26 (0.1)
Hepatic rupture	0	1 (0.0)
Hip fracture	20 (0.1)	25 (0.1)
Humerus fracture	17 (0.1)	16 (0.1)
Hyphaema	0	1 (0.0)
Iatrogenic injury	1 (0.0)	0
Iliotibial band syndrome	0	9 (0.0)
Ilium fracture	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Incisional hernia	8 (0.0)	10 (0.0)
Injury	1 (0.0)	5 (0.0)
Injury corneal	1 (0.0)	2 (0.0)
Injury to brachial plexus due to birth trauma	0	1 (0.0)
Intentional overdose	0	1 (0.0)
Intentional product misuse	0	1 (0.0)
Intervertebral disc injury	4 (0.0)	2 (0.0)
Iris injury	0	1 (0.0)
Jaw fracture	14 (0.1)	10 (0.0)
Joint dislocation	50 (0.2)	50 (0.2)
Joint injury	48 (0.2)	61 (0.3)
Kidney rupture	0	1 (0.0)
Lacrimal structure injury	1 (0.0)	0
Laryngeal injury	0	1 (0.0)
Ligament injury	18 (0.1)	13 (0.1)
Ligament rupture	156 (0.7)	125 (0.6)
Ligament sprain	16 (0.1)	18 (0.1)
Limb crushing injury	2 (0.0)	2 (0.0)
Limb fracture	2 (0.0)	2 (0.0)
Limb injury	63 (0.3)	56 (0.3)
Limb traumatic amputation	3 (0.0)	3 (0.0)
Lisfranc fracture	1 (0.0)	1 (0.0)
Lower limb fracture	56 (0.3)	50 (0.2)
Lumbar vertebral fracture	13 (0.1)	9 (0.0)
Mallet finger	1 (0.0)	2 (0.0)
Maternal drugs affecting foetus	1 (0.0)	0
Meniscus injury	216 (1.0)	212 (1.0)
Multiple fractures	0	5 (0.0)
Multiple injuries	1 (0.0)	0
Muscle injury	4 (0.0)	8 (0.0)
Muscle rupture	26 (0.1)	18 (0.1)
Muscle strain	18 (0.1)	17 (0.1)
Musculoskeletal foreign body	1 (0.0)	2 (0.0)
Nail injury	0	1 (0.0)
Nasal injury	3 (0.0)	5 (0.0)
Neck injury	8 (0.0)	8 (0.0)
Nerve injury	12 (0.1)	16 (0.1)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Nerve root injury lumbar	0	1 (0.0)
Nervous system injury	1 (0.0)	0
Neurological procedural complication	0	1 (0.0)
Oesophageal injury	1 (0.0)	0
Optic nerve injury	1 (0.0)	0
Overdose	2 (0.0)	0
Pancreatic injury	1 (0.0)	0
Paranasal sinus injury	0	1 (0.0)
Patella fracture	12 (0.1)	8 (0.0)
Pelvic fracture	12 (0.1)	7 (0.0)
Penetrating abdominal trauma	2 (0.0)	0
Penis injury	0	1 (0.0)
Periorbital haematoma	1 (0.0)	0
Periorbital haemorrhage	1 (0.0)	0
Peripheral nerve injury	3 (0.0)	7 (0.0)
Persistent corneal epithelial defect	0	1 (0.0)
Pneumothorax traumatic	1 (0.0)	0
Post ablation tubal sterilisation syndrome	1 (0.0)	0
Post concussion syndrome	1 (0.0)	3 (0.0)
Post laminectomy syndrome	0	1 (0.0)
Post procedural complication	1 (0.0)	2 (0.0)
Post procedural diarrhoea	1 (0.0)	2 (0.0)
Post procedural haemorrhage	1 (0.0)	0
Post procedural hypothyroidism	10 (0.0)	10 (0.0)
Post procedural pulmonary embolism	0	1 (0.0)
Post-traumatic neck syndrome	2 (0.0)	1 (0.0)
Post-traumatic pain	1 (0.0)	0
Postoperative adhesion	1 (0.0)	0
Postoperative thrombosis	2 (0.0)	0
Procedural intestinal perforation	1 (0.0)	0
Procedural pain	4 (0.0)	4 (0.0)
Procedural pneumothorax	1 (0.0)	0
Radiation proctitis	0	1 (0.0)
Radius fracture	17 (0.1)	16 (0.1)
Repetitive strain injury	3 (0.0)	1 (0.0)
Respiratory fume inhalation disorder	0	2 (0.0)
Retinal injury	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Rib fracture	17 (0.1)	25 (0.1)
Road traffic accident	29 (0.1)	47 (0.2)
Scapula fracture	0	4 (0.0)
Scar	51 (0.2)	54 (0.2)
Sciatic nerve injury	2 (0.0)	0
Scrotal injury	1 (0.0)	0
Seroma	0	1 (0.0)
Silicosis	1 (0.0)	2 (0.0)
Sinus barotrauma	0	1 (0.0)
Skeletal injury	8 (0.0)	9 (0.0)
Skin abrasion	3 (0.0)	1 (0.0)
Skin injury	0	2 (0.0)
Skin laceration	15 (0.1)	18 (0.1)
Skull fracture	3 (0.0)	5 (0.0)
Skull fractured base	2 (0.0)	1 (0.0)
Snake bite	3 (0.0)	1 (0.0)
Soft tissue injury	1 (0.0)	0
Spinal column injury	8 (0.0)	3 (0.0)
Spinal compression fracture	9 (0.0)	13 (0.1)
Spinal cord injury	3 (0.0)	2 (0.0)
Spinal cord injury cervical	2 (0.0)	0
Spinal cord injury thoracic	0	1 (0.0)
Spinal fracture	12 (0.1)	13 (0.1)
Splenic injury	1 (0.0)	2 (0.0)
Splenic rupture	5 (0.0)	6 (0.0)
Sports injury	4 (0.0)	2 (0.0)
Stab wound	4 (0.0)	1 (0.0)
Sternal fracture	2 (0.0)	1 (0.0)
Stress fracture	7 (0.0)	8 (0.0)
Subarachnoid haematoma	1 (0.0)	0
Subdural haematoma	4 (0.0)	5 (0.0)
Subdural haemorrhage	0	1 (0.0)
Superficial injury of eye	0	1 (0.0)
Suture related complication	1 (0.0)	0
Suture rupture	1 (0.0)	0
Tendon dislocation	1 (0.0)	0
Tendon injury	14 (0.1)	11 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Tendon rupture	69 (0.3)	74 (0.3)
Testicular injury	1 (0.0)	1 (0.0)
Thermal burn	3 (0.0)	3 (0.0)
Thermal burns of eye	1 (0.0)	1 (0.0)
Thoracic vertebral fracture	2 (0.0)	5 (0.0)
Tibia fracture	39 (0.2)	34 (0.2)
Tooth fracture	2 (0.0)	1 (0.0)
Tooth injury	0	1 (0.0)
Traumatic arthritis	3 (0.0)	1 (0.0)
Traumatic ear amputation	1 (0.0)	0
Traumatic haematoma	1 (0.0)	1 (0.0)
Traumatic liver injury	0	1 (0.0)
Traumatic lung injury	0	7 (0.0)
Traumatic renal injury	2 (0.0)	1 (0.0)
Ulna fracture	7 (0.0)	14 (0.1)
Ulnar nerve injury	0	3 (0.0)
Upper limb fracture	81 (0.4)	91 (0.4)
Ureteric injury	1 (0.0)	0
Urethral stricture traumatic	0	1 (0.0)
Uterine perforation	1 (0.0)	0
Uterine rupture	2 (0.0)	0
Vascular pseudoaneurysm	2 (0.0)	2 (0.0)
Venomous sting	0	1 (0.0)
Vitreous injury	1 (0.0)	0
Vth nerve injury	1 (0.0)	1 (0.0)
Wound	1 (0.0)	2 (0.0)
Wrist fracture	80 (0.4)	99 (0.4)
Investigations	1695 (7.7)	1714 (7.8)
Alanine aminotransferase increased	2 (0.0)	1 (0.0)
Androgens abnormal	0	1 (0.0)
Angiocardiogram	3 (0.0)	7 (0.0)
Angiogram	1 (0.0)	2 (0.0)
Angiogram peripheral	0	1 (0.0)
Anti-platelet antibody positive	1 (0.0)	0
Anti-thyroid antibody positive	1 (0.0)	0
Anticoagulation drug level	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Antinuclear antibody positive	0	1 (0.0)
Aortic bruit	0	1 (0.0)
Apnoea test	0	1 (0.0)
Apolipoprotein E	1 (0.0)	0
Arteriogram	1 (0.0)	0
Arthroscopy	141 (0.6)	144 (0.7)
Aspartate aminotransferase increased	1 (0.0)	0
Aspiration bone marrow	1 (0.0)	0
Aspiration breast	1 (0.0)	0
Aspiration bursa	0	1 (0.0)
Aspiration joint	0	2 (0.0)
Aspiration pleural cavity	0	3 (0.0)
Bacterial test positive	0	1 (0.0)
Biopsy	5 (0.0)	7 (0.0)
Biopsy bone	1 (0.0)	0
Biopsy bone marrow	0	1 (0.0)
Biopsy breast	34 (0.2)	30 (0.1)
Biopsy breast normal	15 (0.1)	13 (0.1)
Biopsy cervix	3 (0.0)	7 (0.0)
Biopsy cervix abnormal	1 (0.0)	0
Biopsy cervix normal	2 (0.0)	0
Biopsy colon	4 (0.0)	5 (0.0)
Biopsy colon normal	1 (0.0)	0
Biopsy endometrium normal	1 (0.0)	1 (0.0)
Biopsy larynx normal	1 (0.0)	0
Biopsy liver	2 (0.0)	2 (0.0)
Biopsy liver normal	1 (0.0)	1 (0.0)
Biopsy lung	1 (0.0)	4 (0.0)
Biopsy lymph gland	3 (0.0)	5 (0.0)
Biopsy lymph gland normal	1 (0.0)	0
Biopsy pharynx normal	1 (0.0)	0
Biopsy prostate	9 (0.0)	9 (0.0)
Biopsy prostate normal	1 (0.0)	3 (0.0)
Biopsy salivary gland	0	1 (0.0)
Biopsy site unspecified normal	2 (0.0)	0
Biopsy skin	6 (0.0)	10 (0.0)
Biopsy skin normal	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Biopsy small intestine normal	0	1 (0.0)
Biopsy soft tissue	0	1 (0.0)
Biopsy testes	0	1 (0.0)
Biopsy thyroid gland	2 (0.0)	2 (0.0)
Biopsy thyroid gland normal	0	1 (0.0)
Biopsy uterus	1 (0.0)	0
Biopsy vulva	0	1 (0.0)
Blood bilirubin increased	1 (0.0)	4 (0.0)
Blood calcium abnormal	0	1 (0.0)
Blood calcium decreased	2 (0.0)	0
Blood calcium increased	1 (0.0)	3 (0.0)
Blood cholesterol	4 (0.0)	4 (0.0)
Blood cholesterol increased	689 (3.1)	715 (3.2)
Blood cholinesterase decreased	0	1 (0.0)
Blood chromium increased	1 (0.0)	0
Blood cobalt increased	1 (0.0)	0
Blood creatine phosphokinase increased	0	1 (0.0)
Blood creatinine abnormal	1 (0.0)	0
Blood glucose	2 (0.0)	0
Blood glucose abnormal	3 (0.0)	0
Blood glucose increased	8 (0.0)	9 (0.0)
Blood iron decreased	2 (0.0)	3 (0.0)
Blood magnesium decreased	1 (0.0)	1 (0.0)
Blood oestrogen	0	1 (0.0)
Blood oestrogen decreased	3 (0.0)	2 (0.0)
Blood oestrogen increased	2 (0.0)	1 (0.0)
Blood parathyroid hormone abnormal	0	1 (0.0)
Blood parathyroid hormone increased	0	1 (0.0)
Blood potassium decreased	8 (0.0)	7 (0.0)
Blood pressure diastolic increased	1 (0.0)	1 (0.0)
Blood pressure increased	17 (0.1)	15 (0.1)
Blood pressure measurement	1 (0.0)	1 (0.0)
Blood prolactin increased	1 (0.0)	1 (0.0)
Blood testosterone	0	1 (0.0)
Blood testosterone decreased	130 (0.6)	134 (0.6)
Blood testosterone increased	1 (0.0)	0
Blood thyroid stimulating hormone abnormal	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Blood thyroid stimulating hormone decreased	1 (0.0)	1 (0.0)
Blood thyroid stimulating hormone increased	0	1 (0.0)
Blood triglycerides	1 (0.0)	0
Blood triglycerides increased	48 (0.2)	43 (0.2)
Blood uric acid increased	2 (0.0)	5 (0.0)
Blood urine present	1 (0.0)	0
Blood zinc decreased	1 (0.0)	0
Body mass index decreased	0	1 (0.0)
Body mass index increased	0	1 (0.0)
Bone density abnormal	1 (0.0)	0
Bone density decreased	2 (0.0)	0
Bronchoscopy	2 (0.0)	3 (0.0)
Bronchoscopy abnormal	1 (0.0)	0
C-reactive protein increased	1 (0.0)	2 (0.0)
Carbon dioxide increased	0	1 (0.0)
Cardiac murmur	116 (0.5)	125 (0.6)
Cardiac murmur functional	2 (0.0)	2 (0.0)
Cardiac stress test	0	2 (0.0)
Cardiac stress test abnormal	0	1 (0.0)
Carotid bruit	0	3 (0.0)
Catheterisation cardiac	29 (0.1)	27 (0.1)
Chlamydia test positive	0	1 (0.0)
Coagulation factor V level	1 (0.0)	2 (0.0)
Coagulation factor VIII level decreased	0	1 (0.0)
Colonoscopy	139 (0.6)	120 (0.5)
Colonoscopy abnormal	0	1 (0.0)
Colonoscopy normal	3 (0.0)	1 (0.0)
Colposcopy	4 (0.0)	2 (0.0)
Colposcopy normal	0	1 (0.0)
Computerised tomogram coronary artery	1 (0.0)	0
Continuous glucose monitoring	0	2 (0.0)
Cortisol increased	0	1 (0.0)
Cystoscopy	7 (0.0)	5 (0.0)
Cystoscopy normal	0	1 (0.0)
Cytology abnormal	1 (0.0)	0
Dehydroepiandrosterone increased	1 (0.0)	0
Diagnostic aspiration	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Diagnostic procedure	3 (0.0)	0
Discogram	1 (0.0)	0
Echocardiogram	2 (0.0)	1 (0.0)
Ejection fraction abnormal	1 (0.0)	0
Ejection fraction decreased	2 (0.0)	1 (0.0)
Electrocardiogram PR shortened	1 (0.0)	0
Electrocardiogram QT prolonged	2 (0.0)	1 (0.0)
Electrocardiogram ST segment abnormal	0	1 (0.0)
Electrocardiogram ST segment depression	1 (0.0)	0
Electrocardiogram T wave inversion	2 (0.0)	0
Electrocardiogram abnormal	2 (0.0)	4 (0.0)
Electrocardiogram ambulatory	0	1 (0.0)
Endoscopic retrograde cholangiopancreatography	1 (0.0)	1 (0.0)
Endoscopy	14 (0.1)	11 (0.0)
Endoscopy gastrointestinal	0	1 (0.0)
Endoscopy upper gastrointestinal tract	10 (0.0)	8 (0.0)
Eosinophil count increased	1 (0.0)	0
Epinephrine	0	1 (0.0)
Epstein-Barr virus test positive	0	1 (0.0)
False positive investigation result	1 (0.0)	1 (0.0)
Full blood count	0	1 (0.0)
Gamma-glutamyltransferase abnormal	0	1 (0.0)
Gastrointestinal tract biopsy	0	1 (0.0)
Gene mutation identification test positive	1 (0.0)	1 (0.0)
Glomerular filtration rate	1 (0.0)	0
Glomerular filtration rate decreased	2 (0.0)	0
Glycosylated haemoglobin	0	1 (0.0)
Glycosylated haemoglobin increased	3 (0.0)	1 (0.0)
HIV test positive	77 (0.3)	74 (0.3)
HLA marker study	0	3 (0.0)
HLA-B*27 positive	1 (0.0)	2 (0.0)
Haemoglobin decreased	0	2 (0.0)
Haemoglobin increased	1 (0.0)	0
Heart rate decreased	3 (0.0)	1 (0.0)
Heart rate increased	1 (0.0)	4 (0.0)
Heart rate irregular	28 (0.1)	45 (0.2)
Helicobacter test positive	2 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Hepatic enzyme abnormal	1 (0.0)	0
Hepatic enzyme increased	13 (0.1)	4 (0.0)
Hepatitis A antibody positive	1 (0.0)	0
Hepatitis B antibody positive	1 (0.0)	1 (0.0)
Hepatitis B surface antibody positive	1 (0.0)	1 (0.0)
Hepatitis B test negative	0	1 (0.0)
Hepatitis C antibody positive	3 (0.0)	0
Hepatitis C core antibody negative	0	1 (0.0)
Hepatitis C test negative	0	1 (0.0)
High density lipoprotein decreased	6 (0.0)	4 (0.0)
Hormone level abnormal	7 (0.0)	5 (0.0)
Human papilloma virus test	0	1 (0.0)
Human papilloma virus test positive	29 (0.1)	26 (0.1)
Hysteroscopy	9 (0.0)	5 (0.0)
Intraocular pressure decreased	0	1 (0.0)
Intraocular pressure increased	4 (0.0)	10 (0.0)
Intraocular pressure test	1 (0.0)	0
Investigation	1 (0.0)	0
Laparoscopy	26 (0.1)	18 (0.1)
Lipase increased	0	1 (0.0)
Lipids	0	1 (0.0)
Lipids increased	8 (0.0)	7 (0.0)
Lipoprotein (a) abnormal	1 (0.0)	0
Lipoprotein (a) increased	0	2 (0.0)
Liver function test abnormal	1 (0.0)	1 (0.0)
Liver function test increased	10 (0.0)	5 (0.0)
Low density lipoprotein increased	2 (0.0)	7 (0.0)
Lumbar puncture	0	1 (0.0)
Lumbar puncture normal	1 (0.0)	0
Magnetic resonance imaging	0	1 (0.0)
Magnetic resonance imaging joint	0	1 (0.0)
Mammogram	1 (0.0)	2 (0.0)
Mammogram abnormal	5 (0.0)	1 (0.0)
Mean cell volume increased	0	1 (0.0)
Mediastinoscopy	0	3 (0.0)
Medical observation	1 (0.0)	0
Metabolic function test	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Mumps antibody test positive	1 (0.0)	0
Mycobacterium tuberculosis complex test negative	1 (0.0)	0
Mycobacterium tuberculosis complex test positive	3 (0.0)	1 (0.0)
Nasoendoscopy	2 (0.0)	1 (0.0)
Occult blood positive	0	1 (0.0)
Oesophageal manometry	0	1 (0.0)
Oesophageal pH	0	1 (0.0)
Oesophagogastroduodenoscopy	6 (0.0)	4 (0.0)
Oesophagoscopy	1 (0.0)	0
Oestradiol decreased	1 (0.0)	0
Oestrogen receptor assay negative	0	1 (0.0)
Pelvic laparoscopy	5 (0.0)	1 (0.0)
Plasminogen activator inhibitor increased	0	1 (0.0)
Platelet count decreased	0	2 (0.0)
Precancerous cells present	9 (0.0)	14 (0.1)
Proctoscopy	0	1 (0.0)
Progesterone decreased	1 (0.0)	5 (0.0)
Prostatic specific antigen abnormal	1 (0.0)	0
Prostatic specific antigen increased	23 (0.1)	20 (0.1)
Pulmonary function test decreased	0	2 (0.0)
Red blood cell count increased	0	1 (0.0)
Rheumatoid factor	1 (0.0)	0
SARS-CoV-2 antibody test positive	0	1 (0.0)
Scan myocardial perfusion	0	1 (0.0)
Seroconversion test positive	0	1 (0.0)
Serum ferritin decreased	1 (0.0)	1 (0.0)
Serum ferritin increased	0	1 (0.0)
Sigmoidoscopy	1 (0.0)	1 (0.0)
Sleep study	1 (0.0)	0
Smear cervix abnormal	22 (0.1)	15 (0.1)
Smooth muscle antibody	1 (0.0)	0
Staphylococcus test positive	0	1 (0.0)
Stool analysis abnormal	1 (0.0)	0
Streptococcus test positive	0	1 (0.0)
Thyroid function test abnormal	0	1 (0.0)
Thyroid function test normal	0	1 (0.0)
Total bile acids increased	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Transaminases increased	3 (0.0)	1 (0.0)
Tuberculin test	0	1 (0.0)
Tuberculin test positive	8 (0.0)	9 (0.0)
Ureteroscopy	2 (0.0)	1 (0.0)
Urogram	1 (0.0)	0
Vitamin B12 decreased	4 (0.0)	1 (0.0)
Vitamin D abnormal	0	1 (0.0)
Vitamin D decreased	10 (0.0)	14 (0.1)
Weight decreased	4 (0.0)	2 (0.0)
Weight increased	4 (0.0)	3 (0.0)
White blood cell count decreased	3 (0.0)	1 (0.0)
White blood cell count increased	2 (0.0)	0
X-ray	1 (0.0)	0
Metabolism and nutrition disorders	6587 (29.9)	6472 (29.4)
Abnormal loss of weight	1 (0.0)	1 (0.0)
Abnormal weight gain	0	1 (0.0)
Acidosis	1 (0.0)	0
Calcium deficiency	1 (0.0)	2 (0.0)
Central obesity	2 (0.0)	0
Cholesterosis	2 (0.0)	0
Dairy intolerance	3 (0.0)	1 (0.0)
Decreased appetite	1 (0.0)	5 (0.0)
Dehydration	4 (0.0)	5 (0.0)
Diabetes mellitus	30 (0.1)	22 (0.1)
Diabetes mellitus inadequate control	1 (0.0)	0
Diabetic complication	1 (0.0)	0
Diabetic dyslipidaemia	2 (0.0)	0
Diabetic ketoacidosis	1 (0.0)	3 (0.0)
Disaccharide metabolism disorder	1 (0.0)	0
Dyslipidaemia	537 (2.4)	508 (2.3)
Electrolyte imbalance	1 (0.0)	0
Fluid retention	23 (0.1)	15 (0.1)
Folate deficiency	0	2 (0.0)
Food intolerance	3 (0.0)	2 (0.0)
Fructose intolerance	1 (0.0)	1 (0.0)
Glucose tolerance impaired	249 (1.1)	238 (1.1)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Gluten sensitivity	26 (0.1)	29 (0.1)
Gout	280 (1.3)	288 (1.3)
Haemochromatosis	13 (0.1)	5 (0.0)
Histamine intolerance	0	2 (0.0)
Hyperamylasaemia	1 (0.0)	0
Hypercalcaemia	10 (0.0)	1 (0.0)
Hypercholesterolaemia	1643 (7.5)	1632 (7.4)
Hyperglycaemia	22 (0.1)	20 (0.1)
Hyperhomocysteinaemia	3 (0.0)	1 (0.0)
Hyperinsulinaemia	0	1 (0.0)
Hyperinsulinism	1 (0.0)	0
Hyperkalaemia	5 (0.0)	1 (0.0)
Hyperlactacidaemia	0	1 (0.0)
Hyperlipidaemia	1490 (6.8)	1449 (6.6)
Hypernatraemia	1 (0.0)	0
Hyperphagia	1 (0.0)	0
Hypertriglyceridaemia	89 (0.4)	82 (0.4)
Hyperuricaemia	21 (0.1)	34 (0.2)
Hypocalcaemia	1 (0.0)	1 (0.0)
Hypocholesterolaemia	12 (0.1)	6 (0.0)
Hypoglycaemia	12 (0.1)	9 (0.0)
Hypokalaemia	31 (0.1)	29 (0.1)
Hypolipidaemia	1 (0.0)	4 (0.0)
Hypomagnesaemia	0	5 (0.0)
Hypometabolism	0	1 (0.0)
Hyponatraemia	5 (0.0)	3 (0.0)
Hypophosphataemia	2 (0.0)	0
Hypovitaminosis	1 (0.0)	4 (0.0)
Impaired fasting glucose	30 (0.1)	18 (0.1)
Insulin resistance	15 (0.1)	16 (0.1)
Insulin resistant diabetes	0	1 (0.0)
Insulin-requiring type 2 diabetes mellitus	1 (0.0)	2 (0.0)
Iron deficiency	26 (0.1)	38 (0.2)
Iron metabolism disorder	1 (0.0)	1 (0.0)
Ketoacidosis	1 (0.0)	1 (0.0)
Lactose intolerance	69 (0.3)	78 (0.4)
Latent autoimmune diabetes in adults	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Lipid metabolism disorder	0	1 (0.0)
Lipoedema	2 (0.0)	1 (0.0)
Lipomatosis	0	1 (0.0)
Lipoprotein deficiency	0	1 (0.0)
Magnesium deficiency	2 (0.0)	1 (0.0)
Malnutrition	2 (0.0)	0
Metabolic acidosis	1 (0.0)	0
Metabolic disorder	1 (0.0)	0
Metabolic syndrome	21 (0.1)	6 (0.0)
Monogenic diabetes	0	1 (0.0)
Obesity	1641 (7.5)	1685 (7.7)
Overweight	363 (1.6)	373 (1.7)
Polydipsia	1 (0.0)	0
Postprandial hypoglycaemia	0	1 (0.0)
Protein intolerance	0	1 (0.0)
Refeeding syndrome	0	1 (0.0)
Type 1 diabetes mellitus	94 (0.4)	87 (0.4)
Type 2 diabetes mellitus	1573 (7.1)	1587 (7.2)
Underweight	3 (0.0)	6 (0.0)
Vitamin A deficiency	2 (0.0)	1 (0.0)
Vitamin B complex deficiency	9 (0.0)	10 (0.0)
Vitamin B12 deficiency	76 (0.3)	79 (0.4)
Vitamin B6 deficiency	0	1 (0.0)
Vitamin D deficiency	402 (1.8)	381 (1.7)
Vitamin E deficiency	1 (0.0)	0
Vitamin K deficiency	0	1 (0.0)
Musculoskeletal and connective tissue disorders	4396 (20.0)	4302 (19.5)
Ankle impingement	0	1 (0.0)
Ankylosing spondylitis	8 (0.0)	7 (0.0)
Arthralgia	431 (2.0)	447 (2.0)
Arthritis	243 (1.1)	232 (1.1)
Arthritis reactive	1 (0.0)	1 (0.0)
Arthropathy	17 (0.1)	10 (0.0)
Articular calcification	2 (0.0)	4 (0.0)
Autoimmune arthritis	1 (0.0)	0
Axillary mass	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Back disorder	3 (0.0)	2 (0.0)
Back pain	857 (3.9)	858 (3.9)
Blount's disease	0	1 (0.0)
Bone cyst	5 (0.0)	5 (0.0)
Bone deformity	0	2 (0.0)
Bone disorder	0	2 (0.0)
Bone erosion	0	1 (0.0)
Bone hypertrophy	1 (0.0)	1 (0.0)
Bone lesion	1 (0.0)	1 (0.0)
Bone loss	0	1 (0.0)
Bone pain	1 (0.0)	1 (0.0)
Bursa disorder	1 (0.0)	0
Bursitis	32 (0.1)	56 (0.3)
CREST syndrome	1 (0.0)	1 (0.0)
Cervical spinal stenosis	11 (0.0)	8 (0.0)
Chondromalacia	4 (0.0)	1 (0.0)
Chondropathy	6 (0.0)	8 (0.0)
Coccydynia	2 (0.0)	0
Compartment syndrome	5 (0.0)	5 (0.0)
Connective tissue disorder	0	1 (0.0)
Costochondritis	3 (0.0)	4 (0.0)
Deformity thorax	1 (0.0)	0
Degenerative bone disease	0	1 (0.0)
Diastasis recti abdominis	4 (0.0)	1 (0.0)
Diffuse idiopathic skeletal hyperostosis	2 (0.0)	0
Dupuytren's contracture	13 (0.1)	20 (0.1)
Dwarfism	1 (0.0)	0
Eagle's syndrome	1 (0.0)	0
Enthesopathy	3 (0.0)	1 (0.0)
Epiphysiolysis	1 (0.0)	0
Exostosis	57 (0.3)	56 (0.3)
Exostosis of jaw	0	1 (0.0)
Extremity contracture	2 (0.0)	0
Facet joint syndrome	5 (0.0)	2 (0.0)
Femoroacetabular impingement	2 (0.0)	2 (0.0)
Fibromyalgia	165 (0.7)	120 (0.5)
Finger deformity	1 (0.0)	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Fistula	3 (0.0)	1 (0.0)
Flank pain	1 (0.0)	1 (0.0)
Floating patella	1 (0.0)	2 (0.0)
Foot deformity	110 (0.5)	116 (0.5)
Fracture nonunion	0	1 (0.0)
Gouty arthritis	1 (0.0)	3 (0.0)
Growth retardation	0	1 (0.0)
Haemarthrosis	1 (0.0)	0
Hypermobility syndrome	4 (0.0)	3 (0.0)
Inclusion body myositis	1 (0.0)	1 (0.0)
Intervertebral disc compression	7 (0.0)	11 (0.0)
Intervertebral disc degeneration	176 (0.8)	127 (0.6)
Intervertebral disc disorder	9 (0.0)	14 (0.1)
Intervertebral disc displacement	2 (0.0)	2 (0.0)
Intervertebral disc protrusion	284 (1.3)	266 (1.2)
Jaw cyst	1 (0.0)	1 (0.0)
Jaw disorder	2 (0.0)	4 (0.0)
Joint contracture	1 (0.0)	0
Joint effusion	1 (0.0)	1 (0.0)
Joint instability	4 (0.0)	2 (0.0)
Joint range of motion decreased	2 (0.0)	6 (0.0)
Joint stiffness	2 (0.0)	1 (0.0)
Joint swelling	7 (0.0)	8 (0.0)
Juvenile idiopathic arthritis	2 (0.0)	2 (0.0)
Knee deformity	0	1 (0.0)
Kyphosis	9 (0.0)	5 (0.0)
Ligament calcification	1 (0.0)	0
Ligament disorder	1 (0.0)	2 (0.0)
Ligament laxity	1 (0.0)	1 (0.0)
Limb asymmetry	3 (0.0)	2 (0.0)
Limb deformity	1 (0.0)	1 (0.0)
Limb mass	2 (0.0)	2 (0.0)
Loose body in joint	0	2 (0.0)
Lordosis	0	1 (0.0)
Lumbar spinal stenosis	22 (0.1)	22 (0.1)
Metatarsalgia	2 (0.0)	1 (0.0)
Mixed connective tissue disease	2 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Mobility decreased	1 (0.0)	2 (0.0)
Morphoea	1 (0.0)	1 (0.0)
Muscle atrophy	1 (0.0)	1 (0.0)
Muscle contracture	0	1 (0.0)
Muscle disorder	0	1 (0.0)
Muscle fatigue	0	1 (0.0)
Muscle spasms	129 (0.6)	150 (0.7)
Muscle tightness	3 (0.0)	2 (0.0)
Muscle twitching	4 (0.0)	2 (0.0)
Muscular weakness	7 (0.0)	5 (0.0)
Musculoskeletal chest pain	4 (0.0)	3 (0.0)
Musculoskeletal disorder	1 (0.0)	0
Musculoskeletal pain	3 (0.0)	2 (0.0)
Musculoskeletal stiffness	5 (0.0)	2 (0.0)
Myalgia	99 (0.4)	111 (0.5)
Myalgia intercostal	0	1 (0.0)
Myofascial pain syndrome	3 (0.0)	6 (0.0)
Myopathy	1 (0.0)	1 (0.0)
Myositis	2 (0.0)	1 (0.0)
Neck mass	3 (0.0)	2 (0.0)
Neck pain	103 (0.5)	102 (0.5)
Neuropathic arthropathy	2 (0.0)	0
Os trigonum syndrome	1 (0.0)	0
Osteitis	2 (0.0)	0
Osteitis deformans	0	2 (0.0)
Osteoarthritis	1550 (7.0)	1563 (7.1)
Osteochondritis	1 (0.0)	2 (0.0)
Osteochondrosis	12 (0.1)	11 (0.0)
Osteolysis	0	2 (0.0)
Osteomalacia	1 (0.0)	0
Osteonecrosis	9 (0.0)	11 (0.0)
Osteonecrosis of jaw	0	1 (0.0)
Osteopenia	293 (1.3)	274 (1.2)
Osteoporosis	327 (1.5)	293 (1.3)
Osteoporosis postmenopausal	1 (0.0)	0
Osteosclerosis	1 (0.0)	1 (0.0)
Pain in extremity	64 (0.3)	75 (0.3)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Pain in jaw	3 (0.0)	4 (0.0)
Patellofemoral pain syndrome	8 (0.0)	6 (0.0)
Periarthritis	18 (0.1)	16 (0.1)
Perthes disease	2 (0.0)	0
Plantar fascial fibromatosis	1 (0.0)	5 (0.0)
Plantar fasciitis	50 (0.2)	69 (0.3)
Plica syndrome	0	2 (0.0)
Polyarthritis	14 (0.1)	7 (0.0)
Polymyalgia rheumatica	7 (0.0)	3 (0.0)
Posterior tibial tendon dysfunction	1 (0.0)	1 (0.0)
Prognathism	1 (0.0)	1 (0.0)
Psoriatic arthropathy	5 (0.0)	6 (0.0)
Retrognathia	1 (0.0)	1 (0.0)
Reynold's syndrome	1 (0.0)	0
Rhabdomyolysis	2 (0.0)	3 (0.0)
Rheumatic disorder	1 (0.0)	1 (0.0)
Rheumatic fever	5 (0.0)	6 (0.0)
Rheumatoid arthritis	42 (0.2)	35 (0.2)
Rickets	1 (0.0)	0
Rotator cuff syndrome	242 (1.1)	172 (0.8)
Sacroiliac joint dysfunction	1 (0.0)	1 (0.0)
Sacroiliitis	3 (0.0)	4 (0.0)
Scapholunate dissociation	0	1 (0.0)
Scapular dyskinesis	1 (0.0)	0
Scleroderma	2 (0.0)	2 (0.0)
Scoliosis	82 (0.4)	87 (0.4)
Senile osteoporosis	0	2 (0.0)
Seronegative arthritis	1 (0.0)	1 (0.0)
Sinus tarsi syndrome	1 (0.0)	0
Sjogren's syndrome	5 (0.0)	7 (0.0)
Snapping hip syndrome	0	1 (0.0)
Soft tissue disorder	0	1 (0.0)
Soft tissue mass	0	1 (0.0)
Somatic dysfunction	0	1 (0.0)
Spinal deformity	1 (0.0)	2 (0.0)
Spinal disorder	14 (0.1)	8 (0.0)
Spinal flattening	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Spinal osteoarthritis	189 (0.9)	213 (1.0)
Spinal pain	13 (0.1)	17 (0.1)
Spinal stenosis	61 (0.3)	58 (0.3)
Spinal synovial cyst	0	2 (0.0)
Spondylitis	25 (0.1)	35 (0.2)
Spondyloarthropathy	5 (0.0)	1 (0.0)
Spondylolisthesis	19 (0.1)	14 (0.1)
Spondylolysis	6 (0.0)	0
Symphysiolysis	0	1 (0.0)
Synovial cyst	35 (0.2)	33 (0.1)
Synovitis	1 (0.0)	1 (0.0)
Systemic lupus erythematosus	5 (0.0)	4 (0.0)
Temporomandibular joint syndrome	36 (0.2)	32 (0.1)
Tendon disorder	5 (0.0)	5 (0.0)
Tendon laxity	0	2 (0.0)
Tendon pain	2 (0.0)	1 (0.0)
Tendonitis	56 (0.3)	66 (0.3)
Tenosynovitis	2 (0.0)	4 (0.0)
Tenosynovitis stenosans	10 (0.0)	9 (0.0)
Torticollis	2 (0.0)	4 (0.0)
Trigger finger	49 (0.2)	40 (0.2)
Ulnocarpal abutment syndrome	1 (0.0)	0
Undifferentiated connective tissue disease	0	1 (0.0)
Vertebral foraminal stenosis	1 (0.0)	3 (0.0)
Vertebral osteophyte	4 (0.0)	8 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1868 (8.5)	1884 (8.6)
Abdominal neoplasm	1 (0.0)	0
Abdominal wall neoplasm	0	1 (0.0)
Acanthoma	0	1 (0.0)
Acinic cell carcinoma of salivary gland	1 (0.0)	0
Acoustic neuroma	9 (0.0)	10 (0.0)
Acrochordon	0	3 (0.0)
Acute lymphocytic leukaemia	1 (0.0)	1 (0.0)
Acute myeloid leukaemia	2 (0.0)	1 (0.0)
Adenocarcinoma	0	2 (0.0)
Adenocarcinoma of appendix	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Adenocarcinoma of colon	0	1 (0.0)
Adenocarcinoma of the cervix	0	1 (0.0)
Adenoid cystic carcinoma	1 (0.0)	1 (0.0)
Adenoma benign	8 (0.0)	7 (0.0)
Adrenal adenoma	3 (0.0)	2 (0.0)
Adrenal neoplasm	0	1 (0.0)
Anal cancer	2 (0.0)	0
Angiofibroma	1 (0.0)	0
Angiomyolipoma	0	1 (0.0)
Anogenital warts	1 (0.0)	4 (0.0)
Appendix cancer	2 (0.0)	3 (0.0)
Astrocytoma	1 (0.0)	0
B-cell lymphoma	2 (0.0)	0
Basal cell carcinoma	285 (1.3)	301 (1.4)
Basosquamous carcinoma	3 (0.0)	2 (0.0)
Basosquamous carcinoma of skin	0	2 (0.0)
Benign bone neoplasm	4 (0.0)	6 (0.0)
Benign breast neoplasm	41 (0.2)	30 (0.1)
Benign cardiac neoplasm	0	1 (0.0)
Benign gastric neoplasm	1 (0.0)	0
Benign gastrointestinal neoplasm	1 (0.0)	2 (0.0)
Benign hydatidiform mole	1 (0.0)	0
Benign joint neoplasm	1 (0.0)	0
Benign laryngeal neoplasm	0	1 (0.0)
Benign lung neoplasm	4 (0.0)	12 (0.1)
Benign mediastinal neoplasm	0	1 (0.0)
Benign muscle neoplasm	2 (0.0)	0
Benign neoplasm	7 (0.0)	9 (0.0)
Benign neoplasm of adrenal gland	0	1 (0.0)
Benign neoplasm of bladder	2 (0.0)	0
Benign neoplasm of cornea	1 (0.0)	0
Benign neoplasm of eye	0	1 (0.0)
Benign neoplasm of eyelid	0	1 (0.0)
Benign neoplasm of prostate	0	1 (0.0)
Benign neoplasm of skin	5 (0.0)	6 (0.0)
Benign neoplasm of spinal cord	0	1 (0.0)
Benign neoplasm of testis	2 (0.0)	2 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Benign neoplasm of thymus	1 (0.0)	0
Benign neoplasm of thyroid gland	29 (0.1)	38 (0.2)
Benign ovarian tumour	5 (0.0)	8 (0.0)
Benign pancreatic neoplasm	1 (0.0)	2 (0.0)
Benign renal neoplasm	0	2 (0.0)
Benign salivary gland neoplasm	4 (0.0)	0
Benign small intestinal neoplasm	0	1 (0.0)
Benign uterine neoplasm	6 (0.0)	2 (0.0)
Benign vascular neoplasm	0	2 (0.0)
Bladder cancer	23 (0.1)	12 (0.1)
Bladder cancer stage 0, with cancer in situ	1 (0.0)	0
Bladder neoplasm	1 (0.0)	1 (0.0)
Bladder transitional cell carcinoma	0	1 (0.0)
Bone cancer	1 (0.0)	0
Bone neoplasm	2 (0.0)	2 (0.0)
Bowen's disease	0	1 (0.0)
Brain neoplasm	4 (0.0)	1 (0.0)
Brain neoplasm benign	2 (0.0)	8 (0.0)
Brain neoplasm malignant	1 (0.0)	1 (0.0)
Breast cancer	202 (0.9)	201 (0.9)
Breast cancer female	1 (0.0)	0
Breast cancer in situ	3 (0.0)	1 (0.0)
Breast cancer metastatic	1 (0.0)	0
Breast cancer recurrent	1 (0.0)	0
Breast cancer stage I	7 (0.0)	4 (0.0)
Breast cancer stage II	5 (0.0)	1 (0.0)
Breast cancer stage III	1 (0.0)	1 (0.0)
Breast fibroma	4 (0.0)	3 (0.0)
Breast neoplasm	3 (0.0)	3 (0.0)
Bronchial neoplasm	1 (0.0)	0
Cancer in remission	1 (0.0)	0
Carcinoid tumour	1 (0.0)	0
Carcinoid tumour of the gastrointestinal tract	1 (0.0)	0
Carcinoid tumour pulmonary	1 (0.0)	0
Cervix carcinoma	33 (0.1)	25 (0.1)
Cervix carcinoma stage 0	1 (0.0)	1 (0.0)
Cervix carcinoma stage I	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Cholesteatoma	3 (0.0)	3 (0.0)
Choroid melanoma	1 (0.0)	2 (0.0)
Chromophobe renal cell carcinoma	1 (0.0)	0
Chronic lymphocytic leukaemia	4 (0.0)	4 (0.0)
Chronic myeloid leukaemia	0	1 (0.0)
Chronic myelomonocytic leukaemia	0	1 (0.0)
Clear cell renal cell carcinoma	3 (0.0)	0
Colon adenoma	26 (0.1)	16 (0.1)
Colon cancer	32 (0.1)	30 (0.1)
Colon cancer stage I	0	1 (0.0)
Colon cancer stage II	0	1 (0.0)
Colon cancer stage III	1 (0.0)	0
Colon cancer stage IV	1 (0.0)	0
Colorectal cancer	1 (0.0)	3 (0.0)
Colorectal cancer metastatic	1 (0.0)	0
Cutaneous T-cell lymphoma	1 (0.0)	2 (0.0)
Cutaneous lymphoma	0	1 (0.0)
Dermatofibrosarcoma protuberans	1 (0.0)	0
Desmoid tumour	2 (0.0)	1 (0.0)
Desmoplastic melanoma	0	1 (0.0)
Diffuse large B-cell lymphoma	1 (0.0)	0
Dysplastic naevus	2 (0.0)	3 (0.0)
Ear neoplasm	0	1 (0.0)
Ear neoplasm malignant	0	2 (0.0)
Elastofibroma	1 (0.0)	0
Enchondromatosis	1 (0.0)	2 (0.0)
Endocrine neoplasm malignant	1 (0.0)	0
Endometrial cancer	14 (0.1)	14 (0.1)
Endometrial cancer stage III	1 (0.0)	0
Essential thrombocythaemia	2 (0.0)	1 (0.0)
Ewing's sarcoma	0	1 (0.0)
Extragonadal primary seminoma (pure)	0	2 (0.0)
Eye naevus	1 (0.0)	3 (0.0)
Eyelid haemangioma	1 (0.0)	0
Fallopian tube cancer	1 (0.0)	0
Fibroadenoma of breast	8 (0.0)	10 (0.0)
Fibroma	16 (0.1)	16 (0.1)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Fibrosarcoma	1 (0.0)	0
Fibrous histiocytoma	1 (0.0)	1 (0.0)
Follicle centre lymphoma, follicular grade I, II, III	0	1 (0.0)
Follicular thyroid cancer	0	1 (0.0)
Ganglioneuroblastoma	0	1 (0.0)
Gastric cancer	1 (0.0)	1 (0.0)
Gastric neoplasm	1 (0.0)	0
Gastrinoma	0	1 (0.0)
Gastrointestinal melanoma	1 (0.0)	0
Gastrointestinal stromal tumour	0	1 (0.0)
Gastrointestinal tract adenoma	2 (0.0)	1 (0.0)
Gestational trophoblastic tumour	1 (0.0)	0
Giant cell tumour of tendon sheath	0	1 (0.0)
Glomus tumour	0	1 (0.0)
Haemangioma	2 (0.0)	7 (0.0)
Haemangioma of liver	2 (0.0)	1 (0.0)
Haemangioma of skin	2 (0.0)	1 (0.0)
Haemangioma of spleen	1 (0.0)	0
Hair follicle tumour benign	1 (0.0)	0
Hairy cell leukaemia	0	1 (0.0)
Hepatic adenoma	1 (0.0)	1 (0.0)
Hepatic cancer	2 (0.0)	0
Hodgkin's disease	9 (0.0)	9 (0.0)
Hodgkin's disease nodular sclerosis	0	1 (0.0)
Hypergammaglobulinaemia benign monoclonal	2 (0.0)	4 (0.0)
Intraductal papilloma of breast	0	1 (0.0)
Intraductal proliferative breast lesion	7 (0.0)	7 (0.0)
Intraocular melanoma	1 (0.0)	1 (0.0)
Invasive breast carcinoma	1 (0.0)	0
Invasive ductal breast carcinoma	2 (0.0)	6 (0.0)
Invasive lobular breast carcinoma	1 (0.0)	0
Iris melanoma	0	1 (0.0)
Juvenile melanoma benign	1 (0.0)	0
Kaposi's sarcoma	0	1 (0.0)
Langerhans' cell histiocytosis	1 (0.0)	0
Large granular lymphocytosis	1 (0.0)	0
Large intestine benign neoplasm	3 (0.0)	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Laryngeal cancer	5 (0.0)	2 (0.0)
Laryngeal neoplasm	1 (0.0)	0
Laryngeal papilloma	1 (0.0)	0
Leiomyoma	4 (0.0)	5 (0.0)
Leiomyosarcoma	0	1 (0.0)
Lentigo maligna	1 (0.0)	1 (0.0)
Leukaemia	6 (0.0)	2 (0.0)
Lip and/or oral cavity cancer	4 (0.0)	2 (0.0)
Lip neoplasm malignant stage unspecified	0	1 (0.0)
Lip squamous cell carcinoma	3 (0.0)	2 (0.0)
Lipoma	41 (0.2)	44 (0.2)
Lipoma of breast	1 (0.0)	1 (0.0)
Liposarcoma	0	1 (0.0)
Lobular breast carcinoma in situ	4 (0.0)	2 (0.0)
Lung adenocarcinoma	1 (0.0)	0
Lung carcinoma cell type unspecified stage IV	1 (0.0)	0
Lung neoplasm malignant	11 (0.0)	11 (0.0)
Lymphangioma	1 (0.0)	0
Lymphoma	5 (0.0)	8 (0.0)
Malignant melanoma	108 (0.5)	94 (0.4)
Malignant melanoma in situ	4 (0.0)	2 (0.0)
Malignant melanoma of eyelid	1 (0.0)	1 (0.0)
Malignant melanoma stage I	2 (0.0)	2 (0.0)
Malignant melanoma stage II	1 (0.0)	0
Mantle cell lymphoma	1 (0.0)	1 (0.0)
Melanocytic naevus	18 (0.1)	17 (0.1)
Melanoma recurrent	1 (0.0)	0
Meningioma	8 (0.0)	13 (0.1)
Meningioma benign	8 (0.0)	3 (0.0)
Metaplastic breast carcinoma	1 (0.0)	0
Metastases to bone	1 (0.0)	0
Metastatic malignant melanoma	0	1 (0.0)
Metastatic neoplasm	1 (0.0)	0
Metastatic squamous cell carcinoma	0	1 (0.0)
Monoclonal gammopathy	1 (0.0)	1 (0.0)
Nasopharyngeal cancer	1 (0.0)	0
Neoplasm	1 (0.0)	3 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Neoplasm malignant	3 (0.0)	2 (0.0)
Neoplasm of appendix	1 (0.0)	1 (0.0)
Neoplasm skin	0	1 (0.0)
Nephroblastoma	1 (0.0)	1 (0.0)
Nervous system neoplasm benign	0	1 (0.0)
Neurilemmoma benign	0	2 (0.0)
Neuroendocrine carcinoma	1 (0.0)	0
Neuroendocrine tumour	0	1 (0.0)
Neurofibroma	1 (0.0)	0
Neuroma	11 (0.0)	10 (0.0)
Non-Hodgkin's lymphoma	7 (0.0)	12 (0.1)
Non-small cell lung cancer	0	1 (0.0)
Ocular neoplasm	0	1 (0.0)
Oesophageal adenocarcinoma	1 (0.0)	0
Oesophageal carcinoma	1 (0.0)	0
Oesophageal carcinoma stage 0	1 (0.0)	0
Oral neoplasm	1 (0.0)	0
Oral neoplasm benign	0	1 (0.0)
Oropharyngeal cancer	0	1 (0.0)
Osteochondroma	1 (0.0)	5 (0.0)
Osteoma	0	3 (0.0)
Osteosarcoma	0	2 (0.0)
Ovarian adenoma	1 (0.0)	0
Ovarian cancer	13 (0.1)	16 (0.1)
Ovarian cancer metastatic	0	1 (0.0)
Ovarian cancer stage III	0	1 (0.0)
Ovarian cancer stage IV	1 (0.0)	0
Ovarian dysgerminoma stage unspecified	1 (0.0)	0
Ovarian fibroma	2 (0.0)	0
Ovarian germ cell teratoma	2 (0.0)	0
Ovarian germ cell teratoma benign	1 (0.0)	5 (0.0)
Ovarian neoplasm	1 (0.0)	2 (0.0)
Paget's disease of nipple	1 (0.0)	0
Pancreatic carcinoma	2 (0.0)	0
Pancreatic neoplasm	0	1 (0.0)
Papillary thyroid cancer	10 (0.0)	9 (0.0)
Papilloma	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Paraganglion neoplasm benign	0	1 (0.0)
Paranasal sinus benign neoplasm	1 (0.0)	0
Paraproteinaemia	0	1 (0.0)
Parathyroid tumour	1 (0.0)	1 (0.0)
Parathyroid tumour benign	5 (0.0)	10 (0.0)
Phaeochromocytoma	0	1 (0.0)
Pharyngeal cancer	0	1 (0.0)
Pharyngeal neoplasm	1 (0.0)	0
Phyllodes tumour	1 (0.0)	0
Pineal germinoma	0	1 (0.0)
Pituitary tumour	1 (0.0)	2 (0.0)
Pituitary tumour benign	17 (0.1)	11 (0.0)
Plasma cell myeloma	4 (0.0)	2 (0.0)
Pleural neoplasm	0	1 (0.0)
Polycythaemia vera	1 (0.0)	2 (0.0)
Prolactin-producing pituitary tumour	1 (0.0)	2 (0.0)
Prostate cancer	175 (0.8)	182 (0.8)
Prostate cancer stage I	1 (0.0)	2 (0.0)
Prostate cancer stage III	1 (0.0)	0
Prostate cancer stage IV	1 (0.0)	0
Prostatic adenoma	1 (0.0)	5 (0.0)
Rectal cancer	2 (0.0)	4 (0.0)
Rectal cancer stage III	0	1 (0.0)
Rectal neoplasm	1 (0.0)	0
Renal adenoma	1 (0.0)	0
Renal cancer	15 (0.1)	14 (0.1)
Renal cell carcinoma	4 (0.0)	5 (0.0)
Renal hamartoma	1 (0.0)	1 (0.0)
Renal lipoma	1 (0.0)	0
Renal neoplasm	1 (0.0)	0
Retinoblastoma	1 (0.0)	2 (0.0)
Round cell liposarcoma	1 (0.0)	0
Salivary gland cancer	0	3 (0.0)
Salivary gland neoplasm	0	2 (0.0)
Sarcoma	0	1 (0.0)
Schwannoma	4 (0.0)	5 (0.0)
Seborrhoeic keratosis	17 (0.1)	25 (0.1)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Seminoma	1 (0.0)	1 (0.0)
Sinonasal papilloma	1 (0.0)	0
Skin cancer	23 (0.1)	23 (0.1)
Skin papilloma	15 (0.1)	5 (0.0)
Small intestine carcinoma	1 (0.0)	2 (0.0)
Soft tissue sarcoma	1 (0.0)	1 (0.0)
Spinal cord neoplasm	0	1 (0.0)
Squamous cell breast carcinoma	1 (0.0)	0
Squamous cell carcinoma	79 (0.4)	78 (0.4)
Squamous cell carcinoma of lung	1 (0.0)	0
Squamous cell carcinoma of skin	46 (0.2)	33 (0.1)
Squamous cell carcinoma of the oral cavity	0	1 (0.0)
Squamous cell carcinoma of the tongue	2 (0.0)	2 (0.0)
Squamous cell carcinoma of the vulva	1 (0.0)	0
Sweat gland tumour	0	2 (0.0)
Synovial sarcoma	0	1 (0.0)
T-cell lymphoma	2 (0.0)	1 (0.0)
Teratoma	0	1 (0.0)
Testis cancer	16 (0.1)	15 (0.1)
Throat cancer	5 (0.0)	6 (0.0)
Thymoma	1 (0.0)	0
Thyroid adenoma	2 (0.0)	1 (0.0)
Thyroid cancer	46 (0.2)	39 (0.2)
Thyroid cancer stage IV	1 (0.0)	0
Thyroid neoplasm	2 (0.0)	5 (0.0)
Tongue neoplasm	0	1 (0.0)
Tongue neoplasm malignant stage unspecified	4 (0.0)	1 (0.0)
Tonsil cancer	3 (0.0)	5 (0.0)
Tonsillar neoplasm benign	0	1 (0.0)
Triple negative breast cancer	1 (0.0)	0
Uterine cancer	21 (0.1)	20 (0.1)
Uterine carcinoma in situ	1 (0.0)	0
Uterine leiomyoma	395 (1.8)	406 (1.8)
Uterine neoplasm	2 (0.0)	0
Vulval cancer	2 (0.0)	1 (0.0)
Vulvovaginal warts	1 (0.0)	0
Xanthogranuloma	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Nervous system disorders	2996 (13.6)	2887 (13.1)
Ageusia	1 (0.0)	1 (0.0)
Akathisia	1 (0.0)	0
Amnesia	17 (0.1)	17 (0.1)
Angiopathic neuropathy	1 (0.0)	1 (0.0)
Anosmia	7 (0.0)	6 (0.0)
Arachnoid cyst	5 (0.0)	2 (0.0)
Arachnoiditis	0	1 (0.0)
Ataxia	3 (0.0)	0
Aura	0	1 (0.0)
Autoimmune encephalopathy	1 (0.0)	0
Autonomic nervous system imbalance	0	2 (0.0)
Autonomic neuropathy	2 (0.0)	0
Balance disorder	1 (0.0)	2 (0.0)
Blood brain barrier defect	1 (0.0)	0
Brachial plexopathy	1 (0.0)	1 (0.0)
Brain injury	3 (0.0)	1 (0.0)
Brain stem stroke	1 (0.0)	0
Carotid arterial embolus	0	1 (0.0)
Carotid arteriosclerosis	10 (0.0)	9 (0.0)
Carotid artery disease	9 (0.0)	5 (0.0)
Carotid artery dissection	3 (0.0)	2 (0.0)
Carotid artery occlusion	6 (0.0)	6 (0.0)
Carotid artery stenosis	14 (0.1)	15 (0.1)
Carotid artery thrombosis	0	1 (0.0)
Carpal tunnel syndrome	222 (1.0)	182 (0.8)
Cataplexy	0	1 (0.0)
Cauda equina syndrome	0	1 (0.0)
Central auditory processing disorder	2 (0.0)	0
Cerebellar ataxia	1 (0.0)	0
Cerebellar atrophy	1 (0.0)	0
Cerebellar infarction	2 (0.0)	0
Cerebellar stroke	2 (0.0)	0
Cerebral atrophy	1 (0.0)	0
Cerebral cyst	1 (0.0)	0
Cerebral haemorrhage	2 (0.0)	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Cerebral infarction	2 (0.0)	1 (0.0)
Cerebral ischaemia	1 (0.0)	0
Cerebral microangiopathy	0	1 (0.0)
Cerebral thrombosis	1 (0.0)	0
Cerebral venous sinus thrombosis	0	1 (0.0)
Cerebral venous thrombosis	1 (0.0)	0
Cerebrospinal fluid leakage	0	1 (0.0)
Cerebrovascular accident	92 (0.4)	86 (0.4)
Cerebrovascular disorder	2 (0.0)	1 (0.0)
Cervical cord compression	1 (0.0)	0
Cervical radiculopathy	16 (0.1)	19 (0.1)
Cervicobrachial syndrome	2 (0.0)	1 (0.0)
Cervicogenic headache	0	2 (0.0)
Cervicogenic vertigo	0	1 (0.0)
Chronic inflammatory demyelinating polyradiculoneuropathy	0	3 (0.0)
Circadian rhythm sleep disorder	2 (0.0)	1 (0.0)
Cluster headache	14 (0.1)	8 (0.0)
Cognitive disorder	4 (0.0)	7 (0.0)
Colloid brain cyst	0	1 (0.0)
Coma	2 (0.0)	0
Complex regional pain syndrome	2 (0.0)	8 (0.0)
Convulsive threshold lowered	0	1 (0.0)
Coordination abnormal	1 (0.0)	0
Cramp-fasciculation syndrome	0	1 (0.0)
Cranial nerve disorder	0	1 (0.0)
Cubital tunnel syndrome	1 (0.0)	5 (0.0)
Dementia	5 (0.0)	6 (0.0)
Dementia Alzheimer's type	1 (0.0)	2 (0.0)
Demyelination	1 (0.0)	0
Depressed level of consciousness	1 (0.0)	0
Diabetic neuropathy	100 (0.5)	118 (0.5)
Disturbance in attention	6 (0.0)	3 (0.0)
Dizziness	25 (0.1)	27 (0.1)
Dizziness postural	0	1 (0.0)
Drug withdrawal headache	1 (0.0)	0
Dural arteriovenous fistula	1 (0.0)	0
Dysaesthesia	0	2 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Dysgeusia	0	2 (0.0)
Dyskinesia	1 (0.0)	0
Dyslexia	4 (0.0)	3 (0.0)
Dystonia	3 (0.0)	0
Dystonic tremor	0	1 (0.0)
Embolic stroke	1 (0.0)	0
Encephalopathy	0	3 (0.0)
Epilepsy	44 (0.2)	53 (0.2)
Essential tremor	35 (0.2)	41 (0.2)
Extrapyramidal disorder	1 (0.0)	2 (0.0)
Facial nerve disorder	0	2 (0.0)
Facial neuralgia	3 (0.0)	0
Facial paralysis	20 (0.1)	20 (0.1)
Facial paresis	1 (0.0)	0
Facial spasm	0	1 (0.0)
Febrile convulsion	4 (0.0)	2 (0.0)
Fine motor skill dysfunction	1 (0.0)	0
Focal dyscognitive seizures	0	1 (0.0)
Generalised tonic-clonic seizure	3 (0.0)	5 (0.0)
Glossopharyngeal neuralgia	1 (0.0)	0
Guillain-Barre syndrome	1 (0.0)	1 (0.0)
Haemorrhagic stroke	1 (0.0)	6 (0.0)
Hashimoto's encephalopathy	0	1 (0.0)
Head titubation	2 (0.0)	2 (0.0)
Headache	509 (2.3)	507 (2.3)
Hemiparesis	1 (0.0)	5 (0.0)
Hemiplegia	3 (0.0)	3 (0.0)
Hemiplegic migraine	1 (0.0)	2 (0.0)
Horner's syndrome	2 (0.0)	0
Hydrocephalus	2 (0.0)	7 (0.0)
Hypersomnia	9 (0.0)	11 (0.0)
Hypoaesthesia	14 (0.1)	12 (0.1)
Hypogeusia	1 (0.0)	0
Hyporeflexia	1 (0.0)	0
Hyposmia	1 (0.0)	3 (0.0)
Hypotonia	0	1 (0.0)
Hypoxic-ischaemic encephalopathy	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
IVth nerve paralysis	2 (0.0)	0
Idiopathic generalised epilepsy	0	1 (0.0)
Idiopathic intracranial hypertension	1 (0.0)	3 (0.0)
Incoherent	0	1 (0.0)
Intention tremor	2 (0.0)	2 (0.0)
Intercostal neuralgia	0	1 (0.0)
Intracranial aneurysm	10 (0.0)	11 (0.0)
Intracranial mass	0	1 (0.0)
Intracranial pressure increased	1 (0.0)	2 (0.0)
Irlen syndrome	1 (0.0)	0
Ischaemic stroke	9 (0.0)	9 (0.0)
Juvenile myoclonic epilepsy	0	1 (0.0)
Lacunar infarction	1 (0.0)	0
Lacunar stroke	0	1 (0.0)
Lumbar radiculopathy	27 (0.1)	35 (0.2)
Lumbosacral radiculopathy	2 (0.0)	4 (0.0)
Medication overuse headache	1 (0.0)	0
Meige's syndrome	0	1 (0.0)
Memory impairment	4 (0.0)	3 (0.0)
Mental impairment	1 (0.0)	0
Meralgia paraesthetica	1 (0.0)	1 (0.0)
Migraine	999 (4.5)	995 (4.5)
Migraine with aura	34 (0.2)	32 (0.1)
Migraine without aura	29 (0.1)	25 (0.1)
Mononeuritis	0	1 (0.0)
Monoparesis	1 (0.0)	0
Monoplegia	5 (0.0)	2 (0.0)
Morton's neuralgia	11 (0.0)	12 (0.1)
Motor dysfunction	1 (0.0)	0
Multiple sclerosis	3 (0.0)	6 (0.0)
Muscle contractions involuntary	2 (0.0)	4 (0.0)
Muscle spasticity	1 (0.0)	0
Myasthenia gravis	3 (0.0)	5 (0.0)
Myelopathy	2 (0.0)	2 (0.0)
Myoclonic epilepsy	0	1 (0.0)
Myoclonus	3 (0.0)	3 (0.0)
Narcolepsy	11 (0.0)	19 (0.1)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Nerve compression	25 (0.1)	29 (0.1)
Nervous system disorder	2 (0.0)	1 (0.0)
Neuralgia	42 (0.2)	31 (0.1)
Neuralgic amyotrophy	1 (0.0)	0
Neuritis	1 (0.0)	2 (0.0)
Neurological symptom	1 (0.0)	0
Neuropathy peripheral	226 (1.0)	207 (0.9)
Neuropathy vitamin B6 deficiency	0	1 (0.0)
Normal pressure hydrocephalus	0	2 (0.0)
Notalgia paraesthetica	1 (0.0)	0
Nystagmus	2 (0.0)	3 (0.0)
Occipital neuralgia	3 (0.0)	2 (0.0)
Olfactory nerve disorder	1 (0.0)	0
Optic neuritis	3 (0.0)	1 (0.0)
Paraesthesia	15 (0.1)	12 (0.1)
Paralysis	1 (0.0)	0
Paraparesis	1 (0.0)	2 (0.0)
Paraplegia	1 (0.0)	2 (0.0)
Parkinson's disease	18 (0.1)	15 (0.1)
Parkinsonism	0	2 (0.0)
Parosmia	0	1 (0.0)
Paroxysmal choreoathetosis	0	1 (0.0)
Partial seizures	2 (0.0)	0
Perineurial cyst	1 (0.0)	0
Periodic limb movement disorder	3 (0.0)	6 (0.0)
Peripheral nerve lesion	1 (0.0)	0
Peripheral sensory neuropathy	1 (0.0)	0
Peroneal nerve palsy	10 (0.0)	6 (0.0)
Petit mal epilepsy	2 (0.0)	4 (0.0)
Phantom limb syndrome	1 (0.0)	0
Pineal gland cyst	1 (0.0)	0
Piriformis syndrome	4 (0.0)	1 (0.0)
Polyneuropathy	6 (0.0)	3 (0.0)
Polyneuropathy alcoholic	1 (0.0)	0
Post herpetic neuralgia	3 (0.0)	10 (0.0)
Post polio syndrome	2 (0.0)	1 (0.0)
Post stroke seizure	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Post-traumatic epilepsy	0	1 (0.0)
Post-traumatic headache	1 (0.0)	3 (0.0)
Post-traumatic neuralgia	1 (0.0)	0
Posterior reversible encephalopathy syndrome	0	2 (0.0)
Postural tremor	1 (0.0)	0
Presyncope	4 (0.0)	3 (0.0)
Psychogenic seizure	1 (0.0)	1 (0.0)
Psychomotor hyperactivity	1 (0.0)	3 (0.0)
Radial nerve compression	1 (0.0)	0
Radicular pain	0	1 (0.0)
Radiculitis brachial	1 (0.0)	1 (0.0)
Radiculopathy	9 (0.0)	8 (0.0)
Relapsing multiple sclerosis	1 (0.0)	0
Resting tremor	1 (0.0)	1 (0.0)
Restless legs syndrome	149 (0.7)	168 (0.8)
Ruptured cerebral aneurysm	0	1 (0.0)
Sacral radiculopathy	1 (0.0)	0
Sciatic nerve neuropathy	1 (0.0)	0
Sciatica	131 (0.6)	116 (0.5)
Seizure	54 (0.2)	55 (0.2)
Senile dementia	1 (0.0)	3 (0.0)
Sensory disturbance	0	1 (0.0)
Serotonin syndrome	2 (0.0)	1 (0.0)
Shift work disorder	4 (0.0)	1 (0.0)
Sinus headache	47 (0.2)	36 (0.2)
Sleep deficit	1 (0.0)	1 (0.0)
Small fibre neuropathy	1 (0.0)	2 (0.0)
Somnolence	2 (0.0)	1 (0.0)
Spasmodic dysphonia	2 (0.0)	2 (0.0)
Speech disorder	0	1 (0.0)
Spinal cord disorder	1 (0.0)	0
Spondylitic myelopathy	2 (0.0)	1 (0.0)
Stiff person syndrome	0	1 (0.0)
Subarachnoid haemorrhage	3 (0.0)	4 (0.0)
Syncope	31 (0.1)	25 (0.1)
Tardive dyskinesia	2 (0.0)	1 (0.0)
Tarsal tunnel syndrome	5 (0.0)	2 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Temporal lobe epilepsy	2 (0.0)	1 (0.0)
Tension headache	127 (0.6)	76 (0.3)
Thoracic outlet syndrome	3 (0.0)	4 (0.0)
Thoracic radiculopathy	0	1 (0.0)
Tonic convulsion	0	1 (0.0)
Toxic neuropathy	0	1 (0.0)
Transient global amnesia	3 (0.0)	3 (0.0)
Transient ischaemic attack	67 (0.3)	55 (0.2)
Tremor	36 (0.2)	31 (0.1)
Trigeminal nerve disorder	0	2 (0.0)
Trigeminal neuralgia	15 (0.1)	13 (0.1)
VIth nerve paralysis	2 (0.0)	0
Vertebral artery dissection	1 (0.0)	0
Vertebral artery occlusion	1 (0.0)	0
Vertebral artery stenosis	1 (0.0)	0
Vestibular migraine	2 (0.0)	3 (0.0)
Visual field defect	0	3 (0.0)
Vocal cord paralysis	3 (0.0)	1 (0.0)
Vocal cord paresis	1 (0.0)	0
Writer's cramp	1 (0.0)	0
Pregnancy, puerperium and perinatal conditions	143 (0.6)	153 (0.7)
Abnormal cord insertion	1 (0.0)	0
Abortion	6 (0.0)	2 (0.0)
Abortion incomplete	0	1 (0.0)
Abortion spontaneous	25 (0.1)	26 (0.1)
Breech delivery	0	1 (0.0)
Breech presentation	1 (0.0)	1 (0.0)
Cephalo-pelvic disproportion	1 (0.0)	1 (0.0)
Complication of pregnancy	2 (0.0)	0
Delivery	56 (0.3)	50 (0.2)
Eclampsia	1 (0.0)	0
Ectopic pregnancy	23 (0.1)	31 (0.1)
Foetal death	0	2 (0.0)
Foetal distress syndrome	0	1 (0.0)
Gestational diabetes	12 (0.1)	15 (0.1)
Gestational hypertension	1 (0.0)	4 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
HELLP syndrome	0	1 (0.0)
Habitual abortion	0	1 (0.0)
Intrapartum haemorrhage	0	1 (0.0)
Morning sickness	1 (0.0)	0
Peripartum cardiomyopathy	1 (0.0)	0
Placenta accreta	1 (0.0)	4 (0.0)
Post abortion haemorrhage	0	1 (0.0)
Postpartum haemorrhage	3 (0.0)	3 (0.0)
Pre-eclampsia	8 (0.0)	5 (0.0)
Pregnancy	5 (0.0)	9 (0.0)
Premature baby	1 (0.0)	2 (0.0)
Premature labour	1 (0.0)	0
Premature separation of placenta	0	1 (0.0)
Retained placenta or membranes	1 (0.0)	0
Stillbirth	0	2 (0.0)
Unintended pregnancy	0	1 (0.0)
Product issues	3 (0.0)	2 (0.0)
Device breakage	0	1 (0.0)
Device leakage	1 (0.0)	0
Device malfunction	0	1 (0.0)
Embedded device	1 (0.0)	0
Stent malfunction	1 (0.0)	0
Psychiatric disorders	4759 (21.6)	4853 (22.0)
Abnormal dreams	0	1 (0.0)
Adjustment disorder	4 (0.0)	10 (0.0)
Adjustment disorder with depressed mood	15 (0.1)	7 (0.0)
Adjustment disorder with mixed anxiety and depressed mood	3 (0.0)	3 (0.0)
Aerophobia	0	1 (0.0)
Affect lability	2 (0.0)	1 (0.0)
Affective disorder	17 (0.1)	9 (0.0)
Aggression	0	1 (0.0)
Agitated depression	0	1 (0.0)
Agitation	1 (0.0)	0
Agoraphobia	0	1 (0.0)
Alcohol abuse	20 (0.1)	15 (0.1)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Alcohol problem	0	1 (0.0)
Alcohol use disorder	3 (0.0)	5 (0.0)
Alcohol withdrawal syndrome	0	1 (0.0)
Alcoholism	26 (0.1)	17 (0.1)
Anger	2 (0.0)	3 (0.0)
Anorexia nervosa	3 (0.0)	3 (0.0)
Anxiety	1860 (8.4)	1957 (8.9)
Anxiety disorder	135 (0.6)	139 (0.6)
Attention deficit hyperactivity disorder	574 (2.6)	540 (2.5)
Autism spectrum disorder	19 (0.1)	21 (0.1)
Behaviour disorder	1 (0.0)	1 (0.0)
Binge eating	3 (0.0)	9 (0.0)
Bipolar I disorder	6 (0.0)	11 (0.0)
Bipolar II disorder	17 (0.1)	13 (0.1)
Bipolar disorder	173 (0.8)	177 (0.8)
Borderline personality disorder	4 (0.0)	1 (0.0)
Breathing-related sleep disorder	1 (0.0)	0
Bruxism	2 (0.0)	5 (0.0)
Bulimia nervosa	2 (0.0)	4 (0.0)
Cardiovascular somatic symptom disorder	0	1 (0.0)
Chronic tic disorder	1 (0.0)	0
Conversion disorder	0	1 (0.0)
Cyclothymic disorder	2 (0.0)	3 (0.0)
Delirium tremens	0	1 (0.0)
Dependence	1 (0.0)	1 (0.0)
Depressed mood	3 (0.0)	0
Depression	2034 (9.2)	2073 (9.4)
Depression suicidal	0	1 (0.0)
Depressive symptom	1 (0.0)	0
Dissociative disorder	0	1 (0.0)
Drug abuse	22 (0.1)	17 (0.1)
Drug dependence	13 (0.1)	14 (0.1)
Drug use disorder	1 (0.0)	1 (0.0)
Dysphemia	0	2 (0.0)
Eating disorder	4 (0.0)	3 (0.0)
Encopresis	1 (0.0)	0
Enuresis	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Gambling disorder	0	2 (0.0)
Gastrointestinal somatic symptom disorder	1 (0.0)	0
Gender dysphoria	5 (0.0)	2 (0.0)
Generalised anxiety disorder	101 (0.5)	102 (0.5)
Grief reaction	0	3 (0.0)
Hallucination	1 (0.0)	2 (0.0)
Initial insomnia	0	3 (0.0)
Insomnia	1189 (5.4)	1182 (5.4)
Intentional self-injury	1 (0.0)	0
Intermittent explosive disorder	1 (0.0)	1 (0.0)
Irritability	1 (0.0)	4 (0.0)
Libido decreased	28 (0.1)	24 (0.1)
Major depression	147 (0.7)	154 (0.7)
Mania	1 (0.0)	3 (0.0)
Menopausal depression	1 (0.0)	0
Mental disorder	4 (0.0)	4 (0.0)
Middle insomnia	1 (0.0)	0
Mood swings	3 (0.0)	2 (0.0)
Nicotine dependence	38 (0.2)	21 (0.1)
Nightmare	1 (0.0)	2 (0.0)
Obsessive-compulsive disorder	44 (0.2)	48 (0.2)
Obsessive-compulsive personality disorder	0	1 (0.0)
Obsessive-compulsive symptom	1 (0.0)	0
Oppositional defiant disorder	0	4 (0.0)
Panic attack	32 (0.1)	36 (0.2)
Panic disorder	17 (0.1)	14 (0.1)
Panic reaction	2 (0.0)	2 (0.0)
Parasomnia	0	1 (0.0)
Performance fear	1 (0.0)	0
Perinatal depression	14 (0.1)	16 (0.1)
Persistent depressive disorder	3 (0.0)	15 (0.1)
Personality disorder	0	1 (0.0)
Post-traumatic amnestic disorder	0	1 (0.0)
Post-traumatic stress disorder	121 (0.5)	114 (0.5)
Postpartum anxiety	2 (0.0)	0
Premature ejaculation	1 (0.0)	6 (0.0)
Psychogenic erectile dysfunction	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Psychosexual disorder	0	1 (0.0)
Psychotic disorder	3 (0.0)	3 (0.0)
Rapid eye movements sleep abnormal	1 (0.0)	1 (0.0)
Restlessness	1 (0.0)	3 (0.0)
Schizoaffective disorder	8 (0.0)	4 (0.0)
Schizophrenia	25 (0.1)	29 (0.1)
Seasonal affective disorder	14 (0.1)	8 (0.0)
Selective eating disorder	1 (0.0)	1 (0.0)
Sexual inhibition	0	1 (0.0)
Sleep disorder	24 (0.1)	44 (0.2)
Sleep disorder due to general medical condition, insomnia type	2 (0.0)	0
Sleep terror	2 (0.0)	1 (0.0)
Social anxiety disorder	10 (0.0)	1 (0.0)
Somatic symptom disorder	1 (0.0)	1 (0.0)
Somnambulism	0	2 (0.0)
Stress	6 (0.0)	4 (0.0)
Substance abuse	4 (0.0)	2 (0.0)
Substance dependence	1 (0.0)	1 (0.0)
Substance use disorder	1 (0.0)	0
Suicidal behaviour	1 (0.0)	0
Suicidal ideation	4 (0.0)	4 (0.0)
Suicide attempt	4 (0.0)	3 (0.0)
Tachyphrenia	0	1 (0.0)
Terminal insomnia	1 (0.0)	0
Tic	2 (0.0)	3 (0.0)
Tobacco abuse	10 (0.0)	8 (0.0)
Trichotillomania	2 (0.0)	1 (0.0)
Renal and urinary disorders	1061 (4.8)	1058 (4.8)
Acute kidney injury	6 (0.0)	1 (0.0)
Albuminuria	1 (0.0)	0
Atonic urinary bladder	0	1 (0.0)
Bladder disorder	1 (0.0)	1 (0.0)
Bladder diverticulum	1 (0.0)	0
Bladder dysfunction	0	1 (0.0)
Bladder irritation	0	2 (0.0)
Bladder malposition acquired	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Bladder neck obstruction	1 (0.0)	0
Bladder obstruction	1 (0.0)	1 (0.0)
Bladder outlet obstruction	1 (0.0)	2 (0.0)
Bladder perforation	0	2 (0.0)
Bladder prolapse	23 (0.1)	31 (0.1)
Bladder spasm	9 (0.0)	6 (0.0)
Bladder stenosis	1 (0.0)	0
Calculus bladder	3 (0.0)	4 (0.0)
Calculus urinary	1 (0.0)	4 (0.0)
Chronic kidney disease	101 (0.5)	107 (0.5)
Cystitis glandularis	0	1 (0.0)
Cystitis haemorrhagic	1 (0.0)	0
Cystitis interstitial	14 (0.1)	10 (0.0)
Diabetic nephropathy	4 (0.0)	2 (0.0)
Dysuria	11 (0.0)	7 (0.0)
End stage renal disease	1 (0.0)	1 (0.0)
Focal segmental glomerulosclerosis	2 (0.0)	0
Glomerulonephritis	0	1 (0.0)
Glomerulonephritis membranous	1 (0.0)	2 (0.0)
Haematuria	8 (0.0)	22 (0.1)
Hydronephrosis	10 (0.0)	4 (0.0)
Hypercalciuria	3 (0.0)	5 (0.0)
Hypertensive nephropathy	2 (0.0)	0
Hypertonic bladder	172 (0.8)	176 (0.8)
IgA nephropathy	1 (0.0)	1 (0.0)
Incontinence	14 (0.1)	12 (0.1)
Kidney small	0	1 (0.0)
Lower urinary tract symptoms	3 (0.0)	3 (0.0)
Lupus nephritis	0	1 (0.0)
Microalbuminuria	10 (0.0)	5 (0.0)
Micturition disorder	3 (0.0)	6 (0.0)
Micturition urgency	7 (0.0)	13 (0.1)
Mixed incontinence	3 (0.0)	2 (0.0)
Nephritis	1 (0.0)	3 (0.0)
Nephrogenic diabetes insipidus	1 (0.0)	0
Nephrolithiasis	419 (1.9)	387 (1.8)
Nephropathy	14 (0.1)	15 (0.1)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Nephrotic syndrome	1 (0.0)	3 (0.0)
Neurogenic bladder	2 (0.0)	6 (0.0)
Nocturia	29 (0.1)	31 (0.1)
Pelvi-ureteric obstruction	1 (0.0)	1 (0.0)
Pollakiuria	26 (0.1)	28 (0.1)
Polyuria	4 (0.0)	4 (0.0)
Post streptococcal glomerulonephritis	1 (0.0)	0
Proteinuria	4 (0.0)	9 (0.0)
Reflux nephropathy	1 (0.0)	0
Renal artery stenosis	0	3 (0.0)
Renal atrophy	0	1 (0.0)
Renal colic	2 (0.0)	1 (0.0)
Renal cyst	12 (0.1)	21 (0.1)
Renal disorder	5 (0.0)	2 (0.0)
Renal failure	11 (0.0)	16 (0.1)
Renal impairment	5 (0.0)	3 (0.0)
Renal infarct	1 (0.0)	0
Renal injury	1 (0.0)	0
Renal mass	4 (0.0)	3 (0.0)
Renal necrosis	0	1 (0.0)
Single functional kidney	2 (0.0)	5 (0.0)
Stress urinary incontinence	43 (0.2)	35 (0.2)
Trigonitis	1 (0.0)	1 (0.0)
Ureteral disorder	2 (0.0)	0
Ureteric obstruction	0	1 (0.0)
Ureteric stenosis	1 (0.0)	5 (0.0)
Ureterolithiasis	0	1 (0.0)
Urethral cyst	1 (0.0)	0
Urethral dilatation	0	3 (0.0)
Urethral disorder	1 (0.0)	2 (0.0)
Urethral polyp	0	1 (0.0)
Urethral prolapse	0	1 (0.0)
Urethral stenosis	3 (0.0)	6 (0.0)
Urge incontinence	20 (0.1)	14 (0.1)
Urinary bladder polyp	0	1 (0.0)
Urinary hesitation	6 (0.0)	2 (0.0)
Urinary incontinence	89 (0.4)	98 (0.4)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Urinary retention	22 (0.1)	25 (0.1)
Urinary tract obstruction	1 (0.0)	0
Urinary tract pain	0	1 (0.0)
Urine flow decreased	0	3 (0.0)
Urogenital fistula	0	2 (0.0)
Urogenital haemorrhage	0	1 (0.0)
Vesicoureteric reflux	1 (0.0)	2 (0.0)
Reproductive system and breast disorders	2178 (9.9)	2100 (9.5)
Adenomyosis	10 (0.0)	15 (0.1)
Adnexa uteri cyst	2 (0.0)	0
Adnexa uteri pain	1 (0.0)	0
Adnexal torsion	2 (0.0)	1 (0.0)
Amenorrhoea	21 (0.1)	15 (0.1)
Anisomastia	1 (0.0)	1 (0.0)
Artificial menopause	2 (0.0)	2 (0.0)
Atrophic vulvovaginitis	20 (0.1)	24 (0.1)
Azoospermia	2 (0.0)	1 (0.0)
Balanoposthitis	1 (0.0)	1 (0.0)
Bartholin's cyst	3 (0.0)	1 (0.0)
Benign prostatic hyperplasia	570 (2.6)	556 (2.5)
Breast calcifications	5 (0.0)	2 (0.0)
Breast cyst	19 (0.1)	23 (0.1)
Breast disorder	0	1 (0.0)
Breast dysplasia	0	1 (0.0)
Breast enlargement	6 (0.0)	7 (0.0)
Breast fibrosis	2 (0.0)	0
Breast hyperplasia	2 (0.0)	3 (0.0)
Breast mass	19 (0.1)	20 (0.1)
Breast pain	4 (0.0)	1 (0.0)
Breast swelling	1 (0.0)	0
Calculus prostatic	0	2 (0.0)
Cervical cyst	2 (0.0)	0
Cervical discharge	1 (0.0)	0
Cervical dysplasia	21 (0.1)	15 (0.1)
Cervical polyp	3 (0.0)	3 (0.0)
Cervix disorder	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Colpocele	0	2 (0.0)
Cystocele	6 (0.0)	8 (0.0)
Dysfunctional uterine bleeding	15 (0.1)	9 (0.0)
Dysmenorrhoea	71 (0.3)	84 (0.4)
Dyspareunia	7 (0.0)	4 (0.0)
Ectropion of cervix	1 (0.0)	0
Ejaculation disorder	0	1 (0.0)
Endometrial disorder	0	3 (0.0)
Endometrial hyperplasia	10 (0.0)	4 (0.0)
Endometrial hypertrophy	0	1 (0.0)
Endometrial hypoplasia	1 (0.0)	0
Endometrial thickening	1 (0.0)	1 (0.0)
Endometriosis	204 (0.9)	180 (0.8)
Epididymal cyst	2 (0.0)	2 (0.0)
Epididymal enlargement	0	1 (0.0)
Erectile dysfunction	337 (1.5)	384 (1.7)
Fallopian tube adhesion	0	1 (0.0)
Fallopian tube cyst	0	3 (0.0)
Fallopian tube disorder	1 (0.0)	1 (0.0)
Fallopian tube obstruction	3 (0.0)	5 (0.0)
Female genital tract fistula	1 (0.0)	1 (0.0)
Fibrocystic breast disease	29 (0.1)	26 (0.1)
Genital cyst	0	1 (0.0)
Genital lesion	0	1 (0.0)
Genital rash	1 (0.0)	0
Genitourinary syndrome of menopause	0	1 (0.0)
Gynaecomastia	6 (0.0)	9 (0.0)
Haematospermia	1 (0.0)	1 (0.0)
Infertility	20 (0.1)	15 (0.1)
Infertility female	4 (0.0)	7 (0.0)
Infertility male	2 (0.0)	1 (0.0)
Lactation puerperal increased	0	1 (0.0)
Mammary duct ectasia	1 (0.0)	0
Mastoptosis	1 (0.0)	1 (0.0)
Menometrorrhagia	4 (0.0)	1 (0.0)
Menopausal disorder	0	1 (0.0)
Menopausal symptoms	48 (0.2)	51 (0.2)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Menorrhagia	197 (0.9)	170 (0.8)
Menstrual discomfort	1 (0.0)	0
Menstrual disorder	28 (0.1)	26 (0.1)
Menstruation irregular	38 (0.2)	26 (0.1)
Metrorrhagia	5 (0.0)	6 (0.0)
Micromastia	1 (0.0)	0
Nipple exudate bloody	0	1 (0.0)
Oligomenorrhoea	3 (0.0)	2 (0.0)
Oligospermia	1 (0.0)	0
Organic erectile dysfunction	2 (0.0)	2 (0.0)
Ovarian adhesion	0	1 (0.0)
Ovarian cyst	123 (0.6)	120 (0.5)
Ovarian cyst ruptured	7 (0.0)	1 (0.0)
Ovarian disorder	1 (0.0)	0
Ovarian enlargement	0	1 (0.0)
Ovarian failure	1 (0.0)	3 (0.0)
Ovarian fibrosis	1 (0.0)	2 (0.0)
Ovarian haemorrhage	1 (0.0)	1 (0.0)
Ovarian mass	1 (0.0)	2 (0.0)
Ovarian rupture	2 (0.0)	1 (0.0)
Ovulation pain	0	1 (0.0)
Pelvic cyst	1 (0.0)	0
Pelvic floor muscle weakness	1 (0.0)	0
Pelvic pain	8 (0.0)	3 (0.0)
Pelvic prolapse	2 (0.0)	1 (0.0)
Perineal cyst	0	1 (0.0)
Peyronie's disease	2 (0.0)	6 (0.0)
Polycystic ovaries	112 (0.5)	95 (0.4)
Polymenorrhoea	1 (0.0)	0
Postmenopausal haemorrhage	4 (0.0)	3 (0.0)
Premature menopause	11 (0.0)	5 (0.0)
Premenstrual dysphoric disorder	8 (0.0)	8 (0.0)
Premenstrual headache	0	1 (0.0)
Premenstrual syndrome	5 (0.0)	5 (0.0)
Prostatic calcification	0	1 (0.0)
Prostatic disorder	14 (0.1)	8 (0.0)
Prostatic dysplasia	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Prostatic hypoplasia	0	2 (0.0)
Prostatic mass	1 (0.0)	2 (0.0)
Prostatism	10 (0.0)	7 (0.0)
Prostatitis	11 (0.0)	12 (0.1)
Prostatomegaly	117 (0.5)	118 (0.5)
Pruritus genital	0	1 (0.0)
Rectocele	5 (0.0)	5 (0.0)
Scrotal cyst	1 (0.0)	1 (0.0)
Sexual dysfunction	4 (0.0)	4 (0.0)
Spermatocele	2 (0.0)	0
Testicular atrophy	0	1 (0.0)
Testicular cyst	2 (0.0)	1 (0.0)
Testicular mass	0	1 (0.0)
Testicular pain	2 (0.0)	1 (0.0)
Testicular retraction	0	1 (0.0)
Testicular swelling	0	1 (0.0)
Testicular torsion	4 (0.0)	5 (0.0)
Uterine adhesions	0	1 (0.0)
Uterine cervix stenosis	0	1 (0.0)
Uterine cyst	4 (0.0)	7 (0.0)
Uterine disorder	3 (0.0)	1 (0.0)
Uterine enlargement	1 (0.0)	2 (0.0)
Uterine haemorrhage	20 (0.1)	17 (0.1)
Uterine inflammation	1 (0.0)	0
Uterine malposition	2 (0.0)	2 (0.0)
Uterine mass	0	1 (0.0)
Uterine polyp	17 (0.1)	13 (0.1)
Uterine prolapse	44 (0.2)	40 (0.2)
Uterine scar	1 (0.0)	2 (0.0)
Vaginal cyst	2 (0.0)	1 (0.0)
Vaginal discharge	0	1 (0.0)
Vaginal disorder	0	1 (0.0)
Vaginal fistula	0	1 (0.0)
Vaginal haemorrhage	13 (0.1)	9 (0.0)
Vaginal polyp	0	1 (0.0)
Vaginal prolapse	2 (0.0)	5 (0.0)
Vaginal stricture	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Varicocele	15 (0.1)	12 (0.1)
Varicose veins pelvic	1 (0.0)	0
Vulval disorder	2 (0.0)	0
Vulvar dysplasia	0	1 (0.0)
Vulvovaginal burning sensation	0	1 (0.0)
Vulvovaginal dryness	30 (0.1)	29 (0.1)
Vulvovaginal pain	1 (0.0)	1 (0.0)
Respiratory, thoracic and mediastinal disorders	3386 (15.4)	3469 (15.8)
Acute pulmonary oedema	0	1 (0.0)
Acute respiratory failure	1 (0.0)	0
Adenoidal hypertrophy	14 (0.1)	14 (0.1)
Allergic bronchitis	3 (0.0)	1 (0.0)
Allergic cough	3 (0.0)	4 (0.0)
Allergic pharyngitis	1 (0.0)	0
Allergic respiratory symptom	1 (0.0)	0
Allergic sinusitis	29 (0.1)	31 (0.1)
Apnoea	2 (0.0)	3 (0.0)
Aspiration	0	1 (0.0)
Asthma	1405 (6.4)	1407 (6.4)
Asthma exercise induced	75 (0.3)	52 (0.2)
Asthma late onset	0	1 (0.0)
Asthma-chronic obstructive pulmonary disease overlap syndrome	0	1 (0.0)
Asthmatic crisis	1 (0.0)	0
Atelectasis	0	1 (0.0)
Bronchial hyperreactivity	22 (0.1)	21 (0.1)
Bronchiectasis	7 (0.0)	10 (0.0)
Bronchitis chronic	37 (0.2)	28 (0.1)
Bronchospasm	13 (0.1)	8 (0.0)
Childhood asthma	10 (0.0)	19 (0.1)
Chronic obstructive pulmonary disease	245 (1.1)	255 (1.2)
Chronic respiratory disease	0	1 (0.0)
Chronic respiratory failure	0	2 (0.0)
Cough	35 (0.2)	55 (0.2)
Cough variant asthma	1 (0.0)	3 (0.0)
Cystic lung disease	1 (0.0)	2 (0.0)
Diaphragmatic disorder	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Diaphragmatic paralysis	1 (0.0)	1 (0.0)
Dysphonia	2 (0.0)	7 (0.0)
Dyspnoea	25 (0.1)	25 (0.1)
Dyspnoea exertional	4 (0.0)	7 (0.0)
Emphysema	27 (0.1)	39 (0.2)
Epiglottic oedema	1 (0.0)	0
Epistaxis	9 (0.0)	11 (0.0)
Glottal incompetence	0	1 (0.0)
Haemothorax	0	1 (0.0)
Hypersensitivity pneumonitis	0	1 (0.0)
Hypoxia	4 (0.0)	1 (0.0)
Idiopathic pulmonary fibrosis	0	2 (0.0)
Infantile apnoea	0	1 (0.0)
Interstitial lung disease	2 (0.0)	1 (0.0)
Laryngeal disorder	1 (0.0)	0
Laryngeal oedema	0	1 (0.0)
Laryngeal polyp	0	1 (0.0)
Laryngospasm	0	1 (0.0)
Lung cyst	0	1 (0.0)
Lung disorder	1 (0.0)	2 (0.0)
Mediastinal mass	0	1 (0.0)
Nasal congestion	16 (0.1)	30 (0.1)
Nasal cyst	2 (0.0)	0
Nasal discomfort	1 (0.0)	0
Nasal disorder	0	1 (0.0)
Nasal obstruction	1 (0.0)	2 (0.0)
Nasal polyps	30 (0.1)	29 (0.1)
Nasal septum deviation	159 (0.7)	154 (0.7)
Nasal turbinate hypertrophy	4 (0.0)	6 (0.0)
Obliterative bronchiolitis	0	1 (0.0)
Obstructive airways disorder	0	1 (0.0)
Organising pneumonia	1 (0.0)	0
Oropharyngeal pain	9 (0.0)	9 (0.0)
Paranasal cyst	1 (0.0)	2 (0.0)
Paranasal sinus discomfort	0	1 (0.0)
Paranasal sinus haemorrhage	1 (0.0)	0
Pharyngeal cyst	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Pharyngeal disorder	1 (0.0)	1 (0.0)
Pharyngeal mass	0	1 (0.0)
Pharyngeal polyp	1 (0.0)	1 (0.0)
Pleural calcification	0	1 (0.0)
Pleural effusion	1 (0.0)	2 (0.0)
Pleurisy	2 (0.0)	3 (0.0)
Pneumonia aspiration	0	1 (0.0)
Pneumonitis	0	2 (0.0)
Pneumothorax	16 (0.1)	16 (0.1)
Pneumothorax spontaneous	9 (0.0)	5 (0.0)
Productive cough	1 (0.0)	0
Pulmonary arterial hypertension	0	1 (0.0)
Pulmonary calcification	1 (0.0)	0
Pulmonary embolism	38 (0.2)	39 (0.2)
Pulmonary fibrosis	5 (0.0)	7 (0.0)
Pulmonary granuloma	3 (0.0)	4 (0.0)
Pulmonary hypertension	5 (0.0)	2 (0.0)
Pulmonary mass	13 (0.1)	17 (0.1)
Pulmonary oedema	1 (0.0)	2 (0.0)
Pulmonary sarcoidosis	0	1 (0.0)
Pulmonary thrombosis	1 (0.0)	2 (0.0)
Rales	0	1 (0.0)
Reflux laryngitis	3 (0.0)	10 (0.0)
Respiratory disorder	0	2 (0.0)
Respiratory distress	0	2 (0.0)
Respiratory failure	0	2 (0.0)
Respiratory tract congestion	0	1 (0.0)
Restrictive pulmonary disease	2 (0.0)	1 (0.0)
Rhinitis allergic	896 (4.1)	857 (3.9)
Rhinitis perennial	44 (0.2)	51 (0.2)
Rhinitis ulcerative	0	1 (0.0)
Rhinorrhoea	7 (0.0)	2 (0.0)
Rhonchi	0	1 (0.0)
Sinus congestion	23 (0.1)	21 (0.1)
Sinus disorder	6 (0.0)	10 (0.0)
Sinus pain	0	1 (0.0)
Sinus polyp	6 (0.0)	10 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Sleep apnoea syndrome	614 (2.8)	651 (3.0)
Sneezing	0	1 (0.0)
Snoring	3 (0.0)	6 (0.0)
Thoracic insufficiency syndrome	1 (0.0)	0
Throat clearing	0	1 (0.0)
Throat irritation	0	1 (0.0)
Throat tightness	0	1 (0.0)
Tonsillar disorder	1 (0.0)	0
Tonsillar hypertrophy	13 (0.1)	12 (0.1)
Tonsillar inflammation	2 (0.0)	3 (0.0)
Tonsillolith	3 (0.0)	1 (0.0)
Upper airway resistance syndrome	1 (0.0)	0
Upper-airway cough syndrome	13 (0.1)	15 (0.1)
Vasomotor rhinitis	2 (0.0)	0
Vocal cord cyst	0	1 (0.0)
Vocal cord disorder	0	1 (0.0)
Vocal cord dysfunction	0	1 (0.0)
Vocal cord leukoplakia	0	1 (0.0)
Vocal cord polyp	7 (0.0)	5 (0.0)
Vocal cord thickening	1 (0.0)	2 (0.0)
Wheezing	6 (0.0)	10 (0.0)
Skin and subcutaneous tissue disorders	1612 (7.3)	1648 (7.5)
Acanthosis	1 (0.0)	0
Acanthosis nigricans	3 (0.0)	2 (0.0)
Acne	319 (1.4)	303 (1.4)
Acne cystic	7 (0.0)	8 (0.0)
Actinic cheilitis	0	1 (0.0)
Actinic keratosis	82 (0.4)	73 (0.3)
Alopecia	96 (0.4)	104 (0.5)
Alopecia areata	3 (0.0)	4 (0.0)
Androgenetic alopecia	10 (0.0)	27 (0.1)
Angioedema	1 (0.0)	2 (0.0)
Angiokeratoma	0	1 (0.0)
Blister	0	1 (0.0)
Brow ptosis	1 (0.0)	0
Cafe au lait spots	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Chloasma	1 (0.0)	4 (0.0)
Chronic pigmented purpura	1 (0.0)	0
Chronic spontaneous urticaria	2 (0.0)	7 (0.0)
Cold urticaria	3 (0.0)	1 (0.0)
Cutaneous amyloidosis	0	1 (0.0)
Cutaneous lupus erythematosus	1 (0.0)	4 (0.0)
Dandruff	4 (0.0)	4 (0.0)
Decubitus ulcer	0	1 (0.0)
Dermal cyst	31 (0.1)	20 (0.1)
Dermatitis	43 (0.2)	29 (0.1)
Dermatitis acneiform	0	1 (0.0)
Dermatitis allergic	5 (0.0)	12 (0.1)
Dermatitis atopic	51 (0.2)	42 (0.2)
Dermatitis contact	84 (0.4)	95 (0.4)
Dermatomyositis	1 (0.0)	2 (0.0)
Diabetic dermopathy	0	1 (0.0)
Diabetic foot	2 (0.0)	1 (0.0)
Diabetic ulcer	1 (0.0)	0
Diffuse alopecia	0	1 (0.0)
Drug eruption	37 (0.2)	50 (0.2)
Dry skin	16 (0.1)	14 (0.1)
Dyshidrotic eczema	1 (0.0)	6 (0.0)
Eczema	279 (1.3)	285 (1.3)
Eczema asteatotic	0	1 (0.0)
Eczema nummular	0	1 (0.0)
Eosinophilic cellulitis	0	1 (0.0)
Erythema	0	2 (0.0)
Erythema annulare	1 (0.0)	0
Erythema multiforme	0	1 (0.0)
Excessive skin	0	1 (0.0)
Granuloma annulare	5 (0.0)	5 (0.0)
Granuloma skin	1 (0.0)	0
Guttate psoriasis	0	1 (0.0)
Hair growth abnormal	1 (0.0)	0
Hand dermatitis	17 (0.1)	31 (0.1)
Henoch-Schonlein purpura	1 (0.0)	0
Hidradenitis	8 (0.0)	8 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Hirsutism	7 (0.0)	3 (0.0)
Hyperhidrosis	17 (0.1)	12 (0.1)
Hyperkeratosis	8 (0.0)	4 (0.0)
Hypertrichosis	0	1 (0.0)
Hypertrophic scar	1 (0.0)	0
Hypohidrosis	0	1 (0.0)
Hypotrichosis	0	1 (0.0)
Idiopathic guttate hypomelanosis	1 (0.0)	0
Idiopathic urticaria	6 (0.0)	1 (0.0)
Ingrowing nail	4 (0.0)	0
Ingrown hair	2 (0.0)	1 (0.0)
Intertrigo	2 (0.0)	1 (0.0)
Keloid scar	3 (0.0)	7 (0.0)
Keratosis pilaris	8 (0.0)	9 (0.0)
Lentigo	2 (0.0)	1 (0.0)
Leukoplakia	0	1 (0.0)
Lichen planopilaris	0	1 (0.0)
Lichen planus	6 (0.0)	7 (0.0)
Lichen sclerosus	8 (0.0)	10 (0.0)
Lichenification	0	2 (0.0)
Lichenoid keratosis	0	1 (0.0)
Lipodystrophy acquired	1 (0.0)	0
Madarosis	0	1 (0.0)
Mechanical urticaria	2 (0.0)	8 (0.0)
Melanocytic hyperplasia	0	1 (0.0)
Miliaria	2 (0.0)	2 (0.0)
Myxoid cyst	1 (0.0)	1 (0.0)
Nail bed disorder	0	1 (0.0)
Nail discolouration	1 (0.0)	0
Nail dystrophy	0	2 (0.0)
Nail growth abnormal	0	1 (0.0)
Nail psoriasis	0	1 (0.0)
Necrobiosis lipoidica diabeticorum	1 (0.0)	0
Neurodermatitis	7 (0.0)	4 (0.0)
Night sweats	2 (0.0)	4 (0.0)
Palmoplantar keratoderma	1 (0.0)	0
Panniculitis	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Papulopustular rosacea	1 (0.0)	0
Parapsoriasis	1 (0.0)	0
Peau d'orange	0	1 (0.0)
Perioral dermatitis	1 (0.0)	1 (0.0)
Photodermatosis	1 (0.0)	3 (0.0)
Photosensitivity reaction	1 (0.0)	0
Pigmentation disorder	1 (0.0)	0
Pityriasis	1 (0.0)	0
Pityriasis lichenoides et varioliformis acuta	0	1 (0.0)
Pityriasis rosea	2 (0.0)	0
Polymorphic light eruption	2 (0.0)	0
Precancerous skin lesion	4 (0.0)	3 (0.0)
Pruritus	11 (0.0)	13 (0.1)
Pruritus allergic	10 (0.0)	7 (0.0)
Pseudofolliculitis	1 (0.0)	1 (0.0)
Psoriasis	153 (0.7)	157 (0.7)
Purpura	2 (0.0)	1 (0.0)
Purpura senile	5 (0.0)	2 (0.0)
Rash	30 (0.1)	39 (0.2)
Rash macular	1 (0.0)	0
Rash pruritic	0	2 (0.0)
Rhinophyma	0	1 (0.0)
Rosacea	172 (0.8)	154 (0.7)
Scab	0	1 (0.0)
Seborrhoea	3 (0.0)	1 (0.0)
Seborrhoeic dermatitis	38 (0.2)	27 (0.1)
Sensitive skin	1 (0.0)	3 (0.0)
Skin atrophy	4 (0.0)	0
Skin burning sensation	1 (0.0)	0
Skin discolouration	3 (0.0)	3 (0.0)
Skin disorder	1 (0.0)	1 (0.0)
Skin exfoliation	2 (0.0)	1 (0.0)
Skin fissures	0	1 (0.0)
Skin hyperpigmentation	1 (0.0)	1 (0.0)
Skin hypertrophy	2 (0.0)	0
Skin hypopigmentation	1 (0.0)	1 (0.0)
Skin irritation	1 (0.0)	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Skin lesion	4 (0.0)	10 (0.0)
Skin maceration	0	1 (0.0)
Skin mass	1 (0.0)	3 (0.0)
Skin ulcer	4 (0.0)	1 (0.0)
Solar lentigo	2 (0.0)	0
Stasis dermatitis	0	1 (0.0)
Stevens-Johnson syndrome	1 (0.0)	1 (0.0)
Telangiectasia	1 (0.0)	1 (0.0)
Transient acantholytic dermatosis	5 (0.0)	2 (0.0)
Urticaria	65 (0.3)	85 (0.4)
Urticaria cholinergic	0	1 (0.0)
Urticaria chronic	1 (0.0)	3 (0.0)
Urticaria papular	1 (0.0)	0
Urticaria thermal	1 (0.0)	0
Vitiligo	27 (0.1)	21 (0.1)
Social circumstances	2980 (13.5)	2944 (13.4)
Aborted pregnancy	0	1 (0.0)
Alcohol use	25 (0.1)	21 (0.1)
Alcoholic	0	2 (0.0)
Andropause	1 (0.0)	2 (0.0)
Bereavement	2 (0.0)	0
Blood donor	28 (0.1)	29 (0.1)
Cardiac assistance device user	1 (0.0)	0
Celibacy	8 (0.0)	6 (0.0)
Corrective lens user	272 (1.2)	274 (1.2)
Denture wearer	8 (0.0)	10 (0.0)
Dependence on oxygen therapy	1 (0.0)	0
Disease risk factor	0	1 (0.0)
Drug abuser	1 (0.0)	1 (0.0)
Edentulous	1 (0.0)	0
Electronic cigarette user	5 (0.0)	1 (0.0)
Ex-tobacco user	82 (0.4)	77 (0.3)
Eye prosthesis user	0	2 (0.0)
Familial risk factor	4 (0.0)	2 (0.0)
Hearing aid user	31 (0.1)	22 (0.1)
High risk sexual behaviour	0	2 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Inadequate diet	0	1 (0.0)
Limb prosthesis user	1 (0.0)	0
Menarche	0	2 (0.0)
Menopause	485 (2.2)	475 (2.2)
Multigravida	0	1 (0.0)
Multiparous	0	1 (0.0)
Organ donor	8 (0.0)	15 (0.1)
Orthodontic appliance user	1 (0.0)	0
Orthosis user	1 (0.0)	1 (0.0)
Personal relationship issue	1 (0.0)	0
Physical assault	1 (0.0)	1 (0.0)
Postmenopause	1950 (8.9)	1976 (9.0)
Social alcohol drinker	7 (0.0)	3 (0.0)
Substance use	30 (0.1)	20 (0.1)
Tattoo	1 (0.0)	0
Testicular prosthesis user	1 (0.0)	0
Tobacco user	206 (0.9)	162 (0.7)
Trans-sexualism	4 (0.0)	1 (0.0)
Vegan	0	1 (0.0)
Woman of childbearing potential	1 (0.0)	1 (0.0)
Surgical and medical procedures	8430 (38.3)	8455 (38.4)
Abdominal cavity drainage	0	1 (0.0)
Abdominal exploration	3 (0.0)	1 (0.0)
Abdominal hernia repair	44 (0.2)	41 (0.2)
Abdominal operation	12 (0.1)	8 (0.0)
Abdominal panniculectomy	3 (0.0)	3 (0.0)
Abdominal wall operation	2 (0.0)	2 (0.0)
Abdominoplasty	72 (0.3)	61 (0.3)
Abortion induced	2 (0.0)	3 (0.0)
Abscess drainage	14 (0.1)	16 (0.1)
Acoustic neuroma removal	4 (0.0)	4 (0.0)
Acupuncture	0	1 (0.0)
Adenoidectomy	106 (0.5)	92 (0.4)
Adenotonsillectomy	26 (0.1)	27 (0.1)
Adhesiolysis	1 (0.0)	3 (0.0)
Adrenalectomy	4 (0.0)	2 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Alcohol rehabilitation	0	2 (0.0)
Amblyopia therapy	1 (0.0)	1 (0.0)
Amputation	0	2 (0.0)
Anal fissure excision	1 (0.0)	1 (0.0)
Anal fistula repair	5 (0.0)	6 (0.0)
Anal sphincterotomy	0	1 (0.0)
Aneurysm repair	3 (0.0)	5 (0.0)
Angioplasty	20 (0.1)	19 (0.1)
Ankle arthroplasty	12 (0.1)	14 (0.1)
Ankle operation	62 (0.3)	68 (0.3)
Anorectal operation	7 (0.0)	12 (0.1)
Antibiotic prophylaxis	1 (0.0)	2 (0.0)
Antibiotic therapy	1 (0.0)	0
Anticoagulant therapy	2 (0.0)	3 (0.0)
Antidepressant therapy	1 (0.0)	0
Antiviral prophylaxis	2 (0.0)	0
Antiviral treatment	1 (0.0)	1 (0.0)
Anxiolytic therapy	1 (0.0)	0
Aorta coarctation repair	0	1 (0.0)
Aortic aneurysm repair	7 (0.0)	3 (0.0)
Aortic stent insertion	1 (0.0)	3 (0.0)
Aortic surgery	2 (0.0)	0
Aortic valve repair	3 (0.0)	2 (0.0)
Aortic valve replacement	21 (0.1)	25 (0.1)
Apicectomy	0	1 (0.0)
Appendicectomy	702 (3.2)	693 (3.1)
Arm amputation	1 (0.0)	0
Arterial aneurysm repair	0	1 (0.0)
Arterial bypass operation	1 (0.0)	0
Arterial graft	0	1 (0.0)
Arterial repair	2 (0.0)	2 (0.0)
Arterial stent insertion	2 (0.0)	4 (0.0)
Arterial therapeutic procedure	2 (0.0)	3 (0.0)
Arteriovenous fistula operation	2 (0.0)	1 (0.0)
Arthrodesis	19 (0.1)	24 (0.1)
Arthroscopic surgery	4 (0.0)	3 (0.0)
Arthrotomy	0	2 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Artificial crown procedure	1 (0.0)	3 (0.0)
Artificial insemination	1 (0.0)	0
Artificial urinary sphincter implant	1 (0.0)	2 (0.0)
Astrocytoma surgery	1 (0.0)	0
Atrial appendage closure	1 (0.0)	3 (0.0)
Atrial septal defect repair	9 (0.0)	11 (0.0)
Axillary lymphadenectomy	3 (0.0)	3 (0.0)
Baker's cyst excision	1 (0.0)	0
Bartholin's cyst removal	4 (0.0)	1 (0.0)
Benign breast lump removal	19 (0.1)	19 (0.1)
Benign tumour excision	6 (0.0)	5 (0.0)
Bilateral orchidectomy	2 (0.0)	2 (0.0)
Bile duct stent insertion	1 (0.0)	0
Bile duct stent removal	1 (0.0)	0
Biliary stent placement	1 (0.0)	0
Birth defect correction	1 (0.0)	0
Bladder calculus removal	3 (0.0)	2 (0.0)
Bladder lesion excision	0	1 (0.0)
Bladder neoplasm surgery	6 (0.0)	4 (0.0)
Bladder operation	5 (0.0)	9 (0.0)
Bladder polypectomy	2 (0.0)	1 (0.0)
Bladder repair	9 (0.0)	14 (0.1)
Blepharoplasty	25 (0.1)	24 (0.1)
Blood donation	1 (0.0)	6 (0.0)
Blood pressure management	1 (0.0)	0
Bone anchored hearing aid implantation	0	2 (0.0)
Bone cyst excision	8 (0.0)	9 (0.0)
Bone debridement	2 (0.0)	1 (0.0)
Bone graft	7 (0.0)	3 (0.0)
Bone lesion excision	36 (0.2)	37 (0.2)
Bone marrow donation	2 (0.0)	2 (0.0)
Bone operation	61 (0.3)	45 (0.2)
Bone prosthesis insertion	1 (0.0)	0
Botulinum toxin injection	0	2 (0.0)
Brachytherapy	4 (0.0)	1 (0.0)
Brachytherapy to prostate	3 (0.0)	1 (0.0)
Brain lobectomy	2 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Brain operation	5 (0.0)	7 (0.0)
Brain stent insertion	1 (0.0)	0
Brain tumour operation	5 (0.0)	6 (0.0)
Breast conserving surgery	142 (0.6)	134 (0.6)
Breast cyst excision	12 (0.1)	14 (0.1)
Breast operation	8 (0.0)	7 (0.0)
Breast prosthesis removal	8 (0.0)	0
Breast reconstruction	17 (0.1)	17 (0.1)
Breast tumour excision	3 (0.0)	3 (0.0)
Bunion operation	105 (0.5)	121 (0.5)
Burn operation	2 (0.0)	0
Bursa removal	2 (0.0)	3 (0.0)
Bursal operation	0	2 (0.0)
Caecectomy	1 (0.0)	0
Caecopexy	0	1 (0.0)
Caesarean section	606 (2.8)	637 (2.9)
Calcific deposits removal	2 (0.0)	1 (0.0)
Canalith repositioning procedure	0	1 (0.0)
Cancer surgery	64 (0.3)	54 (0.2)
Capsulorrhaphy	1 (0.0)	0
Cardiac ablation	81 (0.4)	79 (0.4)
Cardiac operation	13 (0.1)	15 (0.1)
Cardiac pacemaker insertion	56 (0.3)	62 (0.3)
Cardiac pacemaker removal	0	3 (0.0)
Cardiac pacemaker replacement	1 (0.0)	2 (0.0)
Cardiovascular event prophylaxis	0	1 (0.0)
Cardioversion	8 (0.0)	9 (0.0)
Carotid artery bypass	1 (0.0)	0
Carotid artery stent insertion	4 (0.0)	5 (0.0)
Carotid endarterectomy	7 (0.0)	6 (0.0)
Carotid revascularisation	0	1 (0.0)
Carpal tunnel decompression	144 (0.7)	124 (0.6)
Carpectomy	1 (0.0)	2 (0.0)
Cartilage graft	2 (0.0)	0
Cartilage operation	3 (0.0)	1 (0.0)
Cataract operation	361 (1.6)	367 (1.7)
Catheter placement	0	2 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Central venous catheter removal	0	1 (0.0)
Central venous catheterisation	4 (0.0)	1 (0.0)
Cerebral cyst excision	0	1 (0.0)
Cerebral endovascular aneurysm repair	0	1 (0.0)
Cerebrovascular accident prophylaxis	1 (0.0)	0
Cerebrovascular operation	0	1 (0.0)
Cervical conisation	2 (0.0)	2 (0.0)
Cervical laser therapy	2 (0.0)	0
Cervical polypectomy	2 (0.0)	2 (0.0)
Cervicectomy	0	4 (0.0)
Cervix cautery	1 (0.0)	0
Cervix cryotherapy	3 (0.0)	0
Cervix operation	1 (0.0)	0
Cheilectomy	2 (0.0)	3 (0.0)
Chemical contraception	0	1 (0.0)
Chemotherapy	14 (0.1)	10 (0.0)
Chest tube insertion	4 (0.0)	3 (0.0)
Chest wall operation	0	1 (0.0)
Cholecystectomy	810 (3.7)	805 (3.7)
Cholecystostomy	2 (0.0)	1 (0.0)
Choledocholithotomy	0	1 (0.0)
Cholelithotomy	7 (0.0)	5 (0.0)
Cholesteatoma removal	0	3 (0.0)
Chondrectomy	1 (0.0)	4 (0.0)
Chondroplasty	36 (0.2)	38 (0.2)
Circumcision	9 (0.0)	10 (0.0)
Cleft lip repair	1 (0.0)	1 (0.0)
Cleft palate repair	4 (0.0)	2 (0.0)
Closed fracture manipulation	1 (0.0)	2 (0.0)
Coccygectomy	2 (0.0)	1 (0.0)
Cochlea implant	9 (0.0)	7 (0.0)
Colectomy	63 (0.3)	56 (0.3)
Colectomy total	3 (0.0)	2 (0.0)
Colon operation	10 (0.0)	4 (0.0)
Colostomy	6 (0.0)	7 (0.0)
Colostomy closure	3 (0.0)	3 (0.0)
Colpocleisis	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Colporrhaphy	2 (0.0)	2 (0.0)
Commissurotomy of pulmonary valve	1 (0.0)	0
Contact lens therapy	1 (0.0)	1 (0.0)
Continuous positive airway pressure	19 (0.1)	13 (0.1)
Contraception	14 (0.1)	19 (0.1)
Contraceptive implant	5 (0.0)	7 (0.0)
Corneal implant	0	1 (0.0)
Corneal operation	3 (0.0)	4 (0.0)
Corneal transplant	16 (0.1)	12 (0.1)
Coronary angioplasty	17 (0.1)	20 (0.1)
Coronary arterial stent insertion	172 (0.8)	170 (0.8)
Coronary artery bypass	106 (0.5)	124 (0.6)
Coronary artery stent removal	1 (0.0)	0
Coronary artery surgery	3 (0.0)	4 (0.0)
Coronary revascularisation	3 (0.0)	4 (0.0)
Cranial nerve decompression	2 (0.0)	0
Cranial operation	7 (0.0)	5 (0.0)
Craniectomy	0	1 (0.0)
Cranioplasty	1 (0.0)	1 (0.0)
Craniotomy	5 (0.0)	10 (0.0)
Cryotherapy	4 (0.0)	6 (0.0)
Cyst drainage	2 (0.0)	0
Cyst removal	18 (0.1)	13 (0.1)
Cystocele repair	3 (0.0)	2 (0.0)
Cystoprostatectomy	1 (0.0)	0
Cytoreductive surgery	1 (0.0)	1 (0.0)
Dacryocystorhinostomy	3 (0.0)	2 (0.0)
Debridement	8 (0.0)	10 (0.0)
Decompressive craniectomy	0	1 (0.0)
Deep brain stimulation	1 (0.0)	3 (0.0)
Dental care	0	1 (0.0)
Dental cosmetic procedure	1 (0.0)	1 (0.0)
Dental implantation	16 (0.1)	14 (0.1)
Dental operation	5 (0.0)	3 (0.0)
Dental prosthesis placement	3 (0.0)	2 (0.0)
Dermabrasion	1 (0.0)	0
Detoxification	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Dialysis	0	1 (0.0)
Diaphragmatic operation	1 (0.0)	1 (0.0)
Diplopia correction	1 (0.0)	0
Diverticulectomy	2 (0.0)	4 (0.0)
Drug delivery device placement	1 (0.0)	2 (0.0)
Drug rehabilitation	1 (0.0)	1 (0.0)
Duodenal operation	1 (0.0)	0
Duodenal switch	0	3 (0.0)
Duodenal ulcer repair	0	1 (0.0)
Duodenectomy	1 (0.0)	0
Dupuytren's contracture operation	4 (0.0)	5 (0.0)
Ear operation	13 (0.1)	8 (0.0)
Ear tube insertion	25 (0.1)	30 (0.1)
Ear tube removal	1 (0.0)	3 (0.0)
Ectopic pregnancy termination	2 (0.0)	1 (0.0)
Elbow operation	23 (0.1)	28 (0.1)
Electrodesiccation	1 (0.0)	0
Endarterectomy	1 (0.0)	0
Endocervical curettage	1 (0.0)	0
Endocrine gland operation	1 (0.0)	0
Endodontic procedure	1 (0.0)	6 (0.0)
Endometrial ablation	119 (0.5)	108 (0.5)
Endometriosis ablation	6 (0.0)	11 (0.0)
Endoscopic sleeve gastroplasty	0	1 (0.0)
Enterorrhaphy	0	1 (0.0)
Enterostomy	2 (0.0)	0
Epidermoid cyst excision	1 (0.0)	1 (0.0)
Epididymal cyst removal	4 (0.0)	0
Epididymal operation	1 (0.0)	0
Epidural injection	1 (0.0)	0
Epiphysiodesis	1 (0.0)	0
Ethmoid sinus surgery	1 (0.0)	1 (0.0)
Eustachian tube operation	1 (0.0)	2 (0.0)
Exeresis	11 (0.0)	11 (0.0)
Explorative laparotomy	6 (0.0)	7 (0.0)
External fixation of fracture	2 (0.0)	1 (0.0)
External nose lesion excision	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Eye excision	3 (0.0)	3 (0.0)
Eye irrigation	0	1 (0.0)
Eye laser surgery	44 (0.2)	27 (0.1)
Eye muscle operation	4 (0.0)	10 (0.0)
Eye operation	31 (0.1)	28 (0.1)
Eye prosthesis insertion	1 (0.0)	0
Eyeglasses therapy	1 (0.0)	1 (0.0)
Eyelid cyst removal	2 (0.0)	3 (0.0)
Eyelid operation	7 (0.0)	8 (0.0)
Face lift	13 (0.1)	11 (0.0)
Facet joint block	0	2 (0.0)
Facial lesion excision	0	2 (0.0)
Facial operation	5 (0.0)	2 (0.0)
Fallopian tube operation	3 (0.0)	3 (0.0)
Fascia release	4 (0.0)	4 (0.0)
Fascial operation	3 (0.0)	4 (0.0)
Fasciotomy	9 (0.0)	8 (0.0)
Female genital operation	1 (0.0)	0
Female sterilisation	713 (3.2)	749 (3.4)
Femoral derotation osteotomy	0	1 (0.0)
Femoral hernia repair	1 (0.0)	2 (0.0)
Finger amputation	11 (0.0)	15 (0.1)
Finger repair operation	7 (0.0)	7 (0.0)
Fistula repair	3 (0.0)	2 (0.0)
Fistulotomy	1 (0.0)	0
Foetal surgery	0	1 (0.0)
Foot amputation	3 (0.0)	1 (0.0)
Foot operation	51 (0.2)	48 (0.2)
Foraminotomy	3 (0.0)	2 (0.0)
Fracture reduction	3 (0.0)	3 (0.0)
Fracture treatment	149 (0.7)	148 (0.7)
Frontal sinus operation	1 (0.0)	0
Fulguration	0	1 (0.0)
Functional endoscopic sinus surgery	3 (0.0)	4 (0.0)
Gallbladder operation	9 (0.0)	9 (0.0)
Gastrectomy	82 (0.4)	100 (0.5)
Gastric banding	28 (0.1)	31 (0.1)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Gastric banding reversal	3 (0.0)	4 (0.0)
Gastric bypass	144 (0.7)	136 (0.6)
Gastric bypass reversal	0	1 (0.0)
Gastric operation	2 (0.0)	8 (0.0)
Gastric stapling	0	4 (0.0)
Gastric ulcer surgery	0	3 (0.0)
Gastroenterostomy	1 (0.0)	2 (0.0)
Gastrointestinal dilation procedure	0	1 (0.0)
Gastrointestinal surgery	3 (0.0)	1 (0.0)
Gastrointestinal ulcer management	3 (0.0)	1 (0.0)
Gastroplasty	1 (0.0)	4 (0.0)
Gastrostomy	1 (0.0)	0
Gastrostomy tube removal	1 (0.0)	0
Gender reassignment therapy	1 (0.0)	0
Genitourinary operation	1 (0.0)	2 (0.0)
Gingival graft	2 (0.0)	7 (0.0)
Gingival operation	0	2 (0.0)
Gingivectomy	0	1 (0.0)
Glaucoma drainage device placement	1 (0.0)	1 (0.0)
Glaucoma surgery	6 (0.0)	10 (0.0)
Glossectomy	1 (0.0)	1 (0.0)
Haemangioma removal	3 (0.0)	3 (0.0)
Haematoma evacuation	0	2 (0.0)
Haemorrhoid operation	51 (0.2)	55 (0.2)
Haemostasis	2 (0.0)	1 (0.0)
Hair transplant	2 (0.0)	4 (0.0)
Hand amputation	1 (0.0)	1 (0.0)
Hand repair operation	3 (0.0)	6 (0.0)
Hearing aid therapy	0	1 (0.0)
Heart valve replacement	8 (0.0)	9 (0.0)
Hepatectomy	2 (0.0)	2 (0.0)
Hepatitis B immunisation	0	1 (0.0)
Hernia diaphragmatic repair	2 (0.0)	0
Hernia hiatus repair	18 (0.1)	38 (0.2)
Hernia repair	148 (0.7)	139 (0.6)
Herpes zoster immunisation	0	1 (0.0)
High frequency ablation	2 (0.0)	2 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Hip arthroplasty	219 (1.0)	206 (0.9)
Hip surgery	28 (0.1)	22 (0.1)
Hormone replacement therapy	12 (0.1)	10 (0.0)
Hormone therapy	1 (0.0)	0
Hospitalisation	1 (0.0)	1 (0.0)
Hydrocele operation	6 (0.0)	7 (0.0)
Hyperbaric oxygen therapy	1 (0.0)	0
Hyperthermic chemotherapy	0	1 (0.0)
Hypophysectomy	1 (0.0)	0
Hysterectomy	1542 (7.0)	1499 (6.8)
Hysteropexy	0	2 (0.0)
Hysterosalpingectomy	0	1 (0.0)
Hysterosalpingo-oophorectomy	18 (0.1)	20 (0.1)
Hysterotomy	1 (0.0)	2 (0.0)
Ileectomy	1 (0.0)	1 (0.0)
Ileostomy	4 (0.0)	3 (0.0)
Ileostomy closure	1 (0.0)	2 (0.0)
Immune tolerance induction	2 (0.0)	1 (0.0)
Immunoglobulin therapy	1 (0.0)	0
Implantable cardiac monitor insertion	4 (0.0)	7 (0.0)
Implantable defibrillator insertion	17 (0.1)	11 (0.0)
Implantable defibrillator removal	1 (0.0)	1 (0.0)
Implantable defibrillator replacement	2 (0.0)	5 (0.0)
In vitro fertilisation	1 (0.0)	3 (0.0)
Incisional drainage	3 (0.0)	6 (0.0)
Incisional hernia repair	2 (0.0)	9 (0.0)
Infection prophylaxis	0	1 (0.0)
Influenza immunisation	1 (0.0)	4 (0.0)
Infusion	0	1 (0.0)
Inguinal hernia repair	263 (1.2)	278 (1.3)
Injection	1 (0.0)	2 (0.0)
Inner ear operation	2 (0.0)	2 (0.0)
Internal fixation of fracture	11 (0.0)	12 (0.1)
Internal fixation of spine	0	1 (0.0)
Intervertebral disc operation	114 (0.5)	126 (0.6)
Intestinal adhesion lysis	1 (0.0)	0
Intestinal anastomosis	1 (0.0)	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Intestinal fistula repair	0	1 (0.0)
Intestinal malrotation repair	0	1 (0.0)
Intestinal operation	15 (0.1)	7 (0.0)
Intestinal polypectomy	0	2 (0.0)
Intestinal resection	20 (0.1)	18 (0.1)
Intra-cerebral aneurysm operation	6 (0.0)	2 (0.0)
Intra-thoracic aortic aneurysm repair	0	1 (0.0)
Intra-uterine contraceptive device insertion	30 (0.1)	31 (0.1)
Intracerebral haematoma evacuation	1 (0.0)	0
Intramedullary rod insertion	3 (0.0)	2 (0.0)
Intraocular lens implant	23 (0.1)	39 (0.2)
Intrauterine contraception	26 (0.1)	34 (0.2)
Iridotomy	2 (0.0)	2 (0.0)
Jaw lesion excision	1 (0.0)	0
Jaw operation	25 (0.1)	30 (0.1)
Jejunal operation	0	1 (0.0)
Jejunostomy	0	1 (0.0)
Joint arthroplasty	19 (0.1)	18 (0.1)
Joint debridement	5 (0.0)	5 (0.0)
Joint dislocation reduction	16 (0.1)	13 (0.1)
Joint fluid drainage	1 (0.0)	0
Joint irrigation	0	1 (0.0)
Joint manipulation	0	4 (0.0)
Joint resurfacing surgery	2 (0.0)	0
Joint stabilisation	1 (0.0)	1 (0.0)
Joint surgery	4 (0.0)	9 (0.0)
Keratectomy	1 (0.0)	1 (0.0)
Keratomileusis	123 (0.6)	115 (0.5)
Keratoplasty	2 (0.0)	1 (0.0)
Keratotomy	3 (0.0)	6 (0.0)
Kidney ablation	1 (0.0)	0
Knee arthroplasty	341 (1.5)	337 (1.5)
Knee operation	190 (0.9)	182 (0.8)
Lacrimal duct procedure	3 (0.0)	5 (0.0)
Lacrimal gland operation	0	1 (0.0)
Laminaplasty	0	1 (0.0)
Laparoscopic surgery	5 (0.0)	5 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Laparotomy	6 (0.0)	5 (0.0)
Large intestinal polypectomy	61 (0.3)	55 (0.2)
Large intestine anastomosis	1 (0.0)	0
Large intestine operation	1 (0.0)	2 (0.0)
Laryngeal cyst removal	0	1 (0.0)
Laryngeal operation	2 (0.0)	1 (0.0)
Laryngeal polypectomy	0	2 (0.0)
Laryngectomy	2 (0.0)	0
Laryngoplasty	0	1 (0.0)
Laser therapy	1 (0.0)	2 (0.0)
Leg amputation	7 (0.0)	8 (0.0)
Lens capsulotomy	5 (0.0)	0
Lens extraction	1 (0.0)	0
Lenticular operation	1 (0.0)	0
Lesion excision	2 (0.0)	1 (0.0)
Ligament operation	173 (0.8)	169 (0.8)
Limb operation	97 (0.4)	102 (0.5)
Limb reattachment surgery	4 (0.0)	1 (0.0)
Limb reconstructive surgery	1 (0.0)	3 (0.0)
Lip operation	1 (0.0)	1 (0.0)
Lipectomy	2 (0.0)	3 (0.0)
Lipoma excision	35 (0.2)	32 (0.1)
Liposuction	13 (0.1)	19 (0.1)
Lithotomy position	0	1 (0.0)
Lithotripsy	44 (0.2)	38 (0.2)
Liver ablation	1 (0.0)	0
Liver operation	0	1 (0.0)
Liver transplant	0	1 (0.0)
Loop electrosurgical excision procedure	15 (0.1)	13 (0.1)
Lower oesophageal sphincter magnetic augmentation	3 (0.0)	3 (0.0)
Lung assist device therapy	1 (0.0)	0
Lung cyst removal	1 (0.0)	0
Lung lobectomy	7 (0.0)	9 (0.0)
Lung neoplasm surgery	1 (0.0)	0
Lung operation	3 (0.0)	5 (0.0)
Lymphadenectomy	13 (0.1)	22 (0.1)
Lymphoid tissue operation	3 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Lymphoma operation	2 (0.0)	2 (0.0)
Mammary ductectomy	1 (0.0)	2 (0.0)
Mammoplasty	237 (1.1)	217 (1.0)
Manipulation	1 (0.0)	0
Mass excision	2 (0.0)	1 (0.0)
Mastectomy	94 (0.4)	96 (0.4)
Mastoidectomy	3 (0.0)	5 (0.0)
Maxillofacial operation	4 (0.0)	2 (0.0)
Mediastinal operation	0	1 (0.0)
Medical cannabis therapy	0	1 (0.0)
Medical device battery replacement	1 (0.0)	2 (0.0)
Medical device implantation	2 (0.0)	3 (0.0)
Medical device removal	6 (0.0)	6 (0.0)
Meningioma surgery	6 (0.0)	4 (0.0)
Meniscus operation	147 (0.7)	148 (0.7)
Meniscus removal	20 (0.1)	29 (0.1)
Metabolic disorder prophylaxis	0	1 (0.0)
Metabolic surgery	52 (0.2)	51 (0.2)
Metacarpal excision	0	1 (0.0)
Metatarsal excision	1 (0.0)	0
Micrographic skin surgery	39 (0.2)	45 (0.2)
Microsurgery to hand	0	1 (0.0)
Middle ear lesion excision	1 (0.0)	0
Middle ear operation	1 (0.0)	0
Middle ear prosthesis insertion	0	1 (0.0)
Mitral valve repair	13 (0.1)	8 (0.0)
Mitral valve replacement	6 (0.0)	8 (0.0)
Modified radical mastectomy	1 (0.0)	0
Mole excision	15 (0.1)	12 (0.1)
Muscle flap operation	1 (0.0)	0
Muscle graft	0	1 (0.0)
Muscle operation	17 (0.1)	22 (0.1)
Muscle reattachment	2 (0.0)	1 (0.0)
Myectomy	0	3 (0.0)
Myomectomy	26 (0.1)	36 (0.2)
Myopia correction	2 (0.0)	5 (0.0)
Myringotomy	7 (0.0)	13 (0.1)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Nail operation	5 (0.0)	1 (0.0)
Nasal operation	13 (0.1)	14 (0.1)
Nasal polypectomy	16 (0.1)	10 (0.0)
Nasal septal operation	134 (0.6)	137 (0.6)
Nasal sinus irrigation	1 (0.0)	1 (0.0)
Nasopharyngeal surgery	0	1 (0.0)
Neck dissection	5 (0.0)	2 (0.0)
Neck lift	0	2 (0.0)
Neck surgery	21 (0.1)	14 (0.1)
Neoplasm prophylaxis	0	1 (0.0)
Nephrectomy	37 (0.2)	37 (0.2)
Nephrostomy	0	2 (0.0)
Nerve block	5 (0.0)	3 (0.0)
Nerve graft	0	1 (0.0)
Nervous system neoplasm surgery	5 (0.0)	2 (0.0)
Neurectomy	16 (0.1)	13 (0.1)
Neuroprosthesis implantation	2 (0.0)	1 (0.0)
Neurosurgery	1 (0.0)	3 (0.0)
Oesophageal dilation procedure	4 (0.0)	7 (0.0)
Oesophageal lesion excision	0	1 (0.0)
Oesophageal operation	4 (0.0)	3 (0.0)
Oesophagectomy	1 (0.0)	1 (0.0)
Oesophagocardiomyotomy	0	2 (0.0)
Oesophagogastrectomy	1 (0.0)	0
Oesophagogastric fundoplasty	21 (0.1)	14 (0.1)
Oestrogen replacement therapy	1 (0.0)	0
Oestrogen therapy	0	1 (0.0)
Oocyte harvest	2 (0.0)	1 (0.0)
Oophorectomy	78 (0.4)	75 (0.3)
Oophorectomy bilateral	60 (0.3)	44 (0.2)
Open reduction of fracture	60 (0.3)	57 (0.3)
Oral cavity neoplasm surgery	1 (0.0)	2 (0.0)
Oral contraception	1 (0.0)	0
Oral surgery	2 (0.0)	3 (0.0)
Orbit plastic repair	1 (0.0)	0
Orbital decompression	0	1 (0.0)
Orchidectomy	19 (0.1)	17 (0.1)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Orchidopexy	5 (0.0)	3 (0.0)
Orthognathic surgery	11 (0.0)	10 (0.0)
Orthopaedic procedure	6 (0.0)	6 (0.0)
Ossicular operation	0	2 (0.0)
Ossiculoplasty	1 (0.0)	1 (0.0)
Ostectomy	9 (0.0)	10 (0.0)
Osteotomy	14 (0.1)	9 (0.0)
Otoplasty	6 (0.0)	6 (0.0)
Ovarian cystectomy	28 (0.1)	40 (0.2)
Ovarian lesion excision	2 (0.0)	2 (0.0)
Ovarian neoplasm surgery	4 (0.0)	1 (0.0)
Ovarian operation	1 (0.0)	3 (0.0)
Ovariocentesis	0	1 (0.0)
Oxygen therapy	0	1 (0.0)
Pain management	0	1 (0.0)
Palatal operation	3 (0.0)	0
Palatoplasty	0	1 (0.0)
Pancreatectomy	2 (0.0)	1 (0.0)
Pancreatic operation	0	1 (0.0)
Pancreatic stent placement	0	1 (0.0)
Pancreatic stent removal	0	1 (0.0)
Pancreaticoduodenectomy	3 (0.0)	4 (0.0)
Papilloma excision	6 (0.0)	2 (0.0)
Paranasal sinus polypectomy	4 (0.0)	9 (0.0)
Paraovarian cystectomy	0	1 (0.0)
Parathyroid gland operation	3 (0.0)	4 (0.0)
Parathyroidectomy	29 (0.1)	15 (0.1)
Parotidectomy	8 (0.0)	2 (0.0)
Patellectomy	0	2 (0.0)
Patent ductus arteriosus repair	2 (0.0)	1 (0.0)
Pelvic floor repair	3 (0.0)	2 (0.0)
Pelvic operation	2 (0.0)	0
Penile prosthesis insertion	8 (0.0)	9 (0.0)
Penis frenulectomy	1 (0.0)	0
Percutaneous coronary intervention	2 (0.0)	5 (0.0)
Pericardial excision	0	1 (0.0)
Peripheral artery bypass	1 (0.0)	3 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Peripheral artery stent insertion	1 (0.0)	1 (0.0)
Peripheral artery surgery	1 (0.0)	0
Peripheral nerve decompression	11 (0.0)	14 (0.1)
Peripheral nerve destruction	0	2 (0.0)
Peripheral nerve neurostimulation	0	3 (0.0)
Peripheral nerve operation	6 (0.0)	18 (0.1)
Peripheral nerve transposition	6 (0.0)	5 (0.0)
Permanent contraceptive tubal implant	1 (0.0)	2 (0.0)
Pharyngeal operation	6 (0.0)	6 (0.0)
Pharyngeal polypectomy	1 (0.0)	0
Phlebectomy	5 (0.0)	12 (0.1)
Photorefractive keratectomy	8 (0.0)	10 (0.0)
Physiotherapy	1 (0.0)	2 (0.0)
Pilonidal sinus repair	19 (0.1)	22 (0.1)
Pituitary tumour removal	5 (0.0)	4 (0.0)
Plastic surgery	6 (0.0)	2 (0.0)
Plastic surgery to the face	7 (0.0)	11 (0.0)
Platelet rich plasma therapy	1 (0.0)	0
Pleural operation	0	4 (0.0)
Pleurectomy	0	1 (0.0)
Pleurodesis	1 (0.0)	0
Pneumocentesis	0	1 (0.0)
Pneumonectomy	2 (0.0)	4 (0.0)
Polypectomy	23 (0.1)	18 (0.1)
Portal shunt procedure	0	1 (0.0)
Postoperative care	0	1 (0.0)
Precancerous lesion excision	3 (0.0)	2 (0.0)
Preventive surgery	1 (0.0)	0
Proctectomy	0	2 (0.0)
Proctocolectomy	1 (0.0)	0
Proctoplasty	1 (0.0)	0
Prophylaxis	2 (0.0)	3 (0.0)
Prophylaxis against HIV infection	6 (0.0)	2 (0.0)
Prostate ablation	2 (0.0)	4 (0.0)
Prostate cryoablation	1 (0.0)	1 (0.0)
Prostatectomy	88 (0.4)	102 (0.5)
Prostatic operation	13 (0.1)	19 (0.1)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Prostatic urethral lift procedure	2 (0.0)	7 (0.0)
Prosthesis implantation	1 (0.0)	1 (0.0)
Psychotherapy	0	1 (0.0)
Pterygium operation	3 (0.0)	3 (0.0)
Ptosis repair	4 (0.0)	2 (0.0)
Pulmonary bullectomy	1 (0.0)	1 (0.0)
Pulmonary resection	3 (0.0)	3 (0.0)
Pulmonary valve repair	1 (0.0)	0
Pulmonary valve replacement	0	1 (0.0)
Punctal plug insertion	1 (0.0)	0
Pyeloplasty	1 (0.0)	1 (0.0)
Pyloromyotomy	2 (0.0)	2 (0.0)
Pyloroplasty	2 (0.0)	7 (0.0)
Pylorus dilation procedure	0	1 (0.0)
Rabies immunisation	0	1 (0.0)
Rachiotomy	1 (0.0)	0
Radiation therapy to ear, nose, or throat	1 (0.0)	0
Radical cystectomy	1 (0.0)	0
Radical hysterectomy	3 (0.0)	6 (0.0)
Radical mastectomy	1 (0.0)	0
Radical prostatectomy	13 (0.1)	10 (0.0)
Radiculotomy	1 (0.0)	1 (0.0)
Radioactive iodine therapy	6 (0.0)	3 (0.0)
Radiotherapy	13 (0.1)	7 (0.0)
Radiotherapy to breast	4 (0.0)	5 (0.0)
Radiotherapy to eye	0	1 (0.0)
Radiotherapy to prostate	5 (0.0)	5 (0.0)
Radiotherapy to skin	1 (0.0)	0
Radiotherapy to thyroid	0	3 (0.0)
Rectal fistula repair	2 (0.0)	3 (0.0)
Rectal lesion excision	2 (0.0)	0
Rectal polypectomy	1 (0.0)	0
Rectal prolapse repair	3 (0.0)	3 (0.0)
Rectocele repair	7 (0.0)	4 (0.0)
Reduction of increased intracranial pressure	1 (0.0)	0
Rehabilitation therapy	1 (0.0)	1 (0.0)
Removal of foreign body	7 (0.0)	11 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Removal of foreign body from eye	0	2 (0.0)
Removal of foreign body from gastrointestinal tract	1 (0.0)	1 (0.0)
Removal of foreign body from joint	1 (0.0)	1 (0.0)
Removal of foreign body from rectum	1 (0.0)	0
Removal of foreign body from throat	1 (0.0)	0
Renal artery stent placement	0	2 (0.0)
Renal cyst excision	2 (0.0)	2 (0.0)
Renal stone removal	57 (0.3)	61 (0.3)
Renal surgery	2 (0.0)	15 (0.1)
Renal tumour excision	2 (0.0)	1 (0.0)
Retinal operation	18 (0.1)	24 (0.1)
Retinopexy	25 (0.1)	16 (0.1)
Rhinoplasty	72 (0.3)	92 (0.4)
Rib excision	4 (0.0)	1 (0.0)
Rotator cuff repair	196 (0.9)	177 (0.8)
Salivary gland operation	3 (0.0)	5 (0.0)
Salivary gland resection	5 (0.0)	2 (0.0)
Salpingectomy	102 (0.5)	101 (0.5)
Salpingo-oophorectomy	2 (0.0)	2 (0.0)
Salpingo-oophorectomy bilateral	13 (0.1)	7 (0.0)
Salpingo-oophorectomy unilateral	4 (0.0)	2 (0.0)
Salpingoplasty	2 (0.0)	2 (0.0)
Salpingostomy	4 (0.0)	2 (0.0)
Sarcoma excision	1 (0.0)	2 (0.0)
Scar excision	3 (0.0)	9 (0.0)
Scleral buckling surgery	3 (0.0)	1 (0.0)
Sclerotherapy	2 (0.0)	1 (0.0)
Scoliosis surgery	6 (0.0)	3 (0.0)
Scrotal cystectomy	0	1 (0.0)
Scrotal operation	2 (0.0)	0
Sebaceous cyst excision	5 (0.0)	7 (0.0)
Seizure prophylaxis	1 (0.0)	0
Septal myectomy	0	1 (0.0)
Sesamoidectomy	1 (0.0)	2 (0.0)
Shoulder arthroplasty	47 (0.2)	41 (0.2)
Shoulder operation	143 (0.6)	99 (0.4)
Sigmoidectomy	6 (0.0)	7 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Simple mastectomy	2 (0.0)	2 (0.0)
Sinuplasty	17 (0.1)	12 (0.1)
Sinus antrostomy	3 (0.0)	0
Sinus operation	81 (0.4)	67 (0.3)
Skin cosmetic procedure	5 (0.0)	7 (0.0)
Skin cryotherapy	1 (0.0)	1 (0.0)
Skin cyst excision	6 (0.0)	1 (0.0)
Skin graft	13 (0.1)	16 (0.1)
Skin lesion removal	19 (0.1)	16 (0.1)
Skin neoplasm excision	175 (0.8)	207 (0.9)
Skin operation	7 (0.0)	5 (0.0)
Skull fracture treatment	1 (0.0)	2 (0.0)
Small intestinal resection	7 (0.0)	4 (0.0)
Small intestine operation	4 (0.0)	2 (0.0)
Soft tissue flap operation	0	1 (0.0)
Spermatic cord operation	1 (0.0)	0
Sphenoid sinus operation	1 (0.0)	1 (0.0)
Spinal cord operation	2 (0.0)	1 (0.0)
Spinal corpectomy	3 (0.0)	1 (0.0)
Spinal decompression	13 (0.1)	13 (0.1)
Spinal deformity correction	0	1 (0.0)
Spinal fracture treatment	6 (0.0)	3 (0.0)
Spinal fusion surgery	187 (0.8)	186 (0.8)
Spinal laminectomy	82 (0.4)	96 (0.4)
Spinal nerve stimulator implantation	14 (0.1)	16 (0.1)
Spinal nerve stimulator removal	0	1 (0.0)
Spinal operation	121 (0.5)	106 (0.5)
Spinal rod insertion	2 (0.0)	1 (0.0)
Spleen operation	0	1 (0.0)
Splenectomy	21 (0.1)	25 (0.1)
Splenic artery embolisation	1 (0.0)	1 (0.0)
Splenorrhaphy	1 (0.0)	0
Stapedectomy	5 (0.0)	4 (0.0)
Stem cell therapy	2 (0.0)	1 (0.0)
Stem cell transplant	2 (0.0)	2 (0.0)
Stent placement	22 (0.1)	30 (0.1)
Sterilisation	20 (0.1)	10 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Sterilisation reversal	3 (0.0)	4 (0.0)
Sternotomy	0	1 (0.0)
Steroid therapy	1 (0.0)	0
Stoma closure	1 (0.0)	0
Stomach lesion excision	2 (0.0)	0
Strabismus correction	24 (0.1)	30 (0.1)
Stricturoplasty	1 (0.0)	0
Subdural haematoma evacuation	1 (0.0)	0
Surgery	9 (0.0)	14 (0.1)
Surgical fixation of rib fracture	1 (0.0)	0
Suture insertion	2 (0.0)	2 (0.0)
Suture removal	0	1 (0.0)
Sympathectomy	0	3 (0.0)
Synovectomy	2 (0.0)	1 (0.0)
Synovial cyst removal	34 (0.2)	24 (0.1)
Talipes correction	1 (0.0)	5 (0.0)
Tarsal tunnel decompression	0	2 (0.0)
Temporomandibular joint surgery	8 (0.0)	2 (0.0)
Tendon graft	3 (0.0)	0
Tendon operation	7 (0.0)	9 (0.0)
Tendon sheath incision	38 (0.2)	26 (0.1)
Tendon transfer	4 (0.0)	3 (0.0)
Tenodesis	1 (0.0)	1 (0.0)
Tenolysis	1 (0.0)	3 (0.0)
Tenonectomy	1 (0.0)	0
Tenoplasty	91 (0.4)	99 (0.4)
Tenotomy	8 (0.0)	20 (0.1)
Testes exploration	1 (0.0)	3 (0.0)
Testicular operation	1 (0.0)	3 (0.0)
Tetralogy of Fallot repair	2 (0.0)	1 (0.0)
Therapeutic aspiration	0	1 (0.0)
Therapeutic embolisation	5 (0.0)	1 (0.0)
Therapeutic nerve ablation	5 (0.0)	1 (0.0)
Therapeutic procedure	4 (0.0)	0
Thermal ablation	1 (0.0)	0
Thoracic operation	4 (0.0)	1 (0.0)
Thoracic outlet surgery	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Thoracoplasty	2 (0.0)	2 (0.0)
Thoracotomy	5 (0.0)	4 (0.0)
Thrombectomy	4 (0.0)	2 (0.0)
Thromboembolectomy	0	1 (0.0)
Thymectomy	2 (0.0)	2 (0.0)
Thyroglossal cyst excision	1 (0.0)	4 (0.0)
Thyroid cystectomy	0	2 (0.0)
Thyroid nodule removal	4 (0.0)	7 (0.0)
Thyroid operation	5 (0.0)	6 (0.0)
Thyroidectomy	162 (0.7)	175 (0.8)
Toe amputation	15 (0.1)	15 (0.1)
Toe operation	28 (0.1)	27 (0.1)
Tongue operation	0	2 (0.0)
Tongue tie operation	1 (0.0)	3 (0.0)
Tonsillectomy	842 (3.8)	793 (3.6)
Tooth extraction	15 (0.1)	19 (0.1)
Tooth repair	0	2 (0.0)
Trabeculectomy	4 (0.0)	5 (0.0)
Trabeculoplasty	0	2 (0.0)
Tracheal fistula repair	1 (0.0)	0
Tracheostomy	4 (0.0)	6 (0.0)
Tracheostomy tube removal	1 (0.0)	1 (0.0)
Transcatheter aortic valve implantation	1 (0.0)	0
Transfusion	10 (0.0)	12 (0.1)
Transgender hormonal therapy	2 (0.0)	2 (0.0)
Transgender operation	3 (0.0)	1 (0.0)
Transplant	3 (0.0)	1 (0.0)
Transurethral bladder resection	5 (0.0)	0
Transurethral incision of prostate	1 (0.0)	0
Transurethral prostatectomy	18 (0.1)	33 (0.1)
Trapeziectomy	0	2 (0.0)
Tumour excision	7 (0.0)	3 (0.0)
Tumour vaccine therapy	1 (0.0)	0
Turbinectomy	11 (0.0)	13 (0.1)
Turbinoplasty	1 (0.0)	2 (0.0)
Tympanomastoidectomy	1 (0.0)	0
Tympanoplasty	16 (0.1)	16 (0.1)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Umbilical hernia repair	105 (0.5)	125 (0.6)
Umbilicoplasty	0	1 (0.0)
Ureteral stent insertion	8 (0.0)	9 (0.0)
Ureteral stent removal	1 (0.0)	1 (0.0)
Ureterectomy	0	1 (0.0)
Ureteric calculus removal	1 (0.0)	0
Ureteric operation	2 (0.0)	2 (0.0)
Ureteric repair	1 (0.0)	3 (0.0)
Ureterolithotomy	0	1 (0.0)
Urethral bulking agent injection	1 (0.0)	0
Urethral dilation procedure	1 (0.0)	1 (0.0)
Urethral operation	7 (0.0)	6 (0.0)
Urethral repair	2 (0.0)	6 (0.0)
Urethral stent insertion	0	1 (0.0)
Urethrectomy	0	1 (0.0)
Urethrotomy	0	1 (0.0)
Urinary bladder suspension	57 (0.3)	54 (0.2)
Urinary calculus removal	1 (0.0)	0
Urinary control neurostimulator implantation	2 (0.0)	3 (0.0)
Urinary incontinence surgery	2 (0.0)	1 (0.0)
Urinary tract operation	2 (0.0)	3 (0.0)
Urogenital fistula repair	0	1 (0.0)
Urostomy	1 (0.0)	0
Uterine cystectomy	1 (0.0)	3 (0.0)
Uterine dilation and curettage	52 (0.2)	64 (0.3)
Uterine irrigation	1 (0.0)	0
Uterine leiomyoma embolisation	2 (0.0)	3 (0.0)
Uterine operation	6 (0.0)	3 (0.0)
Uterine polypectomy	10 (0.0)	6 (0.0)
Uterine prolapse repair	2 (0.0)	1 (0.0)
Uterine repair	1 (0.0)	0
Uterine tumour excision	1 (0.0)	2 (0.0)
Uvulectomy	4 (0.0)	8 (0.0)
Uvulopalatopharyngoplasty	6 (0.0)	10 (0.0)
Uvuloplasty	1 (0.0)	0
Vagal nerve stimulator implantation	1 (0.0)	0
Vaginal fistula repair	0	1 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Vaginal operation	5 (0.0)	2 (0.0)
Vaginal pessary insertion	0	1 (0.0)
Vaginal prolapse repair	5 (0.0)	0
Vaginal ring	1 (0.0)	0
Valvuloplasty cardiac	1 (0.0)	1 (0.0)
Varicocele repair	13 (0.1)	14 (0.1)
Varicose vein operation	23 (0.1)	22 (0.1)
Vascular graft	4 (0.0)	8 (0.0)
Vascular operation	2 (0.0)	3 (0.0)
Vascular stent insertion	10 (0.0)	17 (0.1)
Vasectomy	804 (3.7)	754 (3.4)
Vasectomy reversal	4 (0.0)	3 (0.0)
Vena cava filter insertion	5 (0.0)	0
Venous ligation	1 (0.0)	1 (0.0)
Venous operation	2 (0.0)	3 (0.0)
Venous reconstruction	0	1 (0.0)
Venous stent insertion	2 (0.0)	0
Ventricular drainage	1 (0.0)	0
Ventricular septal defect repair	2 (0.0)	1 (0.0)
Ventriculo-peritoneal shunt	1 (0.0)	5 (0.0)
Vertebroplasty	4 (0.0)	5 (0.0)
Vesicoureteral reflux surgery	0	1 (0.0)
Vessel harvesting	1 (0.0)	0
Vestibular apparatus operation	0	1 (0.0)
Vision correction operation	5 (0.0)	3 (0.0)
Vitamin supplementation	2 (0.0)	0
Vitrectomy	10 (0.0)	10 (0.0)
Vocal cord nodule removal	1 (0.0)	1 (0.0)
Vocal cord operation	0	3 (0.0)
Vocal cord polypectomy	3 (0.0)	3 (0.0)
Vulval operation	1 (0.0)	1 (0.0)
Vulvectomy	2 (0.0)	2 (0.0)
Weight control	2 (0.0)	0
Wisdom teeth removal	158 (0.7)	165 (0.7)
Wound closure	7 (0.0)	9 (0.0)
Wound treatment	2 (0.0)	2 (0.0)
Wrist surgery	41 (0.2)	56 (0.3)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Vascular disorders	5722 (26.0)	5777 (26.2)
Aneurysm	6 (0.0)	2 (0.0)
Aneurysm ruptured	0	1 (0.0)
Angiopathy	3 (0.0)	2 (0.0)
Aortic aneurysm	30 (0.1)	28 (0.1)
Aortic arteriosclerosis	46 (0.2)	37 (0.2)
Aortic dilatation	7 (0.0)	9 (0.0)
Aortic disorder	2 (0.0)	3 (0.0)
Aortic stenosis	8 (0.0)	11 (0.0)
Arterial occlusive disease	5 (0.0)	5 (0.0)
Arterial stenosis	1 (0.0)	0
Arterial thrombosis	1 (0.0)	1 (0.0)
Arteriosclerosis	21 (0.1)	25 (0.1)
Arteriovenous fistula	1 (0.0)	0
Capillary fragility	0	1 (0.0)
Collateral circulation	0	1 (0.0)
Deep vein thrombosis	74 (0.3)	84 (0.4)
Diabetic vascular disorder	1 (0.0)	2 (0.0)
Embolism	1 (0.0)	1 (0.0)
Embolism arterial	2 (0.0)	0
Embolism venous	2 (0.0)	1 (0.0)
Endocrine hypertension	0	1 (0.0)
Erythromelalgia	1 (0.0)	0
Essential hypertension	97 (0.4)	85 (0.4)
Extremity necrosis	1 (0.0)	0
Fibromuscular dysplasia	0	2 (0.0)
Flushing	0	1 (0.0)
Giant cell arteritis	0	2 (0.0)
Haematoma	1 (0.0)	3 (0.0)
Haemorrhage	2 (0.0)	1 (0.0)
Hot flush	134 (0.6)	144 (0.7)
Hypertension	5291 (24.0)	5326 (24.2)
Hypotension	22 (0.1)	11 (0.0)
Infarction	1 (0.0)	1 (0.0)
Intermittent claudication	7 (0.0)	4 (0.0)
Ischaemia	1 (0.0)	0

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)
Kawasaki's disease	1 (0.0)	0
Lymphoedema	12 (0.1)	8 (0.0)
May-Thurner syndrome	2 (0.0)	2 (0.0)
Microangiopathy	1 (0.0)	0
Neovascularisation	1 (0.0)	0
Orthostatic hypertension	1 (0.0)	0
Orthostatic hypotension	2 (0.0)	5 (0.0)
Peripheral arterial occlusive disease	16 (0.1)	13 (0.1)
Peripheral artery aneurysm	2 (0.0)	5 (0.0)
Peripheral artery thrombosis	1 (0.0)	0
Peripheral vascular disorder	18 (0.1)	24 (0.1)
Peripheral venous disease	16 (0.1)	28 (0.1)
Phlebitis	4 (0.0)	0
Phlebosclerosis	1 (0.0)	0
Poor peripheral circulation	1 (0.0)	5 (0.0)
Post thrombotic syndrome	0	1 (0.0)
Prehypertension	2 (0.0)	5 (0.0)
Raynaud's phenomenon	28 (0.1)	41 (0.2)
Spider vein	1 (0.0)	0
Subclavian artery aneurysm	1 (0.0)	0
Subclavian artery occlusion	1 (0.0)	0
Subclavian artery thrombosis	0	1 (0.0)
Subclavian vein thrombosis	1 (0.0)	1 (0.0)
Thrombophlebitis	1 (0.0)	4 (0.0)
Thrombosis	25 (0.1)	22 (0.1)
Varicose vein	75 (0.3)	90 (0.4)
Varicose vein ruptured	1 (0.0)	0
Vasculitis	1 (0.0)	0
Vena cava thrombosis	2 (0.0)	0
Venous haemorrhage	0	1 (0.0)
Venous thrombosis	4 (0.0)	1 (0.0)
Venous thrombosis limb	2 (0.0)	2 (0.0)
White coat hypertension	9 (0.0)	6 (0.0)

14.47. Medical History – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)

Note: MedDRA (v23.1) coding dictionary applied.
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. Subjects with multiple occurrences of the same preferred term are counted only once.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:25) Source Data: admh Table Generation: 27MAR2021 (01:28)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/admh_s002_all_p3_saf

14.48. Baseline Charlson Comorbidities – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=22026)	Placebo (N[a]=22021)	Total (N[a]=44047)
Charlson Comorbidity Index Category	n[b] (%)	n[b] (%)	n[b] (%)
Subjects with any Charlson comorbidity	4628 (21.0)	4511 (20.5)	9139 (20.7)
AIDS/HIV	100 (0.5)	100 (0.5)	200 (0.5)
Any malignancy	812 (3.7)	757 (3.4)	1569 (3.6)
Cerebrovascular disease	227 (1.0)	198 (0.9)	425 (1.0)
Chronic pulmonary disease	1783 (8.1)	1775 (8.1)	3558 (8.1)
Congestive heart failure	109 (0.5)	102 (0.5)	211 (0.5)
Dementia	7 (0.0)	11 (0.0)	18 (0.0)
Diabetes with chronic complication	116 (0.5)	130 (0.6)	246 (0.6)
Diabetes without chronic complication	1700 (7.7)	1699 (7.7)	3399 (7.7)
Hemiplegia or paraplegia	15 (0.1)	25 (0.1)	40 (0.1)
Leukemia	14 (0.1)	11 (0.0)	25 (0.1)
Lymphoma	26 (0.1)	36 (0.2)	62 (0.1)
Metastatic solid tumor	4 (0.0)	3 (0.0)	7 (0.0)
Mild liver disease	152 (0.7)	115 (0.5)	267 (0.6)
Moderate or severe liver disease	2 (0.0)	3 (0.0)	5 (0.0)
Myocardial infarction	225 (1.0)	218 (1.0)	443 (1.0)
Peptic ulcer disease	63 (0.3)	84 (0.4)	147 (0.3)
Peripheral vascular disease	144 (0.7)	139 (0.6)	283 (0.6)
Renal disease	140 (0.6)	153 (0.7)	293 (0.7)
Rheumatic disease	75 (0.3)	71 (0.3)	146 (0.3)

Abbreviation: AIDS = acquired immunodeficiency syndrome.
Note: MedDRA (v23.1) coding dictionary applied.
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. Subjects with multiple occurrences within each category are counted only once. For "Subjects with any Charlson comorbidity," n = number of subjects reporting at least 1 occurrence of any Charlson comorbidity.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:25) Source Data: admh Table Generation: 27MAR2021 (01:28)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/admh_s002_risk_all_p3_saf

14.49. Baseline Charlson Comorbidities, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=13069)	Placebo (N[a]=13095)	Total (N[a]=26164)
Charlson Comorbidity Index Category	n[b] (%)	n[b] (%)	n[b] (%)
Subjects with any Charlson comorbidity	1766 (13.5)	1722 (13.2)	3488 (13.3)
AIDS/HIV	74 (0.6)	69 (0.5)	143 (0.5)
Any malignancy	138 (1.1)	127 (1.0)	265 (1.0)
Cerebrovascular disease	48 (0.4)	42 (0.3)	90 (0.3)
Chronic pulmonary disease	982 (7.5)	954 (7.3)	1936 (7.4)
Congestive heart failure	24 (0.2)	22 (0.2)	46 (0.2)
Diabetes with chronic complication	22 (0.2)	19 (0.1)	41 (0.2)
Diabetes without chronic complication	482 (3.7)	483 (3.7)	965 (3.7)
Hemiplegia or paraplegia	3 (0.0)	15 (0.1)	18 (0.1)
Leukemia	5 (0.0)	3 (0.0)	8 (0.0)
Lymphoma	7 (0.1)	12 (0.1)	19 (0.1)
Metastatic solid tumor	1 (0.0)	0	1 (0.0)
Mild liver disease	62 (0.5)	57 (0.4)	119 (0.5)
Moderate or severe liver disease	0	1 (0.0)	1 (0.0)
Myocardial infarction	35 (0.3)	28 (0.2)	63 (0.2)
Peptic ulcer disease	23 (0.2)	28 (0.2)	51 (0.2)
Peripheral vascular disease	9 (0.1)	12 (0.1)	21 (0.1)
Renal disease	20 (0.2)	23 (0.2)	43 (0.2)
Rheumatic disease	25 (0.2)	26 (0.2)	51 (0.2)

Abbreviation: AIDS = acquired immunodeficiency syndrome.
Note: MedDRA (v23.1) coding dictionary applied.
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. Subjects with multiple occurrences within each category are counted only once. For "Subjects with any Charlson comorbidity," n = number of subjects reporting at least 1 occurrence of any Charlson comorbidity.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:25) Source Data: admh Table Generation: 27MAR2021 (01:28)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/admh_s002_risk_age_p3_saf

14.50. Baseline Charlson Comorbidities, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=8957)	Placebo (N[a]=8926)	Total (N[a]=17883)
Charlson Comorbidity Index Category	n[b] (%)	n[b] (%)	n[b] (%)
Subjects with any Charlson comorbidity	2862 (32.0)	2789 (31.2)	5651 (31.6)
AIDS/HIV	26 (0.3)	31 (0.3)	57 (0.3)
Any malignancy	674 (7.5)	630 (7.1)	1304 (7.3)
Cerebrovascular disease	179 (2.0)	156 (1.7)	335 (1.9)
Chronic pulmonary disease	801 (8.9)	821 (9.2)	1622 (9.1)
Congestive heart failure	85 (0.9)	80 (0.9)	165 (0.9)
Dementia	7 (0.1)	11 (0.1)	18 (0.1)
Diabetes with chronic complication	94 (1.0)	111 (1.2)	205 (1.1)
Diabetes without chronic complication	1218 (13.6)	1216 (13.6)	2434 (13.6)
Hemiplegia or paraplegia	12 (0.1)	10 (0.1)	22 (0.1)
Leukemia	9 (0.1)	8 (0.1)	17 (0.1)
Lymphoma	19 (0.2)	24 (0.3)	43 (0.2)
Metastatic solid tumor	3 (0.0)	3 (0.0)	6 (0.0)
Mild liver disease	90 (1.0)	58 (0.6)	148 (0.8)
Moderate or severe liver disease	2 (0.0)	2 (0.0)	4 (0.0)
Myocardial infarction	190 (2.1)	190 (2.1)	380 (2.1)
Peptic ulcer disease	40 (0.4)	56 (0.6)	96 (0.5)
Peripheral vascular disease	135 (1.5)	127 (1.4)	262 (1.5)
Renal disease	120 (1.3)	130 (1.5)	250 (1.4)
Rheumatic disease	50 (0.6)	45 (0.5)	95 (0.5)

Abbreviation: AIDS = acquired immunodeficiency syndrome.
Note: MedDRA (v23.1) coding dictionary applied.
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. Subjects with multiple occurrences within each category are counted only once. For "Subjects with any Charlson comorbidity," n = number of subjects reporting at least 1 occurrence of any Charlson comorbidity.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:25) Source Data: admh Table Generation: 27MAR2021 (01:28)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/admh_s002_risk_age_p3_saf

14.51. Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=100) n^b (%)	Placebo (N^a=100) n^b (%)	Total (N^a=200) n^b (%)
Sex			
Male	69 (69.0)	66 (66.0)	135 (67.5)
Female	31 (31.0)	34 (34.0)	65 (32.5)
Race			
White	44 (44.0)	37 (37.0)	81 (40.5)
Black or African American	52 (52.0)	57 (57.0)	109 (54.5)
American Indian or Alaska Native	1 (1.0)	2 (2.0)	3 (1.5)
Asian	2 (2.0)	1 (1.0)	3 (1.5)
Multiracial	1 (1.0)	2 (2.0)	3 (1.5)
Not reported	0	1 (1.0)	1 (0.5)
Ethnicity			
Hispanic/Latino	20 (20.0)	12 (12.0)	32 (16.0)
Non-Hispanic/non-Latino	80 (80.0)	87 (87.0)	167 (83.5)
Not reported	0	1 (1.0)	1 (0.5)
Country			
Argentina	3 (3.0)	1 (1.0)	4 (2.0)
Brazil	3 (3.0)	2 (2.0)	5 (2.5)
Germany	2 (2.0)	0	2 (1.0)
South Africa	27 (27.0)	27 (27.0)	54 (27.0)
Turkey	2 (2.0)	2 (2.0)	4 (2.0)
USA	63 (63.0)	68 (68.0)	131 (65.5)
Age group (at vaccination)			
16-55 Years	74 (74.0)	69 (69.0)	143 (71.5)
>55 Years	26 (26.0)	31 (31.0)	57 (28.5)
Age at vaccination (years)			
Mean (SD)	49.0 (9.74)	48.9 (11.15)	48.9 (10.44)
Median	50.0	49.0	49.5
Min, max	(22, 75)	(26, 68)	(22, 75)
Baseline SARS-CoV-2 status			
Positive[c]	15 (15.0)	11 (11.0)	26 (13.0)
Negative[d]	83 (83.0)	88 (88.0)	171 (85.5)
Missing	2 (2.0)	1 (1.0)	3 (1.5)
Body mass index (BMI)			

14.51. Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=100) n^b (%)	Placebo (N^a=100) n^b (%)	Total (N^a=200) n^b (%)
Underweight (<18.5 kg/m^2)	4 (4.0)	1 (1.0)	5 (2.5)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	22 (22.0)	26 (26.0)	48 (24.0)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	35 (35.0)	34 (34.0)	69 (34.5)
Obese (≥30.0 kg/m^2)	39 (39.0)	39 (39.0)	78 (39.0)
Cluster of differentiation 4 (CD4) count			
<200 cells/mm^3	2 (2.0)	2 (2.0)	4 (2.0)
200-500 cells/mm^3	16 (16.0)	28 (28.0)	44 (22.0)
>500 cells/mm^3	78 (78.0)	64 (64.0)	142 (71.0)
Missing	4 (4.0)	6 (6.0)	10 (5.0)
HIV ribonucleic acid (RNA)			
<50 copies/mL	93 (93.0)	96 (96.0)	189 (94.5)
≥50 copies/mL	4 (4.0)	0	4 (2.0)
Missing	3 (3.0)	4 (4.0)	7 (3.5)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (15:14)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adsl s005 demo hiv p3 saf

14.52. Demographic Characteristics – Phase 2/3 Subjects ≥12 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=23157) n[b] (%)	Placebo (N[a]=23150) n[b] (%)	Total (N[a]=46307) n[b] (%)
Sex			
Male	11889 (51.3)	11683 (50.5)	23572 (50.9)
Female	11268 (48.7)	11467 (49.5)	22735 (49.1)
Race			
White	19027 (82.2)	19026 (82.2)	38053 (82.2)
Black or African American	2150 (9.3)	2175 (9.4)	4325 (9.3)
American Indian or Alaska Native	225 (1.0)	220 (1.0)	445 (1.0)
Asian	1024 (4.4)	1013 (4.4)	2037 (4.4)
Native Hawaiian or other Pacific Islander	61 (0.3)	32 (0.1)	93 (0.2)
Multiracial	573 (2.5)	562 (2.4)	1135 (2.5)
Not reported	97 (0.4)	122 (0.5)	219 (0.5)
Racial designation			
Japanese	83 (0.4)	80 (0.3)	163 (0.4)
Ethnicity			
Hispanic/Latino	5836 (25.2)	5825 (25.2)	11661 (25.2)
Non-Hispanic/non-Latino	17208 (74.3)	17208 (74.3)	34416 (74.3)
Not reported	113 (0.5)	117 (0.5)	230 (0.5)
Country			
Argentina	2883 (12.4)	2881 (12.4)	5764 (12.4)
Brazil	1452 (6.3)	1448 (6.3)	2900 (6.3)
Germany	249 (1.1)	250 (1.1)	499 (1.1)
South Africa	401 (1.7)	399 (1.7)	800 (1.7)
Turkey	249 (1.1)	249 (1.1)	498 (1.1)
USA	17923 (77.4)	17923 (77.4)	35846 (77.4)
Age group (at vaccination)			
12-15 Years	1131 (4.9)	1129 (4.9)	2260 (4.9)
16-55 Years	13069 (56.4)	13095 (56.6)	26164 (56.5)
>55 Years	8957 (38.7)	8926 (38.6)	17883 (38.6)
Age at vaccination (years)			
Mean (SD)	48.0 (17.43)	47.8 (17.47)	47.9 (17.45)
Median	50.0	49.0	50.0
Min, max	(12, 89)	(12, 91)	(12, 91)
Baseline SARS-CoV-2 status			

14.52. Demographic Characteristics – Phase 2/3 Subjects ≥12 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=23157) n[b] (%)	Placebo (N[a]=23150) n[b] (%)	Total (N[a]=46307) n[b] (%)
Positive[c]	735 (3.2)	763 (3.3)	1498 (3.2)
Negative[d]	22213 (95.9)	22203 (95.9)	44416 (95.9)
Missing	209 (0.9)	184 (0.8)	393 (0.8)
Body mass index (BMI)			
Number of subjects ≥16 years of age[e]	22026	22021	44047
Underweight (<18.5 kg/m^2)	271 (1.2)	304 (1.4)	575 (1.3)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	6535 (29.7)	6524 (29.6)	13059 (29.6)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	7670 (34.8)	7558 (34.3)	15228 (34.6)
Obese (≥30.0 kg/m^2)	7543 (34.2)	7629 (34.6)	15172 (34.4)
Missing	7 (0.0)	6 (0.0)	13 (0.0)
Body mass index (BMI) 12-15 years of age/Obese[f]			
Number of subjects 12-15 years of age[g]	1131	1129	2260
Yes	143 (12.6)	128 (11.3)	271 (12.0)
No	988 (87.4)	1001 (88.7)	1989 (88.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
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, or the total sample. This value is the denominator for the percentage calculations except for BMI.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
e. The 12- through 15-year age group is not included in the BMI section. This value is the denominator for the percentage calculations for BMI.
f. For the 12- through 15-year age group, obesity is defined as a BMI at or above the 95th percentile from the growth chart.
Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html charts/bmiagerev htm.
g. This value is the denominator for the percentage calculations for this section.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:28)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_s005_demo_12_p3_saf

14.53. Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=23140) n[b] (%)	Placebo (N[a]=23137) n[b] (%)	Total (N[a]=46277) n[b] (%)
Sex			
Male	11882 (51.3)	11674 (50.5)	23556 (50.9)
Female	11258 (48.7)	11463 (49.5)	22721 (49.1)
Race			
White	19013 (82.2)	19010 (82.2)	38023 (82.2)
Black or African American	2150 (9.3)	2175 (9.4)	4325 (9.3)
American Indian or Alaska Native	225 (1.0)	220 (1.0)	445 (1.0)
Asian	1022 (4.4)	1015 (4.4)	2037 (4.4)
Native Hawaiian or other Pacific Islander	60 (0.3)	33 (0.1)	93 (0.2)
Multiracial	573 (2.5)	562 (2.4)	1135 (2.5)
Not reported	97 (0.4)	122 (0.5)	219 (0.5)
All others[c]	1977 (8.5)	1952 (8.4)	3929 (8.5)
Racial Designation			
Japanese	83 (0.4)	80 (0.3)	163 (0.4)
Ethnicity			
Hispanic/Latino	5832 (25.2)	5817 (25.1)	11649 (25.2)
Non-Hispanic/non-Latino	17195 (74.3)	17203 (74.4)	34398 (74.3)
Not reported	113 (0.5)	117 (0.5)	230 (0.5)
Country			
Argentina	2882 (12.5)	2882 (12.5)	5764 (12.5)
Brazil	1452 (6.3)	1448 (6.3)	2900 (6.3)
Germany	249 (1.1)	250 (1.1)	499 (1.1)
South Africa	401 (1.7)	399 (1.7)	800 (1.7)
Turkey	249 (1.1)	249 (1.1)	498 (1.1)
USA	17907 (77.4)	17909 (77.4)	35816 (77.4)
Age group (years)			
12 to 15	1131 (4.9)	1129 (4.9)	2260 (4.9)
16 to 55	13060 (56.4)	13086 (56.6)	26146 (56.5)
>55	8949 (38.7)	8922 (38.6)	17871 (38.6)
≥65	4549 (19.7)	4540 (19.6)	9089 (19.6)
16 to 17	378 (1.6)	376 (1.6)	754 (1.6)
16 to 25	1865 (8.1)	1897 (8.2)	3762 (8.1)
16 to 64	17460 (75.5)	17468 (75.5)	34928 (75.5)

14.53. Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=23140) n[b] (%)	Placebo (N[a]=23137) n[b] (%)	Total (N[a]=46277) n[b] (%)
18 to 64	17082 (73.8)	17092 (73.9)	34174 (73.8)
55 to 64	4868 (21.0)	4842 (20.9)	9710 (21.0)
65 to 74	3626 (15.7)	3648 (15.8)	7274 (15.7)
≥75	923 (4.0)	892 (3.9)	1815 (3.9)
75 to 85	917 (4.0)	886 (3.8)	1803 (3.9)
>85	6 (0.0)	6 (0.0)	12 (0.0)
Comorbidities[d]			
Yes	10356 (44.8)	10304 (44.5)	20660 (44.6)
No	12784 (55.2)	12833 (55.5)	25617 (55.4)
Baseline SARS-CoV-2 status			
Positive[e]	732 (3.2)	762 (3.3)	1494 (3.2)
Negative[f]	22200 (95.9)	22191 (95.9)	44391 (95.9)
Unknown	208 (0.9)	184 (0.8)	392 (0.8)
Age at vaccination (years)			
Mean (SD)	48.0 (17.43)	47.8 (17.46)	47.9 (17.45)
Median	50.0	49.0	50.0
Min, max	(12, 89)	(12, 91)	(12, 91)

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, or the total sample. 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.
d. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2 (≥16 Years of age) or BMI ≥95th percentile (12-15 Years of age).
e. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
f. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 30MAR2021 (22:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_demo_d1_aai

14.54. Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=22255) n[b] (%)	Placebo (N[a]=22410) n[b] (%)	Total (N[a]=44665) n[b] (%)
Sex			
Male	11415 (51.3)	11295 (50.4)	22710 (50.8)
Female	10840 (48.7)	11115 (49.6)	21955 (49.2)
Race			
White	18266 (82.1)	18431 (82.2)	36697 (82.2)
Black or African American	2059 (9.3)	2093 (9.3)	4152 (9.3)
American Indian or Alaska Native	208 (0.9)	192 (0.9)	400 (0.9)
Asian	1000 (4.5)	995 (4.4)	1995 (4.5)
Native Hawaiian or other Pacific Islander	59 (0.3)	32 (0.1)	91 (0.2)
Multiracial	568 (2.6)	548 (2.4)	1116 (2.5)
Not reported	95 (0.4)	119 (0.5)	214 (0.5)
All others[c]	1930 (8.7)	1886 (8.4)	3816 (8.5)
Racial Designation			
Japanese	82 (0.4)	80 (0.4)	162 (0.4)
Ethnicity			
Hispanic/Latino	5534 (24.9)	5536 (24.7)	11070 (24.8)
Non-Hispanic/non-Latino	16614 (74.7)	16758 (74.8)	33372 (74.7)
Not reported	107 (0.5)	116 (0.5)	223 (0.5)
Country			
Argentina	2686 (12.1)	2710 (12.1)	5396 (12.1)
Brazil	1437 (6.5)	1432 (6.4)	2869 (6.4)
Germany	240 (1.1)	243 (1.1)	483 (1.1)
South Africa	391 (1.8)	392 (1.7)	783 (1.8)
Turkey	241 (1.1)	238 (1.1)	479 (1.1)
USA	17260 (77.6)	17395 (77.6)	34655 (77.6)
Age group (years)			
12 to 15	1119 (5.0)	1110 (5.0)	2229 (5.0)
16 to 55	12490 (56.1)	12614 (56.3)	25104 (56.2)
>55	8646 (38.8)	8686 (38.8)	17332 (38.8)
≥65	4407 (19.8)	4429 (19.8)	8836 (19.8)
16 to 17	370 (1.7)	362 (1.6)	732 (1.6)
16 to 25	1792 (8.1)	1808 (8.1)	3600 (8.1)

14.54. Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=22255) n[b] (%)	Placebo (N[a]=22410) n[b] (%)	Total (N[a]=44665) n[b] (%)
16 to 64	16729 (75.2)	16871 (75.3)	33600 (75.2)
18 to 64	16359 (73.5)	16509 (73.7)	32868 (73.6)
55 to 64	4687 (21.1)	4702 (21.0)	9389 (21.0)
65 to 74	3524 (15.8)	3559 (15.9)	7083 (15.9)
≥75	883 (4.0)	870 (3.9)	1753 (3.9)
75 to 85	878 (3.9)	864 (3.9)	1742 (3.9)
>85	5 (0.0)	6 (0.0)	11 (0.0)
Comorbidities[d]			
Yes	9955 (44.7)	9971 (44.5)	19926 (44.6)
No	12300 (55.3)	12439 (55.5)	24739 (55.4)
Baseline SARS-CoV-2 status			
Positive[e]	673 (3.0)	715 (3.2)	1388 (3.1)
Negative[f]	21383 (96.1)	21517 (96.0)	42900 (96.0)
Unknown	199 (0.9)	178 (0.8)	377 (0.8)
Age at vaccination (years)			
Mean (SD)	48.0 (17.49)	47.9 (17.48)	47.9 (17.48)
Median	50.0	50.0	50.0
Min, max	(12, 89)	(12, 91)	(12, 91)

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, or the total sample. 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.
d. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2 (≥16 Years of age) or BMI ≥95th percentile (12-15 Years of age).
e. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
f. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 30MAR2021 (22:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adsl demo 7d wwo eval eff

14.55. E-Diary Transmission (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)
Vaccinated at Dose 1[b]	5033	5032
E-diary		
Not transmitted[c]	72 (1.4)	79 (1.6)
Transmitted[d]		
Day 1	4703 (93.4)	4657 (92.5)
Day 2	4733 (94.0)	4679 (93.0)
Day 3	4622 (91.8)	4674 (92.9)
Day 4	4583 (91.1)	4588 (91.2)
Day 5	4535 (90.1)	4582 (91.1)
Day 6	4562 (90.6)	4532 (90.1)
Day 7	4537 (90.1)	4548 (90.4)
All 7 days[e]	3454 (68.6)	3461 (68.8)
Vaccinated at Dose 2[b]	4964	4934
E-diary		
Not transmitted[c]	360 (7.3)	354 (7.2)
Transmitted[d]		
Day 1	3799 (76.5)	3615 (73.3)
Day 2	4249 (85.6)	3966 (80.4)
Day 3	4197 (84.5)	4063 (82.3)
Day 4	4162 (83.8)	4110 (83.3)
Day 5	4179 (84.2)	4132 (83.7)
Day 6	4182 (84.2)	4127 (83.6)
Day 7	4160 (83.8)	4155 (84.2)
All 7 days[e]	2718 (54.8)	2481 (50.3)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
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 (ie, "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: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_s200_trns_p3_saf

14.56. Concomitant Vaccines Received After Dose 1 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

Vaccine[b]	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=21926) n[c] (%)	Placebo (N[a]=21921) n[c] (%)
Any concomitant vaccine	2705 (12.3)	3167 (14.4)
ANTHRAX VACCINE	0	1 (0.0)
CHOLERA VACCINE	0	1 (0.0)
COVID-19 VACCINE	4 (0.0)	82 (0.4)
COVID-19 VACCINE INACT (VERO)	5 (0.0)	6 (0.0)
COVID-19 VACCINE INACT (VERO) HB02	1 (0.0)	2 (0.0)
COVID-19 VACCINE MRNA (MRNA 1273)	28 (0.1)	131 (0.6)
COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)	0	4 (0.0)
DIPHTHERIA VACCINE	1 (0.0)	0
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID	2 (0.0)	3 (0.0)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 5-COMPONENT;TETANUS VACCINE TOXOID	3 (0.0)	4 (0.0)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	22 (0.1)	32 (0.1)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE;TETANUS VACCINE TOXOID	0	1 (0.0)
DIPHTHERIA VACCINE TOXOID;TETANUS VACCINE TOXOID	8 (0.0)	3 (0.0)
DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE	1 (0.0)	5 (0.0)
DIPHTHERIA VACCINE;TETANUS VACCINE	2 (0.0)	1 (0.0)
HEPATITIS A VACCINE	5 (0.0)	5 (0.0)
HEPATITIS A VACCINE;HEPATITIS B VACCINE	1 (0.0)	0
HEPATITIS B VACCINE	13 (0.1)	15 (0.1)
HEPATITIS B VACCINE RHBSAG (YEAST)	1 (0.0)	0
HEPATITIS VACCINES	1 (0.0)	0
HIB VACCINE CONJ	1 (0.0)	0
HPV VACCINE	7 (0.0)	4 (0.0)
HPV VACCINE VLP RL1 2V (BACULOVIRUS)	0	1 (0.0)
HPV VACCINE VLP RL1 4V (YEAST)	5 (0.0)	3 (0.0)
HPV VACCINE VLP RL1 9V (YEAST)	1 (0.0)	1 (0.0)
IMMUNOGLOBULIN ANTI-CLOSTRIDIUM TETANI TOXIN;TETANUS VACCINE TOXOID	0	1 (0.0)
INFLUENZA VACCINE	2180 (9.9)	2445 (11.2)
INFLUENZA VACCINE INACT SAG 3V	26 (0.1)	27 (0.1)

14.56. Concomitant Vaccines Received After Dose 1 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

Vaccine[b]	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=21926) n[c] (%)	Placebo (N[a]=21921) n[c] (%)
INFLUENZA VACCINE INACT SAG 4V	42 (0.2)	48 (0.2)
INFLUENZA VACCINE INACT SPLIT 3V	71 (0.3)	68 (0.3)
INFLUENZA VACCINE INACT SPLIT 4V	211 (1.0)	238 (1.1)
INFLUENZA VACCINE LIVE REASSORT 4V	0	1 (0.0)
INFLUENZA VACCINE RHA 3V (BACULOVIRUS)	3 (0.0)	2 (0.0)
INFLUENZA VACCINE RHA 4V (BACULOVIRUS)	19 (0.1)	15 (0.1)
INFLUENZA VACCINES	0	1 (0.0)
MEASLES VACCINE LIVE (ENDERS-EDMONSTON);MUMPS VACCINE LIVE (JERYL LYNN);RUBELLA VACCINE LIVE (WISTAR	0	1 (0.0)
MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE	8 (0.0)	7 (0.0)
MENINGOCOCCAL VACCINE	2 (0.0)	5 (0.0)
MENINGOCOCCAL VACCINE A/C/Y/W	1 (0.0)	1 (0.0)
MENINGOCOCCAL VACCINE A/C/Y/W CONJ (CRM197)	1 (0.0)	3 (0.0)
MENINGOCOCCAL VACCINE A/C/Y/W CONJ (DIP TOX)	1 (0.0)	1 (0.0)
MENINGOCOCCAL VACCINE B RFHBP/NADA/NHBA OMV	1 (0.0)	2 (0.0)
MENINGOCOCCAL VACCINE B RFHBPA/FHBPB	0	1 (0.0)
PERTUSSIS VACCINE	1 (0.0)	0
PNEUMOCOCCAL VACCINE	28 (0.1)	54 (0.2)
PNEUMOCOCCAL VACCINE 13V	0	1 (0.0)
PNEUMOCOCCAL VACCINE CONJ 13V (CRM197)	3 (0.0)	6 (0.0)
PNEUMOCOCCAL VACCINE CONJ 7V (CRM197)	0	1 (0.0)
PNEUMOCOCCAL VACCINE POLYSACCH	6 (0.0)	5 (0.0)
PNEUMOCOCCAL VACCINE POLYSACCH 23V	10 (0.0)	6 (0.0)
PNEUMOCOCCAL VACCINE POLYV	1 (0.0)	0
POLIO VACCINE	0	1 (0.0)
RABIES VACCINE	1 (0.0)	1 (0.0)
RUBELLA VACCINE	0	1 (0.0)
TETANUS VACCINE	32 (0.1)	27 (0.1)
TETANUS VACCINE TOXOID	6 (0.0)	5 (0.0)
TYPHOID VACCINE	1 (0.0)	2 (0.0)
VARICELLA ZOSTER VACCINE	71 (0.3)	63 (0.3)
VARICELLA ZOSTER VACCINE LIVE (OKA/MERCK)	1 (0.0)	1 (0.0)
VARICELLA ZOSTER VACCINE RGE (CHO)	63 (0.3)	75 (0.3)
YELLOW FEVER VACCINE	0	2 (0.0)
YELLOW FEVER VACCINE LIVE (17D-204)	1 (0.0)	0

14.56. Concomitant Vaccines Received After Dose 1 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

Vaccine[b]	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=21926) n[c] (%)	Placebo (N[a]=21921) n[c] (%)

Note: WHO DDE v202003 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: 25MAR2021 (19:20) Source Data: adcm Table Generation: 27MAR2021 (01:42)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adsl fu p3 saf

Efficacy

14.57. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=21467)		Placebo (N[a]=21387)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	78	6.380 (21177)	866	6.094 (20999)	91.4	(89.1, 93.3)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102,1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (01:59)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 wo aai

14.58. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=22675)		Placebo (N[a]=22645)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	82	6.649 (22132)	889	6.371 (22001)	91.2	(88.9, 93.0)	>0.9999

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (02:26)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_cov_7pd2_aai

14.59. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	81	6.509 (21642)	873	6.274 (21689)	91.1	(88.8, 93.0)
Age group (years)						
12 to 15	0	0.170 (1109)	18	0.163 (1094)	100.0	(78.1, 100.0)
16 to 55	56	3.766 (12088)	584	3.619 (12142)	90.8	(87.9, 93.1)
>55	25	2.573 (8445)	271	2.491 (8453)	91.1	(86.5, 94.3)
≥65	7	1.267 (4315)	128	1.232 (4326)	94.7	(88.7, 97.9)
16 to 17	0	0.065 (365)	11	0.061 (355)	100.0	(62.4, 100.0)
16 to 25	10	0.511 (1734)	84	0.498 (1740)	88.4	(77.6, 94.6)
16 to 64	74	5.073 (16218)	727	4.879 (16269)	90.2	(87.6, 92.4)
18 to 64	74	5.008 (15853)	716	4.817 (15914)	90.1	(87.4, 92.3)
55 to 64	21	1.442 (4563)	159	1.386 (4559)	87.3	(79.9, 92.4)
65 to 74	6	1.021 (3450)	102	0.992 (3468)	94.3	(87.1, 98.0)
≥75	1	0.246 (865)	26	0.240 (858)	96.2	(77.2, 99.9)
75 to 85	1	0.244 (860)	25	0.238 (852)	96.1	(76.2, 99.9)
>85	0	0.001 (5)	1	0.001 (6)	100.0	(-4055.9, 100.0)
Sex						
Male	44	3.376 (11103)	411	3.181 (10920)	89.9	(86.2, 92.8)
Female	37	3.133 (10539)	462	3.093 (10769)	92.1	(88.9, 94.5)
Race						
White	69	5.379 (17801)	768	5.191 (17880)	91.3	(88.9, 93.3)
Black or African American	4	0.611 (1958)	49	0.601 (1985)	92.0	(78.1, 97.9)
American Indian or Alaska Native	0	0.044 (200)	3	0.039 (182)	100.0	(-114.5, 100.0)
Asian	3	0.268 (976)	24	0.257 (967)	88.0	(60.5, 97.7)
Native Hawaiian or other Pacific Islander	0	0.016 (57)	1	0.008 (31)	100.0	(-1896.2, 100.0)
Multiracial	5	0.164 (561)	22	0.145 (532)	79.9	(45.7, 94.1)
Not reported	0	0.028 (89)	6	0.033 (112)	100.0	(-0.0, 100.0)

14.59. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
All others[f]	8	0.519 (1883)	56	0.481 (1824)	86.8	(72.1, 94.5)
Ethnicity						
Hispanic/Latino	32	1.862 (5408)	245	1.794 (5391)	87.4	(81.8, 91.6)
Non-Hispanic/non-Latino	48	4.615 (16128)	628	4.445 (16186)	92.6	(90.1, 94.6)
Not reported	1	0.033 (106)	0	0.034 (112)	-∞	(NA, NA)
Country						
Argentina	16	1.033 (2655)	110	1.017 (2670)	85.7	(75.7, 92.1)
Brazil	14	0.441 (1419)	82	0.408 (1401)	84.2	(71.9, 91.7)
Germany	0	0.047 (237)	1	0.048 (243)	100.0	(-3868.6, 100.0)
South Africa	0	0.099 (358)	10	0.096 (358)	100.0	(56.6, 100.0)
Turkey	0	0.029 (238)	6	0.026 (232)	100.0	(22.2, 100.0)
USA	51	4.861 (16735)	664	4.678 (16785)	92.6	(90.2, 94.6)
Prior SARS-CoV-2 Status						
Positive at baseline[g]	3	0.190 (639)	6	0.201 (689)	46.9	(-148.7, 91.4)
Positive N-binding only	2	0.147 (494)	5	0.151 (516)	58.9	(-151.3, 96.1)
Positive NAAT only	0	0.014 (50)	1	0.015 (58)	100.0	(-3996.1, 100.0)
Positive NAAT and N-binding	1	0.028 (95)	0	0.035 (114)	-∞	(NA, NA)
Negative at baseline but positive prior to 7 days after Dose 2[h]	0	0.011 (43)	3	0.014 (60)	100.0	(-211.3, 100.0)
Negative prior to 7 days after Dose 2[i]	77	6.247 (20712)	850	6.003 (20712)	91.3	(89.0, 93.2)
Unknown	1	0.062 (248)	14	0.055 (228)	93.7	(58.3, 99.9)

14.59. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
g. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
h. Negative N-binding antibody result and negative NAAT result at Visit 1, positive NAAT result at Visit 2 or at unscheduled visit, if any, prior to 7 days after Dose 2.
i. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1 and Visit 2, and negative NAAT result at unscheduled visit, if any, prior to 7 days after Dose 2.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 30MAR2021 (22:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 sg eval

14.60. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=23040)		Placebo (N[a]=23037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence after Dose 1						
Overall	131	8.412 (22505)	1034	8.124 (22434)	87.8	(85.3, 89.9)
Age group (years)						
12 to 15	3	0.257 (1120)	35	0.250 (1119)	91.6	(73.5, 98.4)
16 to 55	95	4.845 (12645)	693	4.669 (12626)	86.8	(83.6, 89.5)
>55	33	3.310 (8740)	306	3.204 (8689)	89.6	(85.0, 92.9)
≥65	12	1.645 (4455)	138	1.596 (4437)	91.6	(84.8, 95.7)
16 to 17	3	0.094 (373)	19	0.090 (370)	84.8	(48.4, 97.1)
16 to 25	18	0.661 (1811)	114	0.651 (1836)	84.4	(74.3, 91.1)
16 to 64	116	6.511 (16930)	861	6.278 (16878)	87.0	(84.2, 89.4)
18 to 64	113	6.417 (16557)	842	6.188 (16508)	87.1	(84.2, 89.5)
55 to 64	25	1.840 (4738)	185	1.772 (4697)	87.0	(80.2, 91.8)
65 to 74	10	1.319 (3550)	112	1.285 (3560)	91.3	(83.4, 95.9)
≥75	2	0.326 (905)	26	0.310 (877)	92.7	(70.7, 99.2)
75 to 85	2	0.324 (899)	25	0.309 (871)	92.4	(69.4, 99.1)
>85	0	0.002 (6)	1	0.002 (6)	100.0	(-3408.8, 100.0)
Sex						
Male	70	4.355 (11560)	500	4.115 (11312)	86.8	(83.0, 89.9)
Female	61	4.057 (10945)	534	4.009 (11122)	88.7	(85.3, 91.5)
Race						
White	115	6.957 (18538)	916	6.719 (18479)	87.9	(85.3, 90.1)
Black or African American	6	0.783 (2042)	53	0.770 (2063)	88.9	(74.1, 96.1)
American Indian or Alaska Native	1	0.061 (216)	7	0.055 (209)	86.9	(-1.6, 99.7)
Asian	4	0.348 (995)	26	0.337 (990)	85.1	(57.0, 96.2)
Native Hawaiian or other Pacific Islander	0	0.021 (58)	1	0.011 (32)	100.0	(-2000.0, 100.0)
Multiracial	5	0.208 (565)	25	0.190 (546)	81.8	(51.6, 94.6)
Not reported	0	0.035 (91)	6	0.042 (115)	100.0	(-0.7, 100.0)
All others[f]	10	0.672 (1925)	65	0.635 (1892)	85.5	(71.5, 93.3)

14.60. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=23040)		Placebo (N[a]=23037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Ethnicity						
Hispanic/Latino	52	2.351 (5701)	302	2.282 (5673)	83.3	(77.5, 87.8)
Non-Hispanic/non-Latino	78	6.018 (16692)	730	5.799 (16647)	89.7	(87.0, 92.0)
Not reported	1	0.043 (112)	2	0.043 (114)	49.4	(-872.9, 99.1)
Country						
Argentina	32	1.282 (2846)	146	1.269 (2840)	78.3	(68.0, 85.7)
Brazil	14	0.554 (1430)	95	0.520 (1420)	86.1	(75.6, 92.7)
Germany	2	0.067 (246)	1	0.069 (250)	-104.5	(-11965.9, 89.4)
South Africa	0	0.128 (367)	11	0.125 (365)	100.0	(61.1, 100.0)
Turkey	3	0.048 (246)	12	0.045 (244)	76.4	(12.4, 95.7)
USA	80	6.333 (17370)	769	6.095 (17315)	90.0	(87.4, 92.1)
Baseline SARS-CoV-2 status						
Positive[g]	13	0.250 (692)	17	0.265 (736)	19.2	(-76.6, 63.9)
Positive N-binding only	2	0.192 (521)	7	0.198 (542)	70.5	(-54.7, 97.0)
Positive NAAT only	10	0.020 (66)	9	0.020 (69)	-10.5	(-207.3, 59.7)
Positive NAAT and N-binding	1	0.038 (105)	1	0.046 (124)	-20.5	(-9359.2, 98.5)
Negative[h]	116	8.101 (21615)	1015	7.804 (21521)	89.0	(86.6, 91.0)
Unknown	2	0.061 (198)	2	0.055 (177)	9.7	(-1145.4, 93.5)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
g. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
h. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 30MAR2021 (22:32)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_cov_pd1_sg_aai

14.61. Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=23040)		Placebo (N[a]=23037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First Severe COVID-19 occurrence based on CDC-definition after Dose 1	1	8.427 (22473)	45	8.269 (22394)	97.8	(87.2, 99.9)
After Dose 1 to before Dose 2	1	1.348 (22473)	11	1.355 (22394)	90.9	(37.1, 99.8)
Dose 2 to 7 days after Dose 2	0	0.424 (22141)	1	0.422 (22030)	100.0	(-3781.6, 100.0)
≥7 Days after Dose 2	0	6.654 (22113)	33	6.491 (22008)	100.0	(88.5, 100.0)

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = 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 at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 19APR2021 (18:26)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_sev_cdc_pd1_aai

14.62. Summary of Signs and Symptoms for First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
Signs and Symptoms	BNT162b2 (30 µg) (N[a]=77) n[b](%)	Placebo (N[a]=850) n[b](%)	Total (N[a]=927) n[b](%)
Subjects with specific signs and symptoms of COVID-19			
Fever	14 (18.2)	319 (37.5)	333 (35.9)
New or increased cough	36 (46.8)	556 (65.4)	592 (63.9)
New or increased shortness of breath	8 (10.4)	121 (14.2)	129 (13.9)
Chills	15 (19.5)	262 (30.8)	277 (29.9)
New or increased muscle pain	24 (31.2)	395 (46.5)	419 (45.2)
New loss of taste or smell	37 (48.1)	297 (34.9)	334 (36.0)
Sore throat	29 (37.7)	329 (38.7)	358 (38.6)
Diarrhea	11 (14.3)	136 (16.0)	147 (15.9)
Vomiting	3 (3.9)	32 (3.8)	35 (3.8)
Subjects with specific number of signs and symptoms			
1	28 (36.4)	178 (20.9)	206 (22.2)
2	22 (28.6)	233 (27.4)	255 (27.5)
3	15 (19.5)	177 (20.8)	192 (20.7)
4	6 (7.8)	132 (15.5)	138 (14.9)
5	2 (2.6)	70 (8.2)	72 (7.8)
>5	4 (5.2)	60 (7.1)	64 (6.9)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects with first COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 27MAR2021 (02:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adsympt symp cov 7d2 wo eval

14.63. Summary of Signs and Symptoms for First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=81)	Placebo (N[a]=873)	Total (N[a]=954)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	14 (17.3)	325 (37.2)	339 (35.5)
New or increased cough	37 (45.7)	569 (65.2)	606 (63.5)
New or increased shortness of breath	9 (11.1)	125 (14.3)	134 (14.0)
Chills	16 (19.8)	267 (30.6)	283 (29.7)
New or increased muscle pain	27 (33.3)	403 (46.2)	430 (45.1)
New loss of taste or smell	37 (45.7)	307 (35.2)	344 (36.1)
Sore throat	32 (39.5)	337 (38.6)	369 (38.7)
Diarrhea	12 (14.8)	138 (15.8)	150 (15.7)
Vomiting	4 (4.9)	32 (3.7)	36 (3.8)
Subjects with specific number of signs and symptoms			
1	29 (35.8)	184 (21.1)	213 (22.3)
2	23 (28.4)	240 (27.5)	263 (27.6)
3	16 (19.8)	183 (21.0)	199 (20.9)
4	6 (7.4)	134 (15.3)	140 (14.7)
5	3 (3.7)	72 (8.2)	75 (7.9)
>5	4 (4.9)	60 (6.9)	64 (6.7)

a. N = number of subjects with first COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 27MAR2021 (02:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsympt_symp_cov_7d2_eval

14.64. Summary of Signs and Symptoms for First COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
Signs and Symptoms	BNT162b2 (30 µg) (N[a]=131) n[b](%)	Placebo (N[a]=1034) n[b](%)	Total (N[a]=1165) n[b](%)
Subjects with specific signs and symptoms of COVID-19			
Fever	33 (25.2)	393 (38.0)	426 (36.6)
New or increased cough	61 (46.6)	668 (64.6)	729 (62.6)
New or increased shortness of breath	15 (11.5)	150 (14.5)	165 (14.2)
Chills	25 (19.1)	311 (30.1)	336 (28.8)
New or increased muscle pain	42 (32.1)	468 (45.3)	510 (43.8)
New loss of taste or smell	58 (44.3)	370 (35.8)	428 (36.7)
Sore throat	50 (38.2)	403 (39.0)	453 (38.9)
Diarrhea	16 (12.2)	157 (15.2)	173 (14.8)
Vomiting	7 (5.3)	38 (3.7)	45 (3.9)
Subjects with specific number of signs and symptoms			
1	47 (35.9)	215 (20.8)	262 (22.5)
2	36 (27.5)	288 (27.9)	324 (27.8)
3	23 (17.6)	221 (21.4)	244 (20.9)
4	14 (10.7)	149 (14.4)	163 (14.0)
5	5 (3.8)	93 (9.0)	98 (8.4)
>5	6 (4.6)	68 (6.6)	74 (6.4)

a. N = number of subjects with first COVID-19 occurrence after dose 1 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 27MAR2021 (02:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adsympt symp cov d1 aai

14.65. Summary of Signs and Symptoms for First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=1)	Placebo (N^a=21)	Total (N^a=22)
Signs and Symptoms	**n^b(%)**	**n^b(%)**	**n^b(%)**
Subjects with specific signs and symptoms of severe COVID-19			
Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO_2 ≤93% on room air at sea level, or PaO_2/FiO_2 <300 mm Hg)	1 (100.0)	12 (57.1)	13 (59.1)
Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO)	0 (0.0)	9 (42.9)	9 (40.9)
Evidence of shock (SBP <90 mm Hg, DBP <60 mm Hg, or requiring vasopressors)	0 (0.0)	3 (14.3)	3 (13.6)
Significant acute renal, hepatic, or neurologic dysfunction	0 (0.0)	1 (4.8)	1 (4.5)
Admission to an ICU	0 (0.0)	6 (28.6)	6 (27.3)
Subjects with specific number of signs and symptoms			
1	1 (100.0)	15 (71.4)	16 (72.7)
2	0 (0.0)	2 (9.5)	2 (9.1)
3	0 (0.0)	4 (19.0)	4 (18.2)

Abbreviations: DBP = diastolic blood pressure; ECMO = extracorporeal membrane oxygenation; FiO_2 = fraction of inspired oxygen; HR = heart rate;
ICU = intensive care unit; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; PaO_2 = partial pressure of oxygen, arterial; RR = respiratory rate; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2;
SBP = systolic blood pressure; SpO_2 = oxygen saturation as measured by pulse oximetry.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects with first severe COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 27MAR2021 (20:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adsympt symp sev cov 7d2 wo eval

14.66. Summary of Signs and Symptoms for First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=1)	Placebo (N^a=21)	Total (N^a=22)
Signs and Symptoms	**n^b(%)**	**n^b(%)**	**n^b(%)**
Subjects with specific signs and symptoms of severe COVID-19			
Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO_2 ≤93% on room air at sea level, or PaO_2/FiO_2 <300 mm Hg)	1 (100.0)	12 (57.1)	13 (59.1)
Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO)	0 (0.0)	9 (42.9)	9 (40.9)
Evidence of shock (SBP <90 mm Hg, DBP <60 mm Hg, or requiring vasopressors)	0 (0.0)	3 (14.3)	3 (13.6)
Significant acute renal, hepatic, or neurologic dysfunction	0 (0.0)	1 (4.8)	1 (4.5)
Admission to an ICU	0 (0.0)	6 (28.6)	6 (27.3)
Subjects with specific number of signs and symptoms			
1	1 (100.0)	15 (71.4)	16 (72.7)
2	0 (0.0)	2 (9.5)	2 (9.1)
3	0 (0.0)	4 (19.0)	4 (18.2)

Abbreviations: DBP = diastolic blood pressure; ECMO = extracorporeal membrane oxygenation; FiO_2 = fraction of inspired oxygen; HR = heart rate;
ICU = intensive care unit; PaO_2 = partial pressure of oxygen, arterial; RR = respiratory rate; SBP = systolic blood pressure;
SpO_2 = oxygen saturation as measured by pulse oximetry.
a. N = number of subjects with first severe COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 27MAR2021 (20:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsympt_symp_sev_cov_7d2_eval

14.67. Summary of Signs and Symptoms for First Severe COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
Signs and Symptoms	BNT162b2 (30 µg) (N[a]=1) n[b](%)	Placebo (N[a]=30) n[b](%)	Total (N[a]=31) n[b](%)
Subjects with specific signs and symptoms of severe COVID-19			
Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO_2 ≤93% on room air at sea level, or PaO_2/FiO_2 <300 mm Hg)	1 (100.0)	19 (63.3)	20 (64.5)
Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO)	0 (0.0)	14 (46.7)	14 (45.2)
Evidence of shock (SBP <90 mm Hg, DBP <60 mm Hg, or requiring vasopressors)	0 (0.0)	3 (10.0)	3 (9.7)
Significant acute renal, hepatic, or neurologic dysfunction	0 (0.0)	2 (6.7)	2 (6.5)
Admission to an ICU	0 (0.0)	8 (26.7)	8 (25.8)
Subjects with specific number of signs and symptoms			
1	1 (100.0)	20 (66.7)	21 (67.7)
2	0 (0.0)	4 (13.3)	4 (12.9)
3	0 (0.0)	5 (16.7)	5 (16.1)
5	0 (0.0)	1 (3.3)	1 (3.2)

Abbreviations: DBP = diastolic blood pressure; ECMO = extracorporeal membrane oxygenation; FiO_2 = fraction of inspired oxygen; HR = heart rate;
ICU = intensive care unit; PaO_2 = partial pressure of oxygen, arterial; RR = respiratory rate; SBP = systolic blood pressure;
SpO_2 = oxygen saturation as measured by pulse oximetry.
a. N = number of subjects with first severe COVID-19 occurrence after dose 1 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 27MAR2021 (20:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsympt_symp_sev_cov_d1_aai

Local Reactions

14.68. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
16-55 Years	1	Redness[d]						
		Any	2899	156 (5.4)	(4.6, 6.3)	2908	28 (1.0)	(0.6, 1.4)
		Mild	2899	113 (3.9)	(3.2, 4.7)	2908	19 (0.7)	(0.4, 1.0)
		Moderate	2899	36 (1.2)	(0.9, 1.7)	2908	6 (0.2)	(0.1, 0.4)
		Severe	2899	7 (0.2)	(0.1, 0.5)	2908	3 (0.1)	(0.0, 0.3)
		Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Swelling[d]						
		Any	2899	184 (6.3)	(5.5, 7.3)	2908	16 (0.6)	(0.3, 0.9)
		Mild	2899	124 (4.3)	(3.6, 5.1)	2908	6 (0.2)	(0.1, 0.4)
		Moderate	2899	54 (1.9)	(1.4, 2.4)	2908	8 (0.3)	(0.1, 0.5)
		Severe	2899	6 (0.2)	(0.1, 0.4)	2908	2 (0.1)	(0.0, 0.2)
		Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Pain at the injection site[e]						
		Any	2899	2426 (83.7)	(82.3, 85.0)	2908	414 (14.2)	(13.0, 15.6)
		Mild	2899	1464 (50.5)	(48.7, 52.3)	2908	391 (13.4)	(12.2, 14.7)
		Moderate	2899	923 (31.8)	(30.1, 33.6)	2908	20 (0.7)	(0.4, 1.1)
		Severe	2899	39 (1.3)	(1.0, 1.8)	2908	3 (0.1)	(0.0, 0.3)
		Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Any local reaction[f]	2899	2444 (84.3)	(82.9, 85.6)	2908	432 (14.9)	(13.6, 16.2)
	2	Redness[d]						
		Any	2682	151 (5.6)	(4.8, 6.6)	2684	18 (0.7)	(0.4, 1.1)
		Mild	2682	90 (3.4)	(2.7, 4.1)	2684	12 (0.4)	(0.2, 0.8)
		Moderate	2682	50 (1.9)	(1.4, 2.5)	2684	6 (0.2)	(0.1, 0.5)
		Severe	2682	11 (0.4)	(0.2, 0.7)	2684	0	(0.0, 0.1)
		Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Swelling[d]						
		Any	2682	183 (6.8)	(5.9, 7.8)	2684	5 (0.2)	(0.1, 0.4)
		Mild	2682	110 (4.1)	(3.4, 4.9)	2684	3 (0.1)	(0.0, 0.3)
		Moderate	2682	66 (2.5)	(1.9, 3.1)	2684	2 (0.1)	(0.0, 0.3)
		Severe	2682	7 (0.3)	(0.1, 0.5)	2684	0	(0.0, 0.1)
		Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)

14.68. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Pain at the injection site[e]						
		Any	2682	2101 (78.3)	(76.7, 79.9)	2684	312 (11.6)	(10.4, 12.9)
		Mild	2682	1274 (47.5)	(45.6, 49.4)	2684	284 (10.6)	(9.4, 11.8)
		Moderate	2682	788 (29.4)	(27.7, 31.1)	2684	28 (1.0)	(0.7, 1.5)
		Severe	2682	39 (1.5)	(1.0, 2.0)	2684	0	(0.0, 0.1)
		Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Any local reaction[f]	2682	2108 (78.6)	(77.0, 80.1)	2684	325 (12.1)	(10.9, 13.4)
	Any dose	Redness[d]						
		Any	2909	276 (9.5)	(8.4, 10.6)	2921	42 (1.4)	(1.0, 1.9)
		Mild	2909	180 (6.2)	(5.3, 7.1)	2921	27 (0.9)	(0.6, 1.3)
		Moderate	2909	78 (2.7)	(2.1, 3.3)	2921	12 (0.4)	(0.2, 0.7)
		Severe	2909	18 (0.6)	(0.4, 1.0)	2921	3 (0.1)	(0.0, 0.3)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		Swelling[d]						
		Any	2909	309 (10.6)	(9.5, 11.8)	2921	20 (0.7)	(0.4, 1.1)
		Mild	2909	195 (6.7)	(5.8, 7.7)	2921	9 (0.3)	(0.1, 0.6)
		Moderate	2909	101 (3.5)	(2.8, 4.2)	2921	9 (0.3)	(0.1, 0.6)
		Severe	2909	13 (0.4)	(0.2, 0.8)	2921	2 (0.1)	(0.0, 0.2)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		Pain at the injection site[e]						
		Any	2909	2577 (88.6)	(87.4, 89.7)	2921	585 (20.0)	(18.6, 21.5)
		Mild	2909	1280 (44.0)	(42.2, 45.8)	2921	538 (18.4)	(17.0, 19.9)
		Moderate	2909	1223 (42.0)	(40.2, 43.9)	2921	44 (1.5)	(1.1, 2.0)
		Severe	2909	74 (2.5)	(2.0, 3.2)	2921	3 (0.1)	(0.0, 0.3)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		Any local reaction[f]	2909	2590 (89.0)	(87.8, 90.1)	2921	609 (20.8)	(19.4, 22.4)
>55 Years	1	Redness[d]						
		Any	2008	106 (5.3)	(4.3, 6.3)	1989	20 (1.0)	(0.6, 1.5)
		Mild	2008	71 (3.5)	(2.8, 4.4)	1989	13 (0.7)	(0.3, 1.1)
		Moderate	2008	30 (1.5)	(1.0, 2.1)	1989	5 (0.3)	(0.1, 0.6)
		Severe	2008	5 (0.2)	(0.1, 0.6)	1989	2 (0.1)	(0.0, 0.4)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)

14.68. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Swelling[d]						
		Any	2008	141 (7.0)	(5.9, 8.2)	1989	23 (1.2)	(0.7, 1.7)
		Mild	2008	87 (4.3)	(3.5, 5.3)	1989	11 (0.6)	(0.3, 1.0)
		Moderate	2008	52 (2.6)	(1.9, 3.4)	1989	12 (0.6)	(0.3, 1.1)
		Severe	2008	2 (0.1)	(0.0, 0.4)	1989	0	(0.0, 0.2)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Pain at the injection site[e]						
		Any	2008	1408 (70.1)	(68.1, 72.1)	1989	185 (9.3)	(8.1, 10.7)
		Mild	2008	1108 (55.2)	(53.0, 57.4)	1989	177 (8.9)	(7.7, 10.2)
		Moderate	2008	296 (14.7)	(13.2, 16.4)	1989	8 (0.4)	(0.2, 0.8)
		Severe	2008	4 (0.2)	(0.1, 0.5)	1989	0	(0.0, 0.2)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Any local reaction[f]	2008	1433 (71.4)	(69.3, 73.3)	1989	207 (10.4)	(9.1, 11.8)
	2	Redness[d]						
		Any	1860	133 (7.2)	(6.0, 8.4)	1833	14 (0.8)	(0.4, 1.3)
		Mild	1860	65 (3.5)	(2.7, 4.4)	1833	10 (0.5)	(0.3, 1.0)
		Moderate	1860	58 (3.1)	(2.4, 4.0)	1833	3 (0.2)	(0.0, 0.5)
		Severe	1860	10 (0.5)	(0.3, 1.0)	1833	1 (0.1)	(0.0, 0.3)
		Grade 4	1860	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		Swelling[d]						
		Any	1860	145 (7.8)	(6.6, 9.1)	1833	13 (0.7)	(0.4, 1.2)
		Mild	1860	80 (4.3)	(3.4, 5.3)	1833	5 (0.3)	(0.1, 0.6)
		Moderate	1860	61 (3.3)	(2.5, 4.2)	1833	7 (0.4)	(0.2, 0.8)
		Severe	1860	4 (0.2)	(0.1, 0.5)	1833	1 (0.1)	(0.0, 0.3)
		Grade 4	1860	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		Pain at the injection site[e]						
		Any	1860	1230 (66.1)	(63.9, 68.3)	1833	143 (7.8)	(6.6, 9.1)
		Mild	1860	873 (46.9)	(44.6, 49.2)	1833	138 (7.5)	(6.4, 8.8)
		Moderate	1860	347 (18.7)	(16.9, 20.5)	1833	5 (0.3)	(0.1, 0.6)
		Severe	1860	10 (0.5)	(0.3, 1.0)	1833	0	(0.0, 0.2)
		Grade 4	1860	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		Any local reaction[f]	1860	1243 (66.8)	(64.6, 69.0)	1833	158 (8.6)	(7.4, 10.0)

14.68. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any dose	Redness[d]						
		Any	2015	210 (10.4)	(9.1, 11.8)	1994	30 (1.5)	(1.0, 2.1)
		Mild	2015	120 (6.0)	(5.0, 7.1)	1994	20 (1.0)	(0.6, 1.5)
		Moderate	2015	75 (3.7)	(2.9, 4.6)	1994	8 (0.4)	(0.2, 0.8)
		Severe	2015	15 (0.7)	(0.4, 1.2)	1994	2 (0.1)	(0.0, 0.4)
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		Swelling[d]						
		Any	2015	237 (11.8)	(10.4, 13.2)	1994	31 (1.6)	(1.1, 2.2)
		Mild	2015	134 (6.7)	(5.6, 7.8)	1994	12 (0.6)	(0.3, 1.0)
		Moderate	2015	97 (4.8)	(3.9, 5.8)	1994	18 (0.9)	(0.5, 1.4)
		Severe	2015	6 (0.3)	(0.1, 0.6)	1994	1 (0.1)	(0.0, 0.3)
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		Pain at the injection site[e]						
		Any	2015	1576 (78.2)	(76.3, 80.0)	1994	264 (13.2)	(11.8, 14.8)
		Mild	2015	1076 (53.4)	(51.2, 55.6)	1994	251 (12.6)	(11.2, 14.1)
		Moderate	2015	486 (24.1)	(22.3, 26.0)	1994	13 (0.7)	(0.3, 1.1)
		Severe	2015	14 (0.7)	(0.4, 1.2)	1994	0	(0.0, 0.2)
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		Any local reaction[f]	2015	1597 (79.3)	(77.4, 81.0)	1994	294 (14.7)	(13.2, 16.4)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each 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.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adce s010 lr p3 saf

14.69. Onset Days for Local Reactions, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
16-55 Years	1	Redness		
		n[a]	156	28
		Mean (SD)	2.3 (0.98)	1.9 (1.30)
		Median	2.0	1.0
		Min, max	(1, 7)	(1, 5)
		Swelling		
		n[a]	184	16
		Mean (SD)	2.0 (0.80)	1.8 (1.29)
		Median	2.0	1.0
		Min, max	(1, 5)	(1, 5)
		Pain at the injection site		
		n[a]	2426	414
		Mean (SD)	1.4 (0.55)	1.6 (1.16)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 7)
		Any local reaction[b]		
		n[a]	2444	432
		Mean (SD)	1.4 (0.55)	1.6 (1.14)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 7)
	2	Redness		
		n[a]	151	18
		Mean (SD)	2.5 (0.97)	2.2 (1.50)
		Median	2.0	2.0
		Min, max	(1, 6)	(1, 6)
		Swelling		
		n[a]	183	5
		Mean (SD)	2.0 (0.86)	2.0 (1.00)
		Median	2.0	2.0
		Min, max	(1, 5)	(1, 3)
		Pain at the injection site		
		n[a]	2101	312
		Mean (SD)	1.4 (0.59)	1.5 (0.96)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 7)

14.69. Onset Days for Local Reactions, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
		Any local reaction[b]		
		n[a]	2108	325
		Mean (SD)	1.4 (0.59)	1.5 (1.01)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 7)
>55 Years	1	Redness		
		n[a]	106	20
		Mean (SD)	2.3 (0.81)	1.6 (0.50)
		Median	2.0	2.0
		Min, max	(1, 5)	(1, 2)
		Swelling		
		n[a]	141	23
		Mean (SD)	1.9 (0.57)	1.4 (0.73)
		Median	2.0	1.0
		Min, max	(1, 4)	(1, 4)
		Pain at the injection site		
		n[a]	1408	185
		Mean (SD)	1.6 (0.53)	1.8 (1.20)
		Median	2.0	1.0
		Min, max	(1, 5)	(1, 7)
		Any local reaction[b]		
		n[a]	1433	207
		Mean (SD)	1.6 (0.53)	1.8 (1.15)
		Median	2.0	1.0
		Min, max	(1, 5)	(1, 7)
	2	Redness		
		n[a]	133	14
		Mean (SD)	2.8 (1.03)	2.0 (1.30)
		Median	3.0	2.0
		Min, max	(1, 5)	(1, 6)
		Swelling		
		n[a]	145	13
		Mean (SD)	2.1 (0.83)	1.7 (1.18)
		Median	2.0	1.0
		Min, max	(1, 5)	(1, 5)
		Pain at the injection site		

14.69. Onset Days for Local Reactions, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
		n[a]	1230	143
		Mean (SD)	1.6 (0.68)	1.7 (1.19)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 7)
		Any local reaction[b]		
		n[a]	1243	158
		Mean (SD)	1.6 (0.67)	1.7 (1.22)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 7)

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: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adce s050 lr onset p3 saf

14.70. Duration (Days) From First to Last Day of Local Reactions, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
16-55 Years	1	Redness		
		n[a]	156	28
		Mean (SD)	2.2 (1.92)	1.7 (1.39)
		Median	1.0	1.0
		Min, max	(1, 14)	(1, 6)
		Swelling		
		n[a]	184	16
		Mean (SD)	2.0 (1.55)	2.2 (2.46)
		Median	1.0	1.0
		Min, max	(1, 12)	(1, 10)
		Pain at the injection site		
		n[a]	2426	414
		Mean (SD)	2.2 (1.49)	1.6 (1.51)
		Median	2.0	1.0
		Min, max	(1, 22)	(1, 17)
		Unknown[b]	2	1
	2	Redness		
		n[a]	151	18
		Mean (SD)	2.2 (1.60)	1.2 (0.43)
		Median	2.0	1.0
		Min, max	(1, 9)	(1, 2)
		Swelling		
		n[a]	183	5
		Mean (SD)	2.1 (1.50)	2.2 (0.84)
		Median	2.0	2.0
		Min, max	(1, 8)	(1, 3)
		Pain at the injection site		
		n[a]	2101	312
		Mean (SD)	2.5 (2.21)	1.9 (2.84)
		Median	2.0	1.0
		Min, max	(1, 70)	(1, 35)
		Unknown[b]	5	0
>55 Years	1	Redness		
		n[a]	106	20
		Mean (SD)	2.3 (2.33)	1.9 (2.10)

14.70. Duration (Days) From First to Last Day of Local Reactions, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
		Median	2.0	1.0
		Min, max	(1, 20)	(1, 10)
		Swelling		
		n[a]	141	23
		Mean (SD)	1.8 (1.04)	2.6 (2.50)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 11)
		Pain at the injection site		
		n[a]	1408	185
		Mean (SD)	1.9 (1.46)	1.8 (2.16)
		Median	2.0	1.0
		Min, max	(1, 22)	(1, 19)
	2	Redness		
		n[a]	133	14
		Mean (SD)	3.0 (3.92)	1.6 (1.65)
		Median	2.0	1.0
		Min, max	(1, 34)	(1, 7)
		Unknown[b]	3	0
		Swelling		
		n[a]	145	13
		Mean (SD)	2.6 (3.21)	1.8 (1.30)
		Median	2.0	1.0
		Min, max	(1, 34)	(1, 5)
		Pain at the injection site		
		n[a]	1230	143
		Mean (SD)	2.4 (1.99)	1.7 (1.25)
		Median	2.0	1.0
		Min, max	(1, 36)	(1, 7)
		Unknown[b]	3	1

14.70. Duration (Days) From First to Last Day of Local Reactions, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**

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. For symptoms that are ongoing at the time of the next dose, stop date is computed as the next dose date.
Note: Reactions were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each 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.
b. Includes those reactions where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adcevd Table Generation: 27MAR2021 (01:29)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adce s030 lr dur p3 saf

14.71. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Positive	1	Redness[d]						
		Any	177	9 (5.1)	(2.4, 9.4)	187	5 (2.7)	(0.9, 6.1)
		Mild	177	3 (1.7)	(0.4, 4.9)	187	2 (1.1)	(0.1, 3.8)
		Moderate	177	4 (2.3)	(0.6, 5.7)	187	1 (0.5)	(0.0, 2.9)
		Severe	177	2 (1.1)	(0.1, 4.0)	187	2 (1.1)	(0.1, 3.8)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Swelling[d]						
		Any	177	14 (7.9)	(4.4, 12.9)	187	1 (0.5)	(0.0, 2.9)
		Mild	177	5 (2.8)	(0.9, 6.5)	187	0	(0.0, 2.0)
		Moderate	177	8 (4.5)	(2.0, 8.7)	187	0	(0.0, 2.0)
		Severe	177	1 (0.6)	(0.0, 3.1)	187	1 (0.5)	(0.0, 2.9)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Pain at the injection site[e]						
		Any	177	129 (72.9)	(65.7, 79.3)	187	25 (13.4)	(8.8, 19.1)
		Mild	177	71 (40.1)	(32.8, 47.7)	187	21 (11.2)	(7.1, 16.7)
		Moderate	177	54 (30.5)	(23.8, 37.9)	187	3 (1.6)	(0.3, 4.6)
		Severe	177	4 (2.3)	(0.6, 5.7)	187	1 (0.5)	(0.0, 2.9)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Any local reaction[f]	177	133 (75.1)	(68.1, 81.3)	187	27 (14.4)	(9.7, 20.3)
	2	Redness[d]						
		Any	153	6 (3.9)	(1.5, 8.3)	165	1 (0.6)	(0.0, 3.3)
		Mild	153	5 (3.3)	(1.1, 7.5)	165	0	(0.0, 2.2)
		Moderate	153	1 (0.7)	(0.0, 3.6)	165	0	(0.0, 2.2)
		Severe	153	0	(0.0, 2.4)	165	1 (0.6)	(0.0, 3.3)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Swelling[d]						
		Any	153	8 (5.2)	(2.3, 10.0)	165	1 (0.6)	(0.0, 3.3)
		Mild	153	3 (2.0)	(0.4, 5.6)	165	1 (0.6)	(0.0, 3.3)
		Moderate	153	5 (3.3)	(1.1, 7.5)	165	0	(0.0, 2.2)
		Severe	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)

14.71. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Pain at the injection site[e]						
		Any	153	93 (60.8)	(52.6, 68.6)	165	11 (6.7)	(3.4, 11.6)
		Mild	153	53 (34.6)	(27.1, 42.7)	165	9 (5.5)	(2.5, 10.1)
		Moderate	153	34 (22.2)	(15.9, 29.6)	165	2 (1.2)	(0.1, 4.3)
		Severe	153	6 (3.9)	(1.5, 8.3)	165	0	(0.0, 2.2)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Any local reaction[f]	153	95 (62.1)	(53.9, 69.8)	165	12 (7.3)	(3.8, 12.4)
	Any dose	Redness[d]						
		Any	177	15 (8.5)	(4.8, 13.6)	187	5 (2.7)	(0.9, 6.1)
		Mild	177	8 (4.5)	(2.0, 8.7)	187	2 (1.1)	(0.1, 3.8)
		Moderate	177	5 (2.8)	(0.9, 6.5)	187	1 (0.5)	(0.0, 2.9)
		Severe	177	2 (1.1)	(0.1, 4.0)	187	2 (1.1)	(0.1, 3.8)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Swelling[d]						
		Any	177	18 (10.2)	(6.1, 15.6)	187	2 (1.1)	(0.1, 3.8)
		Mild	177	6 (3.4)	(1.3, 7.2)	187	1 (0.5)	(0.0, 2.9)
		Moderate	177	11 (6.2)	(3.1, 10.8)	187	0	(0.0, 2.0)
		Severe	177	1 (0.6)	(0.0, 3.1)	187	1 (0.5)	(0.0, 2.9)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Pain at the injection site[e]						
		Any	177	142 (80.2)	(73.6, 85.8)	187	31 (16.6)	(11.6, 22.7)
		Mild	177	70 (39.5)	(32.3, 47.2)	187	25 (13.4)	(8.8, 19.1)
		Moderate	177	62 (35.0)	(28.0, 42.5)	187	5 (2.7)	(0.9, 6.1)
		Severe	177	10 (5.6)	(2.7, 10.1)	187	1 (0.5)	(0.0, 2.9)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Any local reaction[f]	177	145 (81.9)	(75.4, 87.3)	187	33 (17.6)	(12.5, 23.9)
Negative	1	Redness[d]						
		Any	4701	250 (5.3)	(4.7, 6.0)	4690	43 (0.9)	(0.7, 1.2)
		Mild	4701	178 (3.8)	(3.3, 4.4)	4690	30 (0.6)	(0.4, 0.9)
		Moderate	4701	62 (1.3)	(1.0, 1.7)	4690	10 (0.2)	(0.1, 0.4)
		Severe	4701	10 (0.2)	(0.1, 0.4)	4690	3 (0.1)	(0.0, 0.2)
		Grade 4	4701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)

14.71. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Swelling[d]						
		Any	4701	308 (6.6)	(5.9, 7.3)	4690	38 (0.8)	(0.6, 1.1)
		Mild	4701	203 (4.3)	(3.8, 4.9)	4690	17 (0.4)	(0.2, 0.6)
		Moderate	4701	98 (2.1)	(1.7, 2.5)	4690	20 (0.4)	(0.3, 0.7)
		Severe	4701	7 (0.1)	(0.1, 0.3)	4690	1 (0.0)	(0.0, 0.1)
		Grade 4	4701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Pain at the injection site[e]						
		Any	4701	3682 (78.3)	(77.1, 79.5)	4690	573 (12.2)	(11.3, 13.2)
		Mild	4701	2486 (52.9)	(51.4, 54.3)	4690	546 (11.6)	(10.7, 12.6)
		Moderate	4701	1158 (24.6)	(23.4, 25.9)	4690	25 (0.5)	(0.3, 0.8)
		Severe	4701	38 (0.8)	(0.6, 1.1)	4690	2 (0.0)	(0.0, 0.2)
		Grade 4	4701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Any local reaction[f]	4701	3721 (79.2)	(78.0, 80.3)	4690	611 (13.0)	(12.1, 14.0)
	2	Redness[d]						
		Any	4368	277 (6.3)	(5.6, 7.1)	4334	31 (0.7)	(0.5, 1.0)
		Mild	4368	149 (3.4)	(2.9, 4.0)	4334	22 (0.5)	(0.3, 0.8)
		Moderate	4368	107 (2.4)	(2.0, 3.0)	4334	9 (0.2)	(0.1, 0.4)
		Severe	4368	21 (0.5)	(0.3, 0.7)	4334	0	(0.0, 0.1)
		Grade 4	4368	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Swelling[d]						
		Any	4368	318 (7.3)	(6.5, 8.1)	4334	17 (0.4)	(0.2, 0.6)
		Mild	4368	185 (4.2)	(3.7, 4.9)	4334	7 (0.2)	(0.1, 0.3)
		Moderate	4368	122 (2.8)	(2.3, 3.3)	4334	9 (0.2)	(0.1, 0.4)
		Severe	4368	11 (0.3)	(0.1, 0.5)	4334	1 (0.0)	(0.0, 0.1)
		Grade 4	4368	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Pain at the injection site[e]						
		Any	4368	3224 (73.8)	(72.5, 75.1)	4334	443 (10.2)	(9.3, 11.2)
		Mild	4368	2085 (47.7)	(46.2, 49.2)	4334	412 (9.5)	(8.6, 10.4)
		Moderate	4368	1096 (25.1)	(23.8, 26.4)	4334	31 (0.7)	(0.5, 1.0)
		Severe	4368	43 (1.0)	(0.7, 1.3)	4334	0	(0.0, 0.1)
		Grade 4	4368	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Any local reaction[f]	4368	3242 (74.2)	(72.9, 75.5)	4334	470 (10.8)	(9.9, 11.8)

14.71. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any dose	Redness[d]						
		Any	4718	467 (9.9)	(9.1, 10.8)	4708	67 (1.4)	(1.1, 1.8)
		Mild	4718	288 (6.1)	(5.4, 6.8)	4708	45 (1.0)	(0.7, 1.3)
		Moderate	4718	148 (3.1)	(2.7, 3.7)	4708	19 (0.4)	(0.2, 0.6)
		Severe	4718	31 (0.7)	(0.4, 0.9)	4708	3 (0.1)	(0.0, 0.2)
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Swelling[d]						
		Any	4718	523 (11.1)	(10.2, 12.0)	4708	49 (1.0)	(0.8, 1.4)
		Mild	4718	318 (6.7)	(6.0, 7.5)	4708	20 (0.4)	(0.3, 0.7)
		Moderate	4718	187 (4.0)	(3.4, 4.6)	4708	27 (0.6)	(0.4, 0.8)
		Severe	4718	18 (0.4)	(0.2, 0.6)	4708	2 (0.0)	(0.0, 0.2)
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Pain at the injection site[e]						
		Any	4718	3987 (84.5)	(83.4, 85.5)	4708	816 (17.3)	(16.3, 18.4)
		Mild	4718	2273 (48.2)	(46.7, 49.6)	4708	762 (16.2)	(15.1, 17.3)
		Moderate	4718	1637 (34.7)	(33.3, 36.1)	4708	52 (1.1)	(0.8, 1.4)
		Severe	4718	77 (1.6)	(1.3, 2.0)	4708	2 (0.0)	(0.0, 0.2)
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Any local reaction[f]	4718	4018 (85.2)	(84.1, 86.2)	4708	868 (18.4)	(17.3, 19.6)

14.71. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: Reactions were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each 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.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adce s010 lr base p3 saf

14.72. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	54	2 (3.7)	(0.5, 12.7)	56	3 (5.4)	(1.1, 14.9)
	Mild	54	2 (3.7)	(0.5, 12.7)	56	1 (1.8)	(0.0, 9.6)
	Moderate	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Severe	54	0	(0.0, 6.6)	56	2 (3.6)	(0.4, 12.3)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Swelling[d]						
	Any	54	3 (5.6)	(1.2, 15.4)	56	1 (1.8)	(0.0, 9.6)
	Mild	54	2 (3.7)	(0.5, 12.7)	56	0	(0.0, 6.4)
	Moderate	54	1 (1.9)	(0.0, 9.9)	56	0	(0.0, 6.4)
	Severe	54	0	(0.0, 6.6)	56	1 (1.8)	(0.0, 9.6)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Pain at the injection site[e]						
	Any	54	34 (63.0)	(48.7, 75.7)	56	9 (16.1)	(7.6, 28.3)
	Mild	54	26 (48.1)	(34.3, 62.2)	56	8 (14.3)	(6.4, 26.2)
	Moderate	54	8 (14.8)	(6.6, 27.1)	56	1 (1.8)	(0.0, 9.6)
	Severe	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Any local reaction[f]	54	35 (64.8)	(50.6, 77.3)	56	10 (17.9)	(8.9, 30.4)
2	Redness[d]						
	Any	60	4 (6.7)	(1.8, 16.2)	62	1 (1.6)	(0.0, 8.7)
	Mild	60	3 (5.0)	(1.0, 13.9)	62	1 (1.6)	(0.0, 8.7)
	Moderate	60	1 (1.7)	(0.0, 8.9)	62	0	(0.0, 5.8)
	Severe	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Grade 4	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Swelling[d]						
	Any	60	5 (8.3)	(2.8, 18.4)	62	0	(0.0, 5.8)
	Mild	60	2 (3.3)	(0.4, 11.5)	62	0	(0.0, 5.8)
	Moderate	60	3 (5.0)	(1.0, 13.9)	62	0	(0.0, 5.8)
	Severe	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Grade 4	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Pain at the injection site[e]						
	Any	60	32 (53.3)	(40.0, 66.3)	62	5 (8.1)	(2.7, 17.8)

14.72. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	60	22 (36.7)	(24.6, 50.1)	62	5 (8.1)	(2.7, 17.8)
	Moderate	60	9 (15.0)	(7.1, 26.6)	62	0	(0.0, 5.8)
	Severe	60	1 (1.7)	(0.0, 8.9)	62	0	(0.0, 5.8)
	Grade 4	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Any local reaction[f]	60	32 (53.3)	(40.0, 66.3)	62	5 (8.1)	(2.7, 17.8)
Any dose	Redness[d]						
	Any	72	5 (6.9)	(2.3, 15.5)	74	3 (4.1)	(0.8, 11.4)
	Mild	72	4 (5.6)	(1.5, 13.6)	74	1 (1.4)	(0.0, 7.3)
	Moderate	72	1 (1.4)	(0.0, 7.5)	74	0	(0.0, 4.9)
	Severe	72	0	(0.0, 5.0)	74	2 (2.7)	(0.3, 9.4)
	Grade 4	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	Swelling[d]						
	Any	72	7 (9.7)	(4.0, 19.0)	74	1 (1.4)	(0.0, 7.3)
	Mild	72	4 (5.6)	(1.5, 13.6)	74	0	(0.0, 4.9)
	Moderate	72	3 (4.2)	(0.9, 11.7)	74	0	(0.0, 4.9)
	Severe	72	0	(0.0, 5.0)	74	1 (1.4)	(0.0, 7.3)
	Grade 4	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	Pain at the injection site[e]						
	Any	72	49 (68.1)	(56.0, 78.6)	74	12 (16.2)	(8.7, 26.6)
	Mild	72	35 (48.6)	(36.7, 60.7)	74	11 (14.9)	(7.7, 25.0)
	Moderate	72	13 (18.1)	(10.0, 28.9)	74	1 (1.4)	(0.0, 7.3)
	Severe	72	1 (1.4)	(0.0, 7.5)	74	0	(0.0, 4.9)
	Grade 4	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	Any local reaction[f]	72	49 (68.1)	(56.0, 78.6)	74	13 (17.6)	(9.7, 28.2)

14.72. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Abbreviation: HIV = human immunodeficiency virus.
Note: Reactions were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each 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.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adce s010 lr hiv p3 saf

14.73. Onset Days for Local Reactions (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
1	Redness		
	n[a]	2	3
	Mean (SD)	2.0 (0.00)	1.0 (0.00)
	Median	2.0	1.0
	Min, max	(2, 2)	(1, 1)
	Swelling		
	n[a]	3	1
	Mean (SD)	2.0 (0.00)	2.0 (NE)
	Median	2.0	2.0
	Min, max	(2, 2)	(2, 2)
	Pain at the injection site		
	n[a]	34	9
	Mean (SD)	1.4 (0.50)	2.6 (1.24)
	Median	1.0	2.0
	Min, max	(1, 2)	(1, 5)
	Any local reaction[b]		
	n[a]	35	10
	Mean (SD)	1.4 (0.50)	1.9 (0.99)
	Median	1.0	2.0
	Min, max	(1, 2)	(1, 4)
2	Redness		
	n[a]	4	1
	Mean (SD)	2.0 (0.82)	1.0 (NE)
	Median	2.0	1.0
	Min, max	(1, 3)	(1, 1)
	Swelling		
	n[a]	5	0
	Mean (SD)	1.4 (0.55)	NE (NE)
	Median	1.0	NE
	Min, max	(1, 2)	(NE, NE)
	Pain at the injection site		
	n[a]	32	5
	Mean (SD)	1.6 (0.67)	1.6 (0.89)
	Median	1.5	1.0

14.73. Onset Days for Local Reactions (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
	Min, max	(1, 3)	(1, 3)
	Any local reaction[b]		
	n[a]	32	5
	Mean (SD)	1.6 (0.67)	1.6 (0.89)
	Median	1.0	1.0
	Min, max	(1, 3)	(1, 3)

Abbreviations: HIV = human immunodeficiency virus; 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: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adce s050 lr onset hiv p3 saf

14.74. Duration (Days) From First to Last Day of Local Reactions (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
1	Redness		
	n[a]	2	3
	Mean (SD)	1.5 (0.71)	1.0 (0.00)
	Median	1.5	1.0
	Min, max	(1, 2)	(1, 1)
	Swelling		
	n[a]	3	1
	Mean (SD)	1.3 (0.58)	1.0 (NE)
	Median	1.0	1.0
	Min, max	(1, 2)	(1, 1)
	Pain at the injection site		
	n[a]	34	9
	Mean (SD)	2.0 (1.21)	1.9 (1.36)
	Median	2.0	1.0
	Min, max	(1, 7)	(1, 5)
2	Redness		
	n[a]	4	1
	Mean (SD)	1.3 (0.50)	2.0 (NE)
	Median	1.0	2.0
	Min, max	(1, 2)	(2, 2)
	Swelling		
	n[a]	5	0
	Mean (SD)	1.8 (0.84)	NE (NE)
	Median	2.0	NE
	Min, max	(1, 3)	(NE, NE)
	Pain at the injection site		
	n[a]	32	5
	Mean (SD)	1.8 (1.04)	2.0 (1.41)
	Median	1.0	1.0
	Min, max	(1, 4)	(1, 4)

14.74. Duration (Days) From First to Last Day of Local Reactions (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**

Abbreviations: HIV = human immunodeficiency virus; 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. For symptoms that are ongoing at the time of the next dose, stop date is computed as the next dose date.
Note: Reactions were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each 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.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adcevd Table Generation: 27MAR2021 (01:29)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adce s030 lr dur hiv p3 saf

Systemic Events

14.75. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
16-55 Years	1	Fever						
		≥38.0°C	2899	119 (4.1)	(3.4, 4.9)	2908	25 (0.9)	(0.6, 1.3)
		≥38.0°C to 38.4°C	2899	86 (3.0)	(2.4, 3.7)	2908	16 (0.6)	(0.3, 0.9)
		>38.4°C to 38.9°C	2899	25 (0.9)	(0.6, 1.3)	2908	5 (0.2)	(0.1, 0.4)
		>38.9°C to 40.0°C	2899	8 (0.3)	(0.1, 0.5)	2908	4 (0.1)	(0.0, 0.4)
		>40.0°C	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Fatigue[d]						
		Any	2899	1431 (49.4)	(47.5, 51.2)	2908	960 (33.0)	(31.3, 34.8)
		Mild	2899	760 (26.2)	(24.6, 27.9)	2908	570 (19.6)	(18.2, 21.1)
		Moderate	2899	630 (21.7)	(20.2, 23.3)	2908	372 (12.8)	(11.6, 14.1)
		Severe	2899	41 (1.4)	(1.0, 1.9)	2908	18 (0.6)	(0.4, 1.0)
		Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Headache[d]						
		Any	2899	1262 (43.5)	(41.7, 45.4)	2908	975 (33.5)	(31.8, 35.3)
		Mild	2899	785 (27.1)	(25.5, 28.7)	2908	633 (21.8)	(20.3, 23.3)
		Moderate	2899	444 (15.3)	(14.0, 16.7)	2908	318 (10.9)	(9.8, 12.1)
		Severe	2899	33 (1.1)	(0.8, 1.6)	2908	24 (0.8)	(0.5, 1.2)
		Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Chills[d]						
		Any	2899	479 (16.5)	(15.2, 17.9)	2908	199 (6.8)	(6.0, 7.8)
		Mild	2899	338 (11.7)	(10.5, 12.9)	2908	148 (5.1)	(4.3, 6.0)
		Moderate	2899	126 (4.3)	(3.6, 5.2)	2908	49 (1.7)	(1.2, 2.2)
		Severe	2899	15 (0.5)	(0.3, 0.9)	2908	2 (0.1)	(0.0, 0.2)
		Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Vomiting[e]						
		Any	2899	34 (1.2)	(0.8, 1.6)	2908	36 (1.2)	(0.9, 1.7)
		Mild	2899	29 (1.0)	(0.7, 1.4)	2908	30 (1.0)	(0.7, 1.5)
		Moderate	2899	5 (0.2)	(0.1, 0.4)	2908	5 (0.2)	(0.1, 0.4)
		Severe	2899	0	(0.0, 0.1)	2908	1 (0.0)	(0.0, 0.2)
		Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)

14.75. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Diarrhea[f]						
		Any	2899	309 (10.7)	(9.6, 11.8)	2908	323 (11.1)	(10.0, 12.3)
		Mild	2899	251 (8.7)	(7.7, 9.7)	2908	264 (9.1)	(8.1, 10.2)
		Moderate	2899	55 (1.9)	(1.4, 2.5)	2908	58 (2.0)	(1.5, 2.6)
		Severe	2899	3 (0.1)	(0.0, 0.3)	2908	1 (0.0)	(0.0, 0.2)
		Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		New or worsened muscle pain[d]						
		Any	2899	664 (22.9)	(21.4, 24.5)	2908	329 (11.3)	(10.2, 12.5)
		Mild	2899	353 (12.2)	(11.0, 13.4)	2908	231 (7.9)	(7.0, 9.0)
		Moderate	2899	296 (10.2)	(9.1, 11.4)	2908	96 (3.3)	(2.7, 4.0)
		Severe	2899	15 (0.5)	(0.3, 0.9)	2908	2 (0.1)	(0.0, 0.2)
		Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		New or worsened joint pain[d]						
		Any	2899	342 (11.8)	(10.6, 13.0)	2908	168 (5.8)	(5.0, 6.7)
		Mild	2899	200 (6.9)	(6.0, 7.9)	2908	112 (3.9)	(3.2, 4.6)
		Moderate	2899	137 (4.7)	(4.0, 5.6)	2908	55 (1.9)	(1.4, 2.5)
		Severe	2899	5 (0.2)	(0.1, 0.4)	2908	1 (0.0)	(0.0, 0.2)
		Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Any systemic event[g]	2899	1979 (68.3)	(66.5, 70.0)	2908	1559 (53.6)	(51.8, 55.4)
		Use of antipyretic or pain medication[h]	2899	805 (27.8)	(26.1, 29.4)	2908	398 (13.7)	(12.5, 15.0)
	2	Fever						
		≥38.0°C	2682	440 (16.4)	(15.0, 17.9)	2684	11 (0.4)	(0.2, 0.7)
		≥38.0°C to 38.4°C	2682	254 (9.5)	(8.4, 10.6)	2684	5 (0.2)	(0.1, 0.4)
		>38.4°C to 38.9°C	2682	146 (5.4)	(4.6, 6.4)	2684	4 (0.1)	(0.0, 0.4)
		>38.9°C to 40.0°C	2682	39 (1.5)	(1.0, 2.0)	2684	2 (0.1)	(0.0, 0.3)
		>40.0°C	2682	1 (0.0)	(0.0, 0.2)	2684	0	(0.0, 0.1)
		Fatigue[d]						
		Any	2682	1649 (61.5)	(59.6, 63.3)	2684	614 (22.9)	(21.3, 24.5)
		Mild	2682	558 (20.8)	(19.3, 22.4)	2684	317 (11.8)	(10.6, 13.1)
		Moderate	2682	949 (35.4)	(33.6, 37.2)	2684	283 (10.5)	(9.4, 11.8)

14.75. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Severe	2682	142 (5.3)	(4.5, 6.2)	2684	14 (0.5)	(0.3, 0.9)
		Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Headache[d]						
		Any	2682	1448 (54.0)	(52.1, 55.9)	2684	652 (24.3)	(22.7, 26.0)
		Mild	2682	699 (26.1)	(24.4, 27.8)	2684	404 (15.1)	(13.7, 16.5)
		Moderate	2682	658 (24.5)	(22.9, 26.2)	2684	230 (8.6)	(7.5, 9.7)
		Severe	2682	91 (3.4)	(2.7, 4.1)	2684	18 (0.7)	(0.4, 1.1)
		Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Chills[d]						
		Any	2682	1015 (37.8)	(36.0, 39.7)	2684	114 (4.2)	(3.5, 5.1)
		Mild	2682	477 (17.8)	(16.4, 19.3)	2684	89 (3.3)	(2.7, 4.1)
		Moderate	2682	469 (17.5)	(16.1, 19.0)	2684	23 (0.9)	(0.5, 1.3)
		Severe	2682	69 (2.6)	(2.0, 3.2)	2684	2 (0.1)	(0.0, 0.3)
		Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Vomiting[e]						
		Any	2682	58 (2.2)	(1.6, 2.8)	2684	30 (1.1)	(0.8, 1.6)
		Mild	2682	42 (1.6)	(1.1, 2.1)	2684	20 (0.7)	(0.5, 1.1)
		Moderate	2682	12 (0.4)	(0.2, 0.8)	2684	10 (0.4)	(0.2, 0.7)
		Severe	2682	4 (0.1)	(0.0, 0.4)	2684	0	(0.0, 0.1)
		Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Diarrhea[f]						
		Any	2682	269 (10.0)	(8.9, 11.2)	2684	205 (7.6)	(6.7, 8.7)
		Mild	2682	219 (8.2)	(7.2, 9.3)	2684	169 (6.3)	(5.4, 7.3)
		Moderate	2682	44 (1.6)	(1.2, 2.2)	2684	35 (1.3)	(0.9, 1.8)
		Severe	2682	6 (0.2)	(0.1, 0.5)	2684	1 (0.0)	(0.0, 0.2)
		Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		New or worsened muscle pain[d]						
		Any	2682	1055 (39.3)	(37.5, 41.2)	2684	237 (8.8)	(7.8, 10.0)
		Mild	2682	441 (16.4)	(15.1, 17.9)	2684	150 (5.6)	(4.7, 6.5)
		Moderate	2682	552 (20.6)	(19.1, 22.2)	2684	84 (3.1)	(2.5, 3.9)
		Severe	2682	62 (2.3)	(1.8, 3.0)	2684	3 (0.1)	(0.0, 0.3)
		Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		New or worsened joint pain[d]						

14.75. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	2682	638 (23.8)	(22.2, 25.4)	2684	147 (5.5)	(4.6, 6.4)
		Mild	2682	291 (10.9)	(9.7, 12.1)	2684	82 (3.1)	(2.4, 3.8)
		Moderate	2682	320 (11.9)	(10.7, 13.2)	2684	61 (2.3)	(1.7, 2.9)
		Severe	2682	27 (1.0)	(0.7, 1.5)	2684	4 (0.1)	(0.0, 0.4)
		Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Any systemic event[g]	2682	2034 (75.8)	(74.2, 77.4)	2684	1026 (38.2)	(36.4, 40.1)
		Use of antipyretic or pain medication[h]	2682	1213 (45.2)	(43.3, 47.1)	2684	320 (11.9)	(10.7, 13.2)
	Any dose	Fever						
		≥38.0°C	2909	517 (17.8)	(16.4, 19.2)	2921	34 (1.2)	(0.8, 1.6)
		≥38.0°C to 38.4°C	2909	310 (10.7)	(9.6, 11.8)	2921	20 (0.7)	(0.4, 1.1)
		>38.4°C to 38.9°C	2909	163 (5.6)	(4.8, 6.5)	2921	9 (0.3)	(0.1, 0.6)
		>38.9°C to 40.0°C	2909	43 (1.5)	(1.1, 2.0)	2921	5 (0.2)	(0.1, 0.4)
		>40.0°C	2909	1 (0.0)	(0.0, 0.2)	2921	0	(0.0, 0.1)
		Fatigue[d]						
		Any	2909	2038 (70.1)	(68.4, 71.7)	2921	1172 (40.1)	(38.3, 41.9)
		Mild	2909	672 (23.1)	(21.6, 24.7)	2921	615 (21.1)	(19.6, 22.6)
		Moderate	2909	1191 (40.9)	(39.1, 42.8)	2921	529 (18.1)	(16.7, 19.6)
		Severe	2909	175 (6.0)	(5.2, 6.9)	2921	28 (1.0)	(0.6, 1.4)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		Headache[d]						
		Any	2909	1889 (64.9)	(63.2, 66.7)	2921	1225 (41.9)	(40.1, 43.8)
		Mild	2909	870 (29.9)	(28.2, 31.6)	2921	730 (25.0)	(23.4, 26.6)
		Moderate	2909	901 (31.0)	(29.3, 32.7)	2921	454 (15.5)	(14.2, 16.9)
		Severe	2909	118 (4.1)	(3.4, 4.8)	2921	41 (1.4)	(1.0, 1.9)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		Chills[d]						
		Any	2909	1208 (41.5)	(39.7, 43.3)	2921	270 (9.2)	(8.2, 10.4)
		Mild	2909	594 (20.4)	(19.0, 21.9)	2921	205 (7.0)	(6.1, 8.0)
		Moderate	2909	532 (18.3)	(16.9, 19.7)	2921	61 (2.1)	(1.6, 2.7)
		Severe	2909	82 (2.8)	(2.2, 3.5)	2921	4 (0.1)	(0.0, 0.4)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)

14.75. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Vomiting[e]						
		Any	2909	87 (3.0)	(2.4, 3.7)	2921	60 (2.1)	(1.6, 2.6)
		Mild	2909	67 (2.3)	(1.8, 2.9)	2921	44 (1.5)	(1.1, 2.0)
		Moderate	2909	16 (0.6)	(0.3, 0.9)	2921	15 (0.5)	(0.3, 0.8)
		Severe	2909	4 (0.1)	(0.0, 0.4)	2921	1 (0.0)	(0.0, 0.2)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		Diarrhea[f]						
		Any	2909	492 (16.9)	(15.6, 18.3)	2921	460 (15.7)	(14.4, 17.1)
		Mild	2909	393 (13.5)	(12.3, 14.8)	2921	369 (12.6)	(11.4, 13.9)
		Moderate	2909	90 (3.1)	(2.5, 3.8)	2921	89 (3.0)	(2.5, 3.7)
		Severe	2909	9 (0.3)	(0.1, 0.6)	2921	2 (0.1)	(0.0, 0.2)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		New or worsened muscle pain[d]						
		Any	2909	1325 (45.5)	(43.7, 47.4)	2921	471 (16.1)	(14.8, 17.5)
		Mild	2909	530 (18.2)	(16.8, 19.7)	2921	304 (10.4)	(9.3, 11.6)
		Moderate	2909	721 (24.8)	(23.2, 26.4)	2921	162 (5.5)	(4.7, 6.4)
		Severe	2909	74 (2.5)	(2.0, 3.2)	2921	5 (0.2)	(0.1, 0.4)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		New or worsened joint pain[d]						
		Any	2909	799 (27.5)	(25.9, 29.1)	2921	272 (9.3)	(8.3, 10.4)
		Mild	2909	359 (12.3)	(11.2, 13.6)	2921	161 (5.5)	(4.7, 6.4)
		Moderate	2909	408 (14.0)	(12.8, 15.3)	2921	106 (3.6)	(3.0, 4.4)
		Severe	2909	32 (1.1)	(0.8, 1.5)	2921	5 (0.2)	(0.1, 0.4)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		Any systemic event[g]	2909	2446 (84.1)	(82.7, 85.4)	2921	1797 (61.5)	(59.7, 63.3)
		Use of antipyretic or pain medication[h]	2909	1485 (51.0)	(49.2, 52.9)	2921	605 (20.7)	(19.3, 22.2)
>55 Years	1	Fever						
		≥38.0°C	2008	26 (1.3)	(0.8, 1.9)	1989	8 (0.4)	(0.2, 0.8)
		≥38.0°C to 38.4°C	2008	23 (1.1)	(0.7, 1.7)	1989	3 (0.2)	(0.0, 0.4)
		>38.4°C to 38.9°C	2008	2 (0.1)	(0.0, 0.4)	1989	3 (0.2)	(0.0, 0.4)

14.75. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		>38.9°C to 40.0°C	2008	1 (0.0)	(0.0, 0.3)	1989	2 (0.1)	(0.0, 0.4)
		>40.0°C	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Fatigue[d]						
		Any	2008	677 (33.7)	(31.6, 35.8)	1989	447 (22.5)	(20.7, 24.4)
		Mild	2008	415 (20.7)	(18.9, 22.5)	1989	281 (14.1)	(12.6, 15.7)
		Moderate	2008	259 (12.9)	(11.5, 14.4)	1989	163 (8.2)	(7.0, 9.5)
		Severe	2008	3 (0.1)	(0.0, 0.4)	1989	3 (0.2)	(0.0, 0.4)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Headache[d]						
		Any	2008	503 (25.0)	(23.2, 27.0)	1989	363 (18.3)	(16.6, 20.0)
		Mild	2008	381 (19.0)	(17.3, 20.8)	1989	267 (13.4)	(12.0, 15.0)
		Moderate	2008	120 (6.0)	(5.0, 7.1)	1989	93 (4.7)	(3.8, 5.7)
		Severe	2008	2 (0.1)	(0.0, 0.4)	1989	3 (0.2)	(0.0, 0.4)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Chills[d]						
		Any	2008	130 (6.5)	(5.4, 7.6)	1989	69 (3.5)	(2.7, 4.4)
		Mild	2008	102 (5.1)	(4.2, 6.1)	1989	49 (2.5)	(1.8, 3.2)
		Moderate	2008	28 (1.4)	(0.9, 2.0)	1989	19 (1.0)	(0.6, 1.5)
		Severe	2008	0	(0.0, 0.2)	1989	1 (0.1)	(0.0, 0.3)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Vomiting[e]						
		Any	2008	10 (0.5)	(0.2, 0.9)	1989	9 (0.5)	(0.2, 0.9)
		Mild	2008	9 (0.4)	(0.2, 0.8)	1989	9 (0.5)	(0.2, 0.9)
		Moderate	2008	1 (0.0)	(0.0, 0.3)	1989	0	(0.0, 0.2)
		Severe	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Diarrhea[f]						
		Any	2008	168 (8.4)	(7.2, 9.7)	1989	130 (6.5)	(5.5, 7.7)
		Mild	2008	137 (6.8)	(5.8, 8.0)	1989	109 (5.5)	(4.5, 6.6)
		Moderate	2008	27 (1.3)	(0.9, 2.0)	1989	20 (1.0)	(0.6, 1.5)
		Severe	2008	4 (0.2)	(0.1, 0.5)	1989	1 (0.1)	(0.0, 0.3)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		New or worsened muscle pain[d]						

14.75. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	2008	274 (13.6)	(12.2, 15.2)	1989	165 (8.3)	(7.1, 9.6)
		Mild	2008	183 (9.1)	(7.9, 10.5)	1989	111 (5.6)	(4.6, 6.7)
		Moderate	2008	90 (4.5)	(3.6, 5.5)	1989	51 (2.6)	(1.9, 3.4)
		Severe	2008	1 (0.0)	(0.0, 0.3)	1989	3 (0.2)	(0.0, 0.4)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		New or worsened joint pain[d]						
		Any	2008	175 (8.7)	(7.5, 10.0)	1989	124 (6.2)	(5.2, 7.4)
		Mild	2008	119 (5.9)	(4.9, 7.0)	1989	78 (3.9)	(3.1, 4.9)
		Moderate	2008	53 (2.6)	(2.0, 3.4)	1989	45 (2.3)	(1.7, 3.0)
		Severe	2008	3 (0.1)	(0.0, 0.4)	1989	1 (0.1)	(0.0, 0.3)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Any systemic event[g]	2008	984 (49.0)	(46.8, 51.2)	1989	749 (37.7)	(35.5, 39.8)
		Use of antipyretic or pain medication[h]	2008	382 (19.0)	(17.3, 20.8)	1989	224 (11.3)	(9.9, 12.7)
	2	Fever						
		≥38.0°C	1860	219 (11.8)	(10.3, 13.3)	1833	4 (0.2)	(0.1, 0.6)
		≥38.0°C to 38.4°C	1860	158 (8.5)	(7.3, 9.9)	1833	2 (0.1)	(0.0, 0.4)
		>38.4°C to 38.9°C	1860	54 (2.9)	(2.2, 3.8)	1833	1 (0.1)	(0.0, 0.3)
		>38.9°C to 40.0°C	1860	7 (0.4)	(0.2, 0.8)	1833	1 (0.1)	(0.0, 0.3)
		>40.0°C	1860	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		Fatigue[d]						
		Any	1860	949 (51.0)	(48.7, 53.3)	1833	306 (16.7)	(15.0, 18.5)
		Mild	1860	391 (21.0)	(19.2, 22.9)	1833	183 (10.0)	(8.6, 11.4)
		Moderate	1860	497 (26.7)	(24.7, 28.8)	1833	121 (6.6)	(5.5, 7.8)
		Severe	1860	60 (3.2)	(2.5, 4.1)	1833	2 (0.1)	(0.0, 0.4)
		Grade 4	1860	1 (0.1)	(0.0, 0.3)	1833	0	(0.0, 0.2)
		Headache[d]						
		Any	1860	733 (39.4)	(37.2, 41.7)	1833	259 (14.1)	(12.6, 15.8)
		Mild	1860	464 (24.9)	(23.0, 27.0)	1833	189 (10.3)	(9.0, 11.8)
		Moderate	1860	256 (13.8)	(12.2, 15.4)	1833	65 (3.5)	(2.7, 4.5)
		Severe	1860	13 (0.7)	(0.4, 1.2)	1833	5 (0.3)	(0.1, 0.6)
		Grade 4	1860	0	(0.0, 0.2)	1833	0	(0.0, 0.2)

14.75. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Chills[d]						
		Any	1860	435 (23.4)	(21.5, 25.4)	1833	57 (3.1)	(2.4, 4.0)
		Mild	1860	229 (12.3)	(10.9, 13.9)	1833	45 (2.5)	(1.8, 3.3)
		Moderate	1860	185 (9.9)	(8.6, 11.4)	1833	12 (0.7)	(0.3, 1.1)
		Severe	1860	21 (1.1)	(0.7, 1.7)	1833	0	(0.0, 0.2)
		Grade 4	1860	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		Vomiting[e]						
		Any	1860	13 (0.7)	(0.4, 1.2)	1833	5 (0.3)	(0.1, 0.6)
		Mild	1860	10 (0.5)	(0.3, 1.0)	1833	5 (0.3)	(0.1, 0.6)
		Moderate	1860	1 (0.1)	(0.0, 0.3)	1833	0	(0.0, 0.2)
		Severe	1860	2 (0.1)	(0.0, 0.4)	1833	0	(0.0, 0.2)
		Grade 4	1860	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		Diarrhea[f]						
		Any	1860	152 (8.2)	(7.0, 9.5)	1833	102 (5.6)	(4.6, 6.7)
		Mild	1860	125 (6.7)	(5.6, 8.0)	1833	76 (4.1)	(3.3, 5.2)
		Moderate	1860	25 (1.3)	(0.9, 2.0)	1833	22 (1.2)	(0.8, 1.8)
		Severe	1860	2 (0.1)	(0.0, 0.4)	1833	4 (0.2)	(0.1, 0.6)
		Grade 4	1860	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		New or worsened muscle pain[d]						
		Any	1860	537 (28.9)	(26.8, 31.0)	1833	99 (5.4)	(4.4, 6.5)
		Mild	1860	229 (12.3)	(10.9, 13.9)	1833	65 (3.5)	(2.7, 4.5)
		Moderate	1860	288 (15.5)	(13.9, 17.2)	1833	33 (1.8)	(1.2, 2.5)
		Severe	1860	20 (1.1)	(0.7, 1.7)	1833	1 (0.1)	(0.0, 0.3)
		Grade 4	1860	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		New or worsened joint pain[d]						
		Any	1860	353 (19.0)	(17.2, 20.8)	1833	72 (3.9)	(3.1, 4.9)
		Mild	1860	183 (9.8)	(8.5, 11.3)	1833	44 (2.4)	(1.7, 3.2)
		Moderate	1860	161 (8.7)	(7.4, 10.0)	1833	27 (1.5)	(1.0, 2.1)
		Severe	1860	9 (0.5)	(0.2, 0.9)	1833	1 (0.1)	(0.0, 0.3)
		Grade 4	1860	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		Any systemic event[g]	1860	1203 (64.7)	(62.5, 66.9)	1833	516 (28.2)	(26.1, 30.3)
		Use of antipyretic or pain medication[h]	1860	688 (37.0)	(34.8, 39.2)	1833	170 (9.3)	(8.0, 10.7)

14.75. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any dose	Fever						
		≥38.0°C	2015	232 (11.5)	(10.2, 13.0)	1994	11 (0.6)	(0.3, 1.0)
		≥38.0°C to 38.4°C	2015	168 (8.3)	(7.2, 9.6)	1994	5 (0.3)	(0.1, 0.6)
		>38.4°C to 38.9°C	2015	56 (2.8)	(2.1, 3.6)	1994	3 (0.2)	(0.0, 0.4)
		>38.9°C to 40.0°C	2015	8 (0.4)	(0.2, 0.8)	1994	3 (0.2)	(0.0, 0.4)
		>40.0°C	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		Fatigue[d]						
		Any	2015	1147 (56.9)	(54.7, 59.1)	1994	586 (29.4)	(27.4, 31.4)
		Mild	2015	485 (24.1)	(22.2, 26.0)	1994	341 (17.1)	(15.5, 18.8)
		Moderate	2015	598 (29.7)	(27.7, 31.7)	1994	240 (12.0)	(10.6, 13.5)
		Severe	2015	63 (3.1)	(2.4, 4.0)	1994	5 (0.3)	(0.1, 0.6)
		Grade 4	2015	1 (0.0)	(0.0, 0.3)	1994	0	(0.0, 0.2)
		Headache[d]						
		Any	2015	925 (45.9)	(43.7, 48.1)	1994	492 (24.7)	(22.8, 26.6)
		Mild	2015	588 (29.2)	(27.2, 31.2)	1994	345 (17.3)	(15.7, 19.0)
		Moderate	2015	322 (16.0)	(14.4, 17.7)	1994	139 (7.0)	(5.9, 8.2)
		Severe	2015	15 (0.7)	(0.4, 1.2)	1994	8 (0.4)	(0.2, 0.8)
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		Chills[d]						
		Any	2015	499 (24.8)	(22.9, 26.7)	1994	110 (5.5)	(4.6, 6.6)
		Mild	2015	276 (13.7)	(12.2, 15.3)	1994	80 (4.0)	(3.2, 5.0)
		Moderate	2015	202 (10.0)	(8.7, 11.4)	1994	29 (1.5)	(1.0, 2.1)
		Severe	2015	21 (1.0)	(0.6, 1.6)	1994	1 (0.1)	(0.0, 0.3)
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		Vomiting[e]						
		Any	2015	23 (1.1)	(0.7, 1.7)	1994	14 (0.7)	(0.4, 1.2)
		Mild	2015	19 (0.9)	(0.6, 1.5)	1994	14 (0.7)	(0.4, 1.2)
		Moderate	2015	2 (0.1)	(0.0, 0.4)	1994	0	(0.0, 0.2)
		Severe	2015	2 (0.1)	(0.0, 0.4)	1994	0	(0.0, 0.2)
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		Diarrhea[f]						
		Any	2015	266 (13.2)	(11.8, 14.8)	1994	199 (10.0)	(8.7, 11.4)

14.75. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Mild	2015	210 (10.4)	(9.1, 11.8)	1994	155 (7.8)	(6.6, 9.0)
		Moderate	2015	50 (2.5)	(1.8, 3.3)	1994	39 (2.0)	(1.4, 2.7)
		Severe	2015	6 (0.3)	(0.1, 0.6)	1994	5 (0.3)	(0.1, 0.6)
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		New or worsened muscle pain[d]						
		Any	2015	655 (32.5)	(30.5, 34.6)	1994	221 (11.1)	(9.7, 12.5)
		Mild	2015	296 (14.7)	(13.2, 16.3)	1994	138 (6.9)	(5.8, 8.1)
		Moderate	2015	338 (16.8)	(15.2, 18.5)	1994	79 (4.0)	(3.1, 4.9)
		Severe	2015	21 (1.0)	(0.6, 1.6)	1994	4 (0.2)	(0.1, 0.5)
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		New or worsened joint pain[d]						
		Any	2015	433 (21.5)	(19.7, 23.3)	1994	170 (8.5)	(7.3, 9.8)
		Mild	2015	227 (11.3)	(9.9, 12.7)	1994	98 (4.9)	(4.0, 6.0)
		Moderate	2015	194 (9.6)	(8.4, 11.0)	1994	70 (3.5)	(2.7, 4.4)
		Severe	2015	12 (0.6)	(0.3, 1.0)	1994	2 (0.1)	(0.0, 0.4)
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		Any systemic event[g]	2015	1432 (71.1)	(69.0, 73.0)	1994	919 (46.1)	(43.9, 48.3)
		Use of antipyretic or pain medication[h]	2015	816 (40.5)	(38.3, 42.7)	1994	319 (16.0)	(14.4, 17.7)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. 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: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_s020_se_p3_saf

14.76. Onset Days for Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
16-55 Years	1	Fever (≥38.0°C)		
		n[a]	119	25
		Mean (SD)	2.5 (1.24)	3.7 (2.10)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Fatigue		
		n[a]	1431	960
		Mean (SD)	2.0 (1.23)	2.3 (1.62)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[a]	1262	975
		Mean (SD)	2.4 (1.53)	2.6 (1.71)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Chills		
		n[a]	479	199
		Mean (SD)	2.2 (1.23)	2.9 (1.78)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Vomiting		
		n[a]	34	36
		Mean (SD)	3.8 (1.85)	3.6 (2.03)
		Median	4.0	4.0
		Min, max	(1, 7)	(1, 7)
		Diarrhea		
		n[a]	309	323
		Mean (SD)	3.5 (1.68)	3.6 (1.77)
		Median	3.0	3.0
		Min, max	(1, 7)	(1, 7)
		New or worsened muscle pain		
		n[a]	664	329
		Mean (SD)	2.3 (1.20)	3.1 (1.78)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)

14.76. Onset Days for Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		New or worsened joint pain		
		n[a]	342	168
		Mean (SD)	2.6 (1.43)	3.4 (1.61)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Any systemic event[b]		
		n[a]	1979	1559
		Mean (SD)	2.0 (1.22)	2.3 (1.59)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Use of antipyretic or pain medication		
		n[a]	805	398
		Mean (SD)	2.4 (1.33)	3.4 (1.85)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
	2	Fever (≥38.0°C)		
		n[a]	440	11
		Mean (SD)	2.0 (0.53)	3.6 (2.25)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Fatigue		
		n[a]	1649	614
		Mean (SD)	1.9 (0.76)	2.4 (1.60)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[a]	1448	652
		Mean (SD)	2.1 (1.02)	2.8 (1.75)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Chills		
		n[a]	1015	114
		Mean (SD)	1.9 (0.54)	2.7 (1.63)
		Median	2.0	2.0
		Min, max	(1, 6)	(1, 7)
		Vomiting		

14.76. Onset Days for Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		n[a]	58	30
		Mean (SD)	2.6 (1.38)	3.8 (2.12)
		Median	2.0	4.0
		Min, max	(1, 7)	(1, 7)
		Diarrhea		
		n[a]	269	205
		Mean (SD)	3.2 (1.71)	3.7 (1.92)
		Median	3.0	3.0
		Min, max	(1, 7)	(1, 7)
		New or worsened muscle pain		
		n[a]	1055	237
		Mean (SD)	2.0 (0.66)	3.0 (1.83)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		New or worsened joint pain		
		n[a]	638	147
		Mean (SD)	2.1 (0.81)	3.3 (1.82)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Any systemic event[b]		
		n[a]	2034	1026
		Mean (SD)	1.8 (0.85)	2.4 (1.62)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Use of antipyretic or pain medication		
		n[a]	1213	320
		Mean (SD)	2.0 (0.77)	3.4 (1.79)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
>55 Years	1	Fever (≥38.0°C)		
		n[a]	26	8
		Mean (SD)	2.3 (1.23)	4.1 (1.64)
		Median	2.0	4.0
		Min, max	(1, 6)	(2, 7)
		Fatigue		
		n[a]	677	447

14.76. Onset Days for Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Mean (SD)	2.2 (1.27)	2.6 (1.69)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[a]	503	363
		Mean (SD)	2.5 (1.52)	2.8 (1.75)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Chills		
		n[a]	130	69
		Mean (SD)	2.5 (1.52)	3.0 (1.87)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Vomiting		
		n[a]	10	9
		Mean (SD)	3.1 (1.91)	3.7 (1.73)
		Median	2.5	4.0
		Min, max	(1, 7)	(1, 7)
		Diarrhea		
		n[a]	168	130
		Mean (SD)	3.4 (1.77)	3.6 (1.71)
		Median	3.0	3.0
		Min, max	(1, 7)	(1, 7)
		New or worsened muscle pain		
		n[a]	274	165
		Mean (SD)	2.6 (1.45)	3.5 (1.84)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		New or worsened joint pain		
		n[a]	175	124
		Mean (SD)	2.9 (1.62)	3.7 (1.78)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Any systemic event[b]		
		n[a]	984	749
		Mean (SD)	2.2 (1.37)	2.6 (1.65)

14.76. Onset Days for Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Use of antipyretic or pain medication		
		n[a]	382	224
		Mean (SD)	2.6 (1.48)	3.2 (1.90)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
	2	Fever (≥38.0°C)		
		n[a]	219	4
		Mean (SD)	2.0 (0.34)	4.3 (2.50)
		Median	2.0	4.5
		Min, max	(1, 6)	(1, 7)
		Fatigue		
		n[a]	949	306
		Mean (SD)	2.0 (0.95)	2.8 (1.78)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[a]	733	259
		Mean (SD)	2.2 (1.12)	2.9 (1.87)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Chills		
		n[a]	435	57
		Mean (SD)	2.0 (0.60)	3.0 (1.88)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Vomiting		
		n[a]	13	5
		Mean (SD)	3.3 (1.97)	4.2 (1.79)
		Median	2.0	4.0
		Min, max	(2, 7)	(2, 7)
		Diarrhea		
		n[a]	152	102
		Mean (SD)	3.4 (1.70)	3.5 (1.52)
		Median	3.0	3.0

14.76. Onset Days for Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Min, max	(1, 7)	(1, 7)
		New or worsened muscle pain		
		n[a]	537	99
		Mean (SD)	2.1 (0.88)	3.1 (1.72)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		New or worsened joint pain		
		n[a]	353	72
		Mean (SD)	2.2 (0.98)	3.5 (1.88)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Any systemic event[b]		
		n[a]	1203	516
		Mean (SD)	2.0 (0.96)	2.7 (1.73)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Use of antipyretic or pain medication		
		n[a]	688	170
		Mean (SD)	2.1 (0.93)	3.4 (1.95)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)

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: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adce s060 se onset p3 saf

14.77. Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
16-55 Years	1	Fever (≥38.0°C)		
		n[a]	119	25
		Mean (SD)	1.2 (0.87)	1.7 (1.52)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 7)
		Unknown[b]	0	1
		Fatigue		
		n[a]	1431	960
		Mean (SD)	2.5 (2.50)	2.9 (2.89)
		Median	1.0	2.0
		Min, max	(1, 23)	(1, 23)
		Unknown[b]	6	5
		Headache		
		n[a]	1262	975
		Mean (SD)	2.4 (2.45)	2.6 (2.62)
		Median	1.0	1.0
		Min, max	(1, 25)	(1, 22)
		Unknown[b]	5	4
		Chills		
		n[a]	479	199
		Mean (SD)	1.6 (1.34)	2.1 (2.77)
		Median	1.0	1.0
		Min, max	(1, 9)	(1, 31)
		Unknown[b]	1	2
		Vomiting		
		n[a]	34	36
		Mean (SD)	1.5 (1.13)	1.4 (0.91)
		Median	1.0	1.0
		Min, max	(1, 5)	(1, 4)
		Diarrhea		
		n[a]	309	323
		Mean (SD)	2.0 (2.97)	1.8 (1.91)
		Median	1.0	1.0
		Min, max	(1, 39)	(1, 23)
		Unknown[b]	1	0

14.77. Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		New or worsened muscle pain		
		n[a]	664	329
		Mean (SD)	1.7 (1.63)	2.0 (2.56)
		Median	1.0	1.0
		Min, max	(1, 17)	(1, 31)
		Unknown[b]	1	1
		New or worsened joint pain		
		n[a]	342	168
		Mean (SD)	1.6 (1.74)	2.2 (2.38)
		Median	1.0	1.0
		Min, max	(1, 24)	(1, 17)
		Unknown[b]	2	0
		Use of antipyretic or pain medication		
		n[a]	805	398
		Mean (SD)	1.9 (1.76)	2.2 (2.44)
		Median	1.0	1.0
		Min, max	(1, 16)	(1, 23)
		Unknown[b]	1	4
	2	Fever (≥38.0°C)		
		n[a]	440	11
		Mean (SD)	1.1 (0.51)	2.1 (2.08)
		Median	1.0	1.0
		Min, max	(1, 8)	(1, 6)
		Unknown[b]	0	1
		Fatigue		
		n[a]	1649	614
		Mean (SD)	2.2 (2.14)	2.8 (3.04)
		Median	1.0	2.0
		Min, max	(1, 35)	(1, 38)
		Unknown[b]	5	10
		Headache		
		n[a]	1448	652
		Mean (SD)	2.2 (2.01)	2.4 (3.00)
		Median	1.0	1.0
		Min, max	(1, 25)	(1, 35)
		Unknown[b]	5	10
		Chills		

14.77. Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		n[a]	1015	114
		Mean (SD)	1.3 (0.81)	2.2 (1.99)
		Median	1.0	1.0
		Min, max	(1, 11)	(1, 10)
		Unknown[b]	3	2
		Vomiting		
		n[a]	58	30
		Mean (SD)	2.4 (5.27)	1.5 (1.15)
		Median	1.0	1.0
		Min, max	(1, 37)	(1, 6)
		Unknown[b]	1	1
		Diarrhea		
		n[a]	269	205
		Mean (SD)	1.8 (2.31)	2.1 (3.32)
		Median	1.0	1.0
		Min, max	(1, 31)	(1, 33)
		Unknown[b]	1	3
		New or worsened muscle pain		
		n[a]	1055	237
		Mean (SD)	1.5 (1.34)	2.3 (2.71)
		Median	1.0	1.0
		Min, max	(1, 23)	(1, 27)
		Unknown[b]	3	1
		New or worsened joint pain		
		n[a]	638	147
		Mean (SD)	1.6 (1.75)	2.2 (2.28)
		Median	1.0	1.0
		Min, max	(1, 28)	(1, 16)
		Unknown[b]	5	2
		Use of antipyretic or pain medication		
		n[a]	1213	320
		Mean (SD)	1.9 (2.00)	2.1 (2.83)
		Median	1.0	1.0
		Min, max	(1, 34)	(1, 38)
		Unknown[b]	6	9
>55 Years	1	Fever (≥38.0°C)		
		n[a]	26	8

14.77. Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Mean (SD)	1.1 (0.33)	2.0 (2.45)
		Median	1.0	1.0
		Min, max	(1, 2)	(1, 8)
		Fatigue		
		n[a]	677	447
		Mean (SD)	2.4 (2.74)	2.8 (3.40)
		Median	1.0	1.0
		Min, max	(1, 34)	(1, 23)
		Unknown[b]	1	3
		Headache		
		n[a]	503	363
		Mean (SD)	2.0 (1.86)	2.3 (2.66)
		Median	1.0	1.0
		Min, max	(1, 17)	(1, 20)
		Unknown[b]	0	4
		Chills		
		n[a]	130	69
		Mean (SD)	1.6 (1.35)	2.1 (2.13)
		Median	1.0	1.0
		Min, max	(1, 11)	(1, 13)
		Unknown[b]	1	1
		Vomiting		
		n[a]	10	9
		Mean (SD)	1.6 (1.58)	1.5 (1.07)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 4)
		Unknown[b]	0	1
		Diarrhea		
		n[a]	168	130
		Mean (SD)	1.8 (1.58)	2.3 (3.37)
		Median	1.0	1.0
		Min, max	(1, 8)	(1, 22)
		Unknown[b]	1	1
		New or worsened muscle pain		
		n[a]	274	165
		Mean (SD)	1.5 (1.37)	1.8 (2.44)
		Median	1.0	1.0

14.77. Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Min, max	(1, 14)	(1, 18)
		Unknown[b]	1	0
		New or worsened joint pain		
		n[a]	175	124
		Mean (SD)	1.9 (3.26)	1.9 (2.33)
		Median	1.0	1.0
		Min, max	(1, 36)	(1, 17)
		Use of antipyretic or pain medication		
		n[a]	382	224
		Mean (SD)	2.0 (2.49)	2.8 (3.27)
		Median	1.0	1.0
		Min, max	(1, 31)	(1, 22)
		Unknown[b]	5	7
	2	Fever (≥38.0°C)		
		n[a]	219	4
		Mean (SD)	1.1 (0.35)	1.8 (1.50)
		Median	1.0	1.0
		Min, max	(1, 4)	(1, 4)
		Fatigue		
		n[a]	949	306
		Mean (SD)	2.1 (1.88)	2.7 (4.88)
		Median	1.0	1.0
		Min, max	(1, 20)	(1, 69)
		Unknown[b]	3	9
		Headache		
		n[a]	733	259
		Mean (SD)	1.8 (1.43)	2.4 (2.81)
		Median	1.0	1.0
		Min, max	(1, 12)	(1, 34)
		Unknown[b]	2	3
		Chills		
		n[a]	435	57
		Mean (SD)	1.2 (0.62)	2.3 (2.72)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 16)
		Unknown[b]	1	2

14.77. Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Vomiting		
		n[a]	13	5
		Mean (SD)	1.2 (0.38)	1.0 (0.00)
		Median	1.0	1.0
		Min, max	(1, 2)	(1, 1)
		Diarrhea		
		n[a]	152	102
		Mean (SD)	1.8 (1.43)	2.1 (2.83)
		Median	1.0	1.0
		Min, max	(1, 9)	(1, 26)
		Unknown[b]	2	2
		New or worsened muscle pain		
		n[a]	537	99
		Mean (SD)	1.4 (0.94)	1.6 (1.29)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 8)
		Unknown[b]	1	3
		New or worsened joint pain		
		n[a]	353	72
		Mean (SD)	1.5 (2.02)	2.0 (1.71)
		Median	1.0	1.0
		Min, max	(1, 32)	(1, 8)
		Unknown[b]	2	1
		Use of antipyretic or pain medication		
		n[a]	688	170
		Mean (SD)	1.8 (1.86)	2.0 (1.96)
		Median	1.0	1.0
		Min, max	(1, 30)	(1, 10)
		Unknown[b]	3	9

14.77. Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**

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. For symptoms that are ongoing at the time of the next dose, stop date is computed as the next dose date.
Note: Events and use of antipyretic or pain medication were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each 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.
b. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adcevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_s040_se_dur_p3_saf

14.78. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Positive	1	Fever						
		≥38.0°C	177	22 (12.4)	(8.0, 18.2)	187	4 (2.1)	(0.6, 5.4)
		≥38.0°C to 38.4°C	177	17 (9.6)	(5.7, 14.9)	187	1 (0.5)	(0.0, 2.9)
		>38.4°C to 38.9°C	177	4 (2.3)	(0.6, 5.7)	187	1 (0.5)	(0.0, 2.9)
		>38.9°C to 40.0°C	177	1 (0.6)	(0.0, 3.1)	187	2 (1.1)	(0.1, 3.8)
		>40.0°C	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Fatigue[d]						
		Any	177	80 (45.2)	(37.7, 52.8)	187	35 (18.7)	(13.4, 25.1)
		Mild	177	32 (18.1)	(12.7, 24.6)	187	20 (10.7)	(6.7, 16.0)
		Moderate	177	47 (26.6)	(20.2, 33.7)	187	15 (8.0)	(4.6, 12.9)
		Severe	177	1 (0.6)	(0.0, 3.1)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Headache[d]						
		Any	177	70 (39.5)	(32.3, 47.2)	187	43 (23.0)	(17.2, 29.7)
		Mild	177	36 (20.3)	(14.7, 27.0)	187	31 (16.6)	(11.6, 22.7)
		Moderate	177	31 (17.5)	(12.2, 23.9)	187	9 (4.8)	(2.2, 8.9)
		Severe	177	3 (1.7)	(0.4, 4.9)	187	3 (1.6)	(0.3, 4.6)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Chills[d]						
		Any	177	49 (27.7)	(21.2, 34.9)	187	7 (3.7)	(1.5, 7.6)
		Mild	177	33 (18.6)	(13.2, 25.2)	187	4 (2.1)	(0.6, 5.4)
		Moderate	177	14 (7.9)	(4.4, 12.9)	187	3 (1.6)	(0.3, 4.6)
		Severe	177	2 (1.1)	(0.1, 4.0)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Vomiting[e]						
		Any	177	4 (2.3)	(0.6, 5.7)	187	3 (1.6)	(0.3, 4.6)
		Mild	177	3 (1.7)	(0.4, 4.9)	187	3 (1.6)	(0.3, 4.6)
		Moderate	177	1 (0.6)	(0.0, 3.1)	187	0	(0.0, 2.0)
		Severe	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Diarrhea[f]						

14.78. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	177	10 (5.6)	(2.7, 10.1)	187	13 (7.0)	(3.8, 11.6)
		Mild	177	9 (5.1)	(2.4, 9.4)	187	10 (5.3)	(2.6, 9.6)
		Moderate	177	1 (0.6)	(0.0, 3.1)	187	3 (1.6)	(0.3, 4.6)
		Severe	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		New or worsened muscle pain[d]						
		Any	177	55 (31.1)	(24.3, 38.5)	187	20 (10.7)	(6.7, 16.0)
		Mild	177	18 (10.2)	(6.1, 15.6)	187	13 (7.0)	(3.8, 11.6)
		Moderate	177	35 (19.8)	(14.2, 26.4)	187	7 (3.7)	(1.5, 7.6)
		Severe	177	2 (1.1)	(0.1, 4.0)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		New or worsened joint pain[d]						
		Any	177	33 (18.6)	(13.2, 25.2)	187	10 (5.3)	(2.6, 9.6)
		Mild	177	20 (11.3)	(7.0, 16.9)	187	5 (2.7)	(0.9, 6.1)
		Moderate	177	12 (6.8)	(3.6, 11.5)	187	5 (2.7)	(0.9, 6.1)
		Severe	177	1 (0.6)	(0.0, 3.1)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Any systemic event[g]	177	115 (65.0)	(57.5, 72.0)	187	77 (41.2)	(34.0, 48.6)
		Use of antipyretic or pain medication[h]	177	67 (37.9)	(30.7, 45.4)	187	28 (15.0)	(10.2, 20.9)
	2	Fever						
		≥38.0°C	153	12 (7.8)	(4.1, 13.3)	165	1 (0.6)	(0.0, 3.3)
		≥38.0°C to 38.4°C	153	11 (7.2)	(3.6, 12.5)	165	0	(0.0, 2.2)
		>38.4°C to 38.9°C	153	1 (0.7)	(0.0, 3.6)	165	1 (0.6)	(0.0, 3.3)
		>38.9°C to 40.0°C	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		>40.0°C	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Fatigue[d]						
		Any	153	56 (36.6)	(29.0, 44.8)	165	27 (16.4)	(11.1, 22.9)
		Mild	153	23 (15.0)	(9.8, 21.7)	165	11 (6.7)	(3.4, 11.6)
		Moderate	153	29 (19.0)	(13.1, 26.1)	165	15 (9.1)	(5.2, 14.6)
		Severe	153	4 (2.6)	(0.7, 6.6)	165	1 (0.6)	(0.0, 3.3)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)

14.78. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Headache[d]						
		Any	153	54 (35.3)	(27.7, 43.4)	165	32 (19.4)	(13.7, 26.3)
		Mild	153	29 (19.0)	(13.1, 26.1)	165	18 (10.9)	(6.6, 16.7)
		Moderate	153	22 (14.4)	(9.2, 21.0)	165	11 (6.7)	(3.4, 11.6)
		Severe	153	3 (2.0)	(0.4, 5.6)	165	3 (1.8)	(0.4, 5.2)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Chills[d]						
		Any	153	29 (19.0)	(13.1, 26.1)	165	2 (1.2)	(0.1, 4.3)
		Mild	153	15 (9.8)	(5.6, 15.7)	165	2 (1.2)	(0.1, 4.3)
		Moderate	153	14 (9.2)	(5.1, 14.9)	165	0	(0.0, 2.2)
		Severe	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Vomiting[e]						
		Any	153	2 (1.3)	(0.2, 4.6)	165	4 (2.4)	(0.7, 6.1)
		Mild	153	1 (0.7)	(0.0, 3.6)	165	2 (1.2)	(0.1, 4.3)
		Moderate	153	0	(0.0, 2.4)	165	2 (1.2)	(0.1, 4.3)
		Severe	153	1 (0.7)	(0.0, 3.6)	165	0	(0.0, 2.2)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Diarrhea[f]						
		Any	153	10 (6.5)	(3.2, 11.7)	165	16 (9.7)	(5.6, 15.3)
		Mild	153	6 (3.9)	(1.5, 8.3)	165	10 (6.1)	(2.9, 10.9)
		Moderate	153	4 (2.6)	(0.7, 6.6)	165	4 (2.4)	(0.7, 6.1)
		Severe	153	0	(0.0, 2.4)	165	2 (1.2)	(0.1, 4.3)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		New or worsened muscle pain[d]						
		Any	153	42 (27.5)	(20.6, 35.2)	165	14 (8.5)	(4.7, 13.8)
		Mild	153	16 (10.5)	(6.1, 16.4)	165	7 (4.2)	(1.7, 8.5)
		Moderate	153	21 (13.7)	(8.7, 20.2)	165	7 (4.2)	(1.7, 8.5)
		Severe	153	5 (3.3)	(1.1, 7.5)	165	0	(0.0, 2.2)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		New or worsened joint pain[d]						
		Any	153	27 (17.6)	(12.0, 24.6)	165	9 (5.5)	(2.5, 10.1)

14.78. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Mild	153	12 (7.8)	(4.1, 13.3)	165	7 (4.2)	(1.7, 8.5)
		Moderate	153	15 (9.8)	(5.6, 15.7)	165	2 (1.2)	(0.1, 4.3)
		Severe	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Any systemic event[g]	153	87 (56.9)	(48.6, 64.8)	165	50 (30.3)	(23.4, 37.9)
		Use of antipyretic or pain medication[h]	153	48 (31.4)	(24.1, 39.4)	165	16 (9.7)	(5.6, 15.3)
	Any dose	Fever						
		≥38.0°C	177	31 (17.5)	(12.2, 23.9)	187	5 (2.7)	(0.9, 6.1)
		≥38.0°C to 38.4°C	177	25 (14.1)	(9.4, 20.1)	187	1 (0.5)	(0.0, 2.9)
		>38.4°C to 38.9°C	177	5 (2.8)	(0.9, 6.5)	187	2 (1.1)	(0.1, 3.8)
		>38.9°C to 40.0°C	177	1 (0.6)	(0.0, 3.1)	187	2 (1.1)	(0.1, 3.8)
		>40.0°C	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Fatigue[d]						
		Any	177	96 (54.2)	(46.6, 61.7)	187	50 (26.7)	(20.5, 33.7)
		Mild	177	33 (18.6)	(13.2, 25.2)	187	24 (12.8)	(8.4, 18.5)
		Moderate	177	59 (33.3)	(26.4, 40.8)	187	25 (13.4)	(8.8, 19.1)
		Severe	177	4 (2.3)	(0.6, 5.7)	187	1 (0.5)	(0.0, 2.9)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Headache[d]						
		Any	177	88 (49.7)	(42.1, 57.3)	187	59 (31.6)	(25.0, 38.7)
		Mild	177	39 (22.0)	(16.2, 28.9)	187	35 (18.7)	(13.4, 25.1)
		Moderate	177	43 (24.3)	(18.2, 31.3)	187	18 (9.6)	(5.8, 14.8)
		Severe	177	6 (3.4)	(1.3, 7.2)	187	6 (3.2)	(1.2, 6.9)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Chills[d]						
		Any	177	58 (32.8)	(25.9, 40.2)	187	9 (4.8)	(2.2, 8.9)
		Mild	177	34 (19.2)	(13.7, 25.8)	187	6 (3.2)	(1.2, 6.9)
		Moderate	177	22 (12.4)	(8.0, 18.2)	187	3 (1.6)	(0.3, 4.6)
		Severe	177	2 (1.1)	(0.1, 4.0)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Vomiting[e]						

14.78. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	177	6 (3.4)	(1.3, 7.2)	187	6 (3.2)	(1.2, 6.9)
		Mild	177	4 (2.3)	(0.6, 5.7)	187	4 (2.1)	(0.6, 5.4)
		Moderate	177	1 (0.6)	(0.0, 3.1)	187	2 (1.1)	(0.1, 3.8)
		Severe	177	1 (0.6)	(0.0, 3.1)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Diarrhea[f]						
		Any	177	18 (10.2)	(6.1, 15.6)	187	27 (14.4)	(9.7, 20.3)
		Mild	177	13 (7.3)	(4.0, 12.2)	187	18 (9.6)	(5.8, 14.8)
		Moderate	177	5 (2.8)	(0.9, 6.5)	187	7 (3.7)	(1.5, 7.6)
		Severe	177	0	(0.0, 2.1)	187	2 (1.1)	(0.1, 3.8)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		New or worsened muscle pain[d]						
		Any	177	71 (40.1)	(32.8, 47.7)	187	30 (16.0)	(11.1, 22.1)
		Mild	177	23 (13.0)	(8.4, 18.9)	187	16 (8.6)	(5.0, 13.5)
		Moderate	177	42 (23.7)	(17.7, 30.7)	187	14 (7.5)	(4.2, 12.2)
		Severe	177	6 (3.4)	(1.3, 7.2)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		New or worsened joint pain[d]						
		Any	177	48 (27.1)	(20.7, 34.3)	187	19 (10.2)	(6.2, 15.4)
		Mild	177	25 (14.1)	(9.4, 20.1)	187	12 (6.4)	(3.4, 10.9)
		Moderate	177	22 (12.4)	(8.0, 18.2)	187	7 (3.7)	(1.5, 7.6)
		Severe	177	1 (0.6)	(0.0, 3.1)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Any systemic event[g]	177	129 (72.9)	(65.7, 79.3)	187	96 (51.3)	(43.9, 58.7)
		Use of antipyretic or pain medication[h]	177	77 (43.5)	(36.1, 51.1)	187	38 (20.3)	(14.8, 26.8)
Negative	1	Fever						
		≥38.0°C	4701	121 (2.6)	(2.1, 3.1)	4690	29 (0.6)	(0.4, 0.9)
		≥38.0°C to 38.4°C	4701	92 (2.0)	(1.6, 2.4)	4690	18 (0.4)	(0.2, 0.6)
		>38.4°C to 38.9°C	4701	22 (0.5)	(0.3, 0.7)	4690	7 (0.1)	(0.1, 0.3)
		>38.9°C to 40.0°C	4701	7 (0.1)	(0.1, 0.3)	4690	4 (0.1)	(0.0, 0.2)
		>40.0°C	4701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)

14.78. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Fatigue[d]						
		Any	4701	2011 (42.8)	(41.4, 44.2)	4690	1368 (29.2)	(27.9, 30.5)
		Mild	4701	1138 (24.2)	(23.0, 25.5)	4690	829 (17.7)	(16.6, 18.8)
		Moderate	4701	832 (17.7)	(16.6, 18.8)	4690	519 (11.1)	(10.2, 12.0)
		Severe	4701	41 (0.9)	(0.6, 1.2)	4690	20 (0.4)	(0.3, 0.7)
		Grade 4	4701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Headache[d]						
		Any	4701	1680 (35.7)	(34.4, 37.1)	4690	1291 (27.5)	(26.3, 28.8)
		Mild	4701	1122 (23.9)	(22.7, 25.1)	4690	865 (18.4)	(17.3, 19.6)
		Moderate	4701	527 (11.2)	(10.3, 12.1)	4690	402 (8.6)	(7.8, 9.4)
		Severe	4701	31 (0.7)	(0.4, 0.9)	4690	24 (0.5)	(0.3, 0.8)
		Grade 4	4701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Chills[d]						
		Any	4701	549 (11.7)	(10.8, 12.6)	4690	260 (5.5)	(4.9, 6.2)
		Mild	4701	401 (8.5)	(7.7, 9.4)	4690	192 (4.1)	(3.5, 4.7)
		Moderate	4701	136 (2.9)	(2.4, 3.4)	4690	65 (1.4)	(1.1, 1.8)
		Severe	4701	12 (0.3)	(0.1, 0.4)	4690	3 (0.1)	(0.0, 0.2)
		Grade 4	4701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Vomiting[e]						
		Any	4701	39 (0.8)	(0.6, 1.1)	4690	41 (0.9)	(0.6, 1.2)
		Mild	4701	35 (0.7)	(0.5, 1.0)	4690	35 (0.7)	(0.5, 1.0)
		Moderate	4701	4 (0.1)	(0.0, 0.2)	4690	5 (0.1)	(0.0, 0.2)
		Severe	4701	0	(0.0, 0.1)	4690	1 (0.0)	(0.0, 0.1)
		Grade 4	4701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Diarrhea[f]						
		Any	4701	462 (9.8)	(9.0, 10.7)	4690	439 (9.4)	(8.5, 10.2)
		Mild	4701	375 (8.0)	(7.2, 8.8)	4690	362 (7.7)	(7.0, 8.5)
		Moderate	4701	80 (1.7)	(1.4, 2.1)	4690	75 (1.6)	(1.3, 2.0)
		Severe	4701	7 (0.1)	(0.1, 0.3)	4690	2 (0.0)	(0.0, 0.2)
		Grade 4	4701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		New or worsened muscle pain[d]						
		Any	4701	875 (18.6)	(17.5, 19.8)	4690	471 (10.0)	(9.2, 10.9)
		Mild	4701	515 (11.0)	(10.1, 11.9)	4690	327 (7.0)	(6.3, 7.7)

14.78. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Moderate	4701	347 (7.4)	(6.6, 8.2)	4690	139 (3.0)	(2.5, 3.5)
		Severe	4701	13 (0.3)	(0.1, 0.5)	4690	5 (0.1)	(0.0, 0.2)
		Grade 4	4701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		New or worsened joint pain[d]						
		Any	4701	480 (10.2)	(9.4, 11.1)	4690	282 (6.0)	(5.3, 6.7)
		Mild	4701	298 (6.3)	(5.7, 7.1)	4690	185 (3.9)	(3.4, 4.5)
		Moderate	4701	176 (3.7)	(3.2, 4.3)	4690	95 (2.0)	(1.6, 2.5)
		Severe	4701	6 (0.1)	(0.0, 0.3)	4690	2 (0.0)	(0.0, 0.2)
		Grade 4	4701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Any systemic event[g]	4701	2825 (60.1)	(58.7, 61.5)	4690	2223 (47.4)	(46.0, 48.8)
		Use of antipyretic or pain medication[h]	4701	1109 (23.6)	(22.4, 24.8)	4690	592 (12.6)	(11.7, 13.6)
	2	Fever						
		≥38.0°C	4368	645 (14.8)	(13.7, 15.9)	4334	13 (0.3)	(0.2, 0.5)
		≥38.0°C to 38.4°C	4368	399 (9.1)	(8.3, 10.0)	4334	7 (0.2)	(0.1, 0.3)
		>38.4°C to 38.9°C	4368	199 (4.6)	(4.0, 5.2)	4334	3 (0.1)	(0.0, 0.2)
		>38.9°C to 40.0°C	4368	46 (1.1)	(0.8, 1.4)	4334	3 (0.1)	(0.0, 0.2)
		>40.0°C	4368	1 (0.0)	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Fatigue[d]						
		Any	4368	2532 (58.0)	(56.5, 59.4)	4334	889 (20.5)	(19.3, 21.7)
		Mild	4368	923 (21.1)	(19.9, 22.4)	4334	489 (11.3)	(10.4, 12.3)
		Moderate	4368	1411 (32.3)	(30.9, 33.7)	4334	385 (8.9)	(8.1, 9.8)
		Severe	4368	197 (4.5)	(3.9, 5.2)	4334	15 (0.3)	(0.2, 0.6)
		Grade 4	4368	1 (0.0)	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Headache[d]						
		Any	4368	2118 (48.5)	(47.0, 50.0)	4334	875 (20.2)	(19.0, 21.4)
		Mild	4368	1130 (25.9)	(24.6, 27.2)	4334	574 (13.2)	(12.2, 14.3)
		Moderate	4368	889 (20.4)	(19.2, 21.6)	4334	281 (6.5)	(5.8, 7.3)
		Severe	4368	99 (2.3)	(1.8, 2.8)	4334	20 (0.5)	(0.3, 0.7)
		Grade 4	4368	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Chills[d]						
		Any	4368	1417 (32.4)	(31.1, 33.9)	4334	168 (3.9)	(3.3, 4.5)

14.78. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Mild	4368	690 (15.8)	(14.7, 16.9)	4334	132 (3.0)	(2.6, 3.6)
		Moderate	4368	637 (14.6)	(13.5, 15.7)	4334	34 (0.8)	(0.5, 1.1)
		Severe	4368	90 (2.1)	(1.7, 2.5)	4334	2 (0.0)	(0.0, 0.2)
		Grade 4	4368	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Vomiting[e]						
		Any	4368	69 (1.6)	(1.2, 2.0)	4334	31 (0.7)	(0.5, 1.0)
		Mild	4368	51 (1.2)	(0.9, 1.5)	4334	23 (0.5)	(0.3, 0.8)
		Moderate	4368	13 (0.3)	(0.2, 0.5)	4334	8 (0.2)	(0.1, 0.4)
		Severe	4368	5 (0.1)	(0.0, 0.3)	4334	0	(0.0, 0.1)
		Grade 4	4368	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Diarrhea[f]						
		Any	4368	410 (9.4)	(8.5, 10.3)	4334	289 (6.7)	(5.9, 7.5)
		Mild	4368	337 (7.7)	(6.9, 8.5)	4334	233 (5.4)	(4.7, 6.1)
		Moderate	4368	65 (1.5)	(1.2, 1.9)	4334	53 (1.2)	(0.9, 1.6)
		Severe	4368	8 (0.2)	(0.1, 0.4)	4334	3 (0.1)	(0.0, 0.2)
		Grade 4	4368	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		New or worsened muscle pain[d]						
		Any	4368	1548 (35.4)	(34.0, 36.9)	4334	319 (7.4)	(6.6, 8.2)
		Mild	4368	654 (15.0)	(13.9, 16.1)	4334	206 (4.8)	(4.1, 5.4)
		Moderate	4368	817 (18.7)	(17.6, 19.9)	4334	109 (2.5)	(2.1, 3.0)
		Severe	4368	77 (1.8)	(1.4, 2.2)	4334	4 (0.1)	(0.0, 0.2)
		Grade 4	4368	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		New or worsened joint pain[d]						
		Any	4368	962 (22.0)	(20.8, 23.3)	4334	209 (4.8)	(4.2, 5.5)
		Mild	4368	461 (10.6)	(9.7, 11.5)	4334	118 (2.7)	(2.3, 3.3)
		Moderate	4368	465 (10.6)	(9.7, 11.6)	4334	86 (2.0)	(1.6, 2.4)
		Severe	4368	36 (0.8)	(0.6, 1.1)	4334	5 (0.1)	(0.0, 0.3)
		Grade 4	4368	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Any systemic event[g]	4368	3137 (71.8)	(70.5, 73.1)	4334	1485 (34.3)	(32.9, 35.7)
		Use of antipyretic or pain medication[h]	4368	1845 (42.2)	(40.8, 43.7)	4334	470 (10.8)	(9.9, 11.8)

14.78. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any dose	Fever						
		≥38.0°C	4718	714 (15.1)	(14.1, 16.2)	4708	39 (0.8)	(0.6, 1.1)
		≥38.0°C to 38.4°C	4718	451 (9.6)	(8.7, 10.4)	4708	24 (0.5)	(0.3, 0.8)
		>38.4°C to 38.9°C	4718	213 (4.5)	(3.9, 5.1)	4708	9 (0.2)	(0.1, 0.4)
		>38.9°C to 40.0°C	4718	49 (1.0)	(0.8, 1.4)	4708	6 (0.1)	(0.0, 0.3)
		>40.0°C	4718	1 (0.0)	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Fatigue[d]						
		Any	4718	3069 (65.0)	(63.7, 66.4)	4708	1701 (36.1)	(34.8, 37.5)
		Mild	4718	1118 (23.7)	(22.5, 24.9)	4708	930 (19.8)	(18.6, 20.9)
		Moderate	4718	1719 (36.4)	(35.1, 37.8)	4708	740 (15.7)	(14.7, 16.8)
		Severe	4718	231 (4.9)	(4.3, 5.6)	4708	31 (0.7)	(0.4, 0.9)
		Grade 4	4718	1 (0.0)	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Headache[d]						
		Any	4718	2708 (57.4)	(56.0, 58.8)	4708	1650 (35.0)	(33.7, 36.4)
		Mild	4718	1410 (29.9)	(28.6, 31.2)	4708	1035 (22.0)	(20.8, 23.2)
		Moderate	4718	1174 (24.9)	(23.7, 26.1)	4708	572 (12.1)	(11.2, 13.1)
		Severe	4718	124 (2.6)	(2.2, 3.1)	4708	43 (0.9)	(0.7, 1.2)
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Chills[d]						
		Any	4718	1638 (34.7)	(33.4, 36.1)	4708	369 (7.8)	(7.1, 8.6)
		Mild	4718	832 (17.6)	(16.6, 18.8)	4708	278 (5.9)	(5.2, 6.6)
		Moderate	4718	706 (15.0)	(14.0, 16.0)	4708	86 (1.8)	(1.5, 2.3)
		Severe	4718	100 (2.1)	(1.7, 2.6)	4708	5 (0.1)	(0.0, 0.2)
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Vomiting[e]						
		Any	4718	103 (2.2)	(1.8, 2.6)	4708	67 (1.4)	(1.1, 1.8)
		Mild	4718	82 (1.7)	(1.4, 2.2)	4708	53 (1.1)	(0.8, 1.5)
		Moderate	4718	16 (0.3)	(0.2, 0.6)	4708	13 (0.3)	(0.1, 0.5)
		Severe	4718	5 (0.1)	(0.0, 0.2)	4708	1 (0.0)	(0.0, 0.1)
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Diarrhea[f]						
		Any	4718	735 (15.6)	(14.6, 16.6)	4708	629 (13.4)	(12.4, 14.4)
		Mild	4718	586 (12.4)	(11.5, 13.4)	4708	503 (10.7)	(9.8, 11.6)

14.78. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Moderate	4718	134 (2.8)	(2.4, 3.4)	4708	121 (2.6)	(2.1, 3.1)
		Severe	4718	15 (0.3)	(0.2, 0.5)	4708	5 (0.1)	(0.0, 0.2)
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		New or worsened muscle pain[d]						
		Any	4718	1901 (40.3)	(38.9, 41.7)	4708	658 (14.0)	(13.0, 15.0)
		Mild	4718	802 (17.0)	(15.9, 18.1)	4708	423 (9.0)	(8.2, 9.8)
		Moderate	4718	1011 (21.4)	(20.3, 22.6)	4708	226 (4.8)	(4.2, 5.5)
		Severe	4718	88 (1.9)	(1.5, 2.3)	4708	9 (0.2)	(0.1, 0.4)
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		New or worsened joint pain[d]						
		Any	4718	1179 (25.0)	(23.8, 26.3)	4708	422 (9.0)	(8.2, 9.8)
		Mild	4718	560 (11.9)	(11.0, 12.8)	4708	246 (5.2)	(4.6, 5.9)
		Moderate	4718	577 (12.2)	(11.3, 13.2)	4708	169 (3.6)	(3.1, 4.2)
		Severe	4718	42 (0.9)	(0.6, 1.2)	4708	7 (0.1)	(0.1, 0.3)
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Any systemic event[g]	4718	3725 (79.0)	(77.8, 80.1)	4708	2609 (55.4)	(54.0, 56.8)
		Use of antipyretic or pain medication[h]	4718	2209 (46.8)	(45.4, 48.3)	4708	881 (18.7)	(17.6, 19.9)

14.78. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. 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: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
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14.79. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	≥38.0°C	54	1 (1.9)	(0.0, 9.9)	56	4 (7.1)	(2.0, 17.3)
	≥38.0°C to 38.4°C	54	1 (1.9)	(0.0, 9.9)	56	2 (3.6)	(0.4, 12.3)
	>38.4°C to 38.9°C	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	>38.9°C to 40.0°C	54	0	(0.0, 6.6)	56	2 (3.6)	(0.4, 12.3)
	>40.0°C	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Fatigue[d]						
	Any	54	22 (40.7)	(27.6, 55.0)	56	15 (26.8)	(15.8, 40.3)
	Mild	54	15 (27.8)	(16.5, 41.6)	56	9 (16.1)	(7.6, 28.3)
	Moderate	54	7 (13.0)	(5.4, 24.9)	56	5 (8.9)	(3.0, 19.6)
	Severe	54	0	(0.0, 6.6)	56	1 (1.8)	(0.0, 9.6)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Headache[d]						
	Any	54	11 (20.4)	(10.6, 33.5)	56	18 (32.1)	(20.3, 46.0)
	Mild	54	7 (13.0)	(5.4, 24.9)	56	10 (17.9)	(8.9, 30.4)
	Moderate	54	4 (7.4)	(2.1, 17.9)	56	7 (12.5)	(5.2, 24.1)
	Severe	54	0	(0.0, 6.6)	56	1 (1.8)	(0.0, 9.6)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Chills[d]						
	Any	54	6 (11.1)	(4.2, 22.6)	56	5 (8.9)	(3.0, 19.6)
	Mild	54	5 (9.3)	(3.1, 20.3)	56	4 (7.1)	(2.0, 17.3)
	Moderate	54	1 (1.9)	(0.0, 9.9)	56	1 (1.8)	(0.0, 9.6)
	Severe	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Vomiting[e]						
	Any	54	1 (1.9)	(0.0, 9.9)	56	3 (5.4)	(1.1, 14.9)
	Mild	54	1 (1.9)	(0.0, 9.9)	56	1 (1.8)	(0.0, 9.6)
	Moderate	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Severe	54	0	(0.0, 6.6)	56	2 (3.6)	(0.4, 12.3)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Diarrhea[f]						
	Any	54	5 (9.3)	(3.1, 20.3)	56	8 (14.3)	(6.4, 26.2)
	Mild	54	5 (9.3)	(3.1, 20.3)	56	6 (10.7)	(4.0, 21.9)

14.79. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	54	0	(0.0, 6.6)	56	1 (1.8)	(0.0, 9.6)
	Severe	54	0	(0.0, 6.6)	56	1 (1.8)	(0.0, 9.6)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	New or worsened muscle pain[d]						
	Any	54	9 (16.7)	(7.9, 29.3)	56	10 (17.9)	(8.9, 30.4)
	Mild	54	7 (13.0)	(5.4, 24.9)	56	7 (12.5)	(5.2, 24.1)
	Moderate	54	2 (3.7)	(0.5, 12.7)	56	3 (5.4)	(1.1, 14.9)
	Severe	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	New or worsened joint pain[d]						
	Any	54	5 (9.3)	(3.1, 20.3)	56	7 (12.5)	(5.2, 24.1)
	Mild	54	5 (9.3)	(3.1, 20.3)	56	4 (7.1)	(2.0, 17.3)
	Moderate	54	0	(0.0, 6.6)	56	3 (5.4)	(1.1, 14.9)
	Severe	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Any systemic event[g]	54	32 (59.3)	(45.0, 72.4)	56	32 (57.1)	(43.2, 70.3)
	Use of antipyretic or pain medication[h]	54	7 (13.0)	(5.4, 24.9)	56	8 (14.3)	(6.4, 26.2)
2	Fever						
	≥38.0°C	60	9 (15.0)	(7.1, 26.6)	62	5 (8.1)	(2.7, 17.8)
	≥38.0°C to 38.4°C	60	4 (6.7)	(1.8, 16.2)	62	5 (8.1)	(2.7, 17.8)
	>38.4°C to 38.9°C	60	4 (6.7)	(1.8, 16.2)	62	0	(0.0, 5.8)
	>38.9°C to 40.0°C	60	1 (1.7)	(0.0, 8.9)	62	0	(0.0, 5.8)
	>40.0°C	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Fatigue[d]						
	Any	60	24 (40.0)	(27.6, 53.5)	62	12 (19.4)	(10.4, 31.4)
	Mild	60	12 (20.0)	(10.8, 32.3)	62	5 (8.1)	(2.7, 17.8)
	Moderate	60	9 (15.0)	(7.1, 26.6)	62	7 (11.3)	(4.7, 21.9)
	Severe	60	3 (5.0)	(1.0, 13.9)	62	0	(0.0, 5.8)
	Grade 4	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Headache[d]						
	Any	60	18 (30.0)	(18.8, 43.2)	62	12 (19.4)	(10.4, 31.4)
	Mild	60	8 (13.3)	(5.9, 24.6)	62	8 (12.9)	(5.7, 23.9)
	Moderate	60	8 (13.3)	(5.9, 24.6)	62	4 (6.5)	(1.8, 15.7)
	Severe	60	2 (3.3)	(0.4, 11.5)	62	0	(0.0, 5.8)

14.79. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Grade 4	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Chills[d]						
	Any	60	14 (23.3)	(13.4, 36.0)	62	4 (6.5)	(1.8, 15.7)
	Mild	60	5 (8.3)	(2.8, 18.4)	62	3 (4.8)	(1.0, 13.5)
	Moderate	60	8 (13.3)	(5.9, 24.6)	62	1 (1.6)	(0.0, 8.7)
	Severe	60	1 (1.7)	(0.0, 8.9)	62	0	(0.0, 5.8)
	Grade 4	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Vomiting[e]						
	Any	60	2 (3.3)	(0.4, 11.5)	62	2 (3.2)	(0.4, 11.2)
	Mild	60	1 (1.7)	(0.0, 8.9)	62	1 (1.6)	(0.0, 8.7)
	Moderate	60	1 (1.7)	(0.0, 8.9)	62	1 (1.6)	(0.0, 8.7)
	Severe	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Grade 4	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Diarrhea[f]						
	Any	60	4 (6.7)	(1.8, 16.2)	62	9 (14.5)	(6.9, 25.8)
	Mild	60	1 (1.7)	(0.0, 8.9)	62	6 (9.7)	(3.6, 19.9)
	Moderate	60	2 (3.3)	(0.4, 11.5)	62	3 (4.8)	(1.0, 13.5)
	Severe	60	1 (1.7)	(0.0, 8.9)	62	0	(0.0, 5.8)
	Grade 4	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	New or worsened muscle pain[d]						
	Any	60	10 (16.7)	(8.3, 28.5)	62	5 (8.1)	(2.7, 17.8)
	Mild	60	5 (8.3)	(2.8, 18.4)	62	1 (1.6)	(0.0, 8.7)
	Moderate	60	5 (8.3)	(2.8, 18.4)	62	4 (6.5)	(1.8, 15.7)
	Severe	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Grade 4	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	New or worsened joint pain[d]						
	Any	60	10 (16.7)	(8.3, 28.5)	62	5 (8.1)	(2.7, 17.8)
	Mild	60	4 (6.7)	(1.8, 16.2)	62	1 (1.6)	(0.0, 8.7)
	Moderate	60	6 (10.0)	(3.8, 20.5)	62	4 (6.5)	(1.8, 15.7)
	Severe	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Grade 4	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Any systemic event[g]	60	36 (60.0)	(46.5, 72.4)	62	23 (37.1)	(25.2, 50.3)
	Use of antipyretic or pain medication[h]	60	16 (26.7)	(16.1, 39.7)	62	7 (11.3)	(4.7, 21.9)

14.79. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Any dose	Fever						
	≥38.0°C	72	9 (12.5)	(5.9, 22.4)	74	7 (9.5)	(3.9, 18.5)
	≥38.0°C to 38.4°C	72	4 (5.6)	(1.5, 13.6)	74	5 (6.8)	(2.2, 15.1)
	>38.4°C to 38.9°C	72	4 (5.6)	(1.5, 13.6)	74	0	(0.0, 4.9)
	>38.9°C to 40.0°C	72	1 (1.4)	(0.0, 7.5)	74	2 (2.7)	(0.3, 9.4)
	>40.0°C	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	Fatigue[d]						
	Any	72	34 (47.2)	(35.3, 59.3)	74	20 (27.0)	(17.4, 38.6)
	Mild	72	18 (25.0)	(15.5, 36.6)	74	8 (10.8)	(4.8, 20.2)
	Moderate	72	13 (18.1)	(10.0, 28.9)	74	11 (14.9)	(7.7, 25.0)
	Severe	72	3 (4.2)	(0.9, 11.7)	74	1 (1.4)	(0.0, 7.3)
	Grade 4	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	Headache[d]						
	Any	72	24 (33.3)	(22.7, 45.4)	74	23 (31.1)	(20.8, 42.9)
	Mild	72	12 (16.7)	(8.9, 27.3)	74	13 (17.6)	(9.7, 28.2)
	Moderate	72	10 (13.9)	(6.9, 24.1)	74	9 (12.2)	(5.7, 21.8)
	Severe	72	2 (2.8)	(0.3, 9.7)	74	1 (1.4)	(0.0, 7.3)
	Grade 4	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	Chills[d]						
	Any	72	17 (23.6)	(14.4, 35.1)	74	9 (12.2)	(5.7, 21.8)
	Mild	72	7 (9.7)	(4.0, 19.0)	74	7 (9.5)	(3.9, 18.5)
	Moderate	72	9 (12.5)	(5.9, 22.4)	74	2 (2.7)	(0.3, 9.4)
	Severe	72	1 (1.4)	(0.0, 7.5)	74	0	(0.0, 4.9)
	Grade 4	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	Vomiting[e]						
	Any	72	3 (4.2)	(0.9, 11.7)	74	3 (4.1)	(0.8, 11.4)
	Mild	72	2 (2.8)	(0.3, 9.7)	74	1 (1.4)	(0.0, 7.3)
	Moderate	72	1 (1.4)	(0.0, 7.5)	74	0	(0.0, 4.9)
	Severe	72	0	(0.0, 5.0)	74	2 (2.7)	(0.3, 9.4)
	Grade 4	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	Diarrhea[f]						
	Any	72	8 (11.1)	(4.9, 20.7)	74	15 (20.3)	(11.8, 31.2)
	Mild	72	5 (6.9)	(2.3, 15.5)	74	10 (13.5)	(6.7, 23.5)
	Moderate	72	2 (2.8)	(0.3, 9.7)	74	4 (5.4)	(1.5, 13.3)
	Severe	72	1 (1.4)	(0.0, 7.5)	74	1 (1.4)	(0.0, 7.3)

14.79. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Grade 4	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	New or worsened muscle pain[d]						
	Any	72	17 (23.6)	(14.4, 35.1)	74	14 (18.9)	(10.7, 29.7)
	Mild	72	11 (15.3)	(7.9, 25.7)	74	8 (10.8)	(4.8, 20.2)
	Moderate	72	6 (8.3)	(3.1, 17.3)	74	6 (8.1)	(3.0, 16.8)
	Severe	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	Grade 4	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	New or worsened joint pain[d]						
	Any	72	13 (18.1)	(10.0, 28.9)	74	11 (14.9)	(7.7, 25.0)
	Mild	72	7 (9.7)	(4.0, 19.0)	74	5 (6.8)	(2.2, 15.1)
	Moderate	72	6 (8.3)	(3.1, 17.3)	74	6 (8.1)	(3.0, 16.8)
	Severe	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	Grade 4	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	Any systemic event[g]	72	50 (69.4)	(57.5, 79.8)	74	39 (52.7)	(40.7, 64.4)
	Use of antipyretic or pain medication[h]	72	20 (27.8)	(17.9, 39.6)	74	12 (16.2)	(8.7, 26.6)

Abbreviation: HIV = human immunodeficiency virus.
Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. 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: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adce s020 se hiv p3 saf

14.80. Onset Days for Systemic Events (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
1	Fever (≥38.0°C)		
	n[a]	1	4
	Mean (SD)	2.0 (NE)	2.5 (2.38)
	Median	2.0	1.5
	Min, max	(2, 2)	(1, 6)
	Fatigue		
	n[a]	22	15
	Mean (SD)	1.9 (0.71)	2.8 (1.97)
	Median	2.0	2.0
	Min, max	(1, 4)	(1, 7)
	Headache		
	n[a]	11	18
	Mean (SD)	2.0 (1.34)	2.6 (1.98)
	Median	1.0	1.5
	Min, max	(1, 4)	(1, 7)
	Chills		
	n[a]	6	5
	Mean (SD)	2.2 (1.17)	2.2 (2.68)
	Median	2.0	1.0
	Min, max	(1, 4)	(1, 7)
	Vomiting		
	n[a]	1	3
	Mean (SD)	3.0 (NE)	2.0 (1.00)
	Median	3.0	2.0
	Min, max	(3, 3)	(1, 3)
	Diarrhea		
	n[a]	5	8
	Mean (SD)	4.0 (2.24)	4.0 (2.00)
	Median	4.0	3.5
	Min, max	(1, 7)	(2, 7)
	New or worsened muscle pain		
	n[a]	9	10
	Mean (SD)	3.2 (2.05)	2.3 (1.34)
	Median	2.0	2.0

14.80. Onset Days for Systemic Events (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
	Min, max	(1, 7)	(1, 5)
	New or worsened joint pain		
	n[a]	5	7
	Mean (SD)	2.8 (1.79)	3.0 (2.16)
	Median	2.0	2.0
	Min, max	(2, 6)	(1, 7)
	Any systemic event[b]		
	n[a]	32	32
	Mean (SD)	2.0 (1.40)	2.6 (1.76)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Use of antipyretic or pain medication		
	n[a]	7	8
	Mean (SD)	2.1 (0.38)	2.3 (1.49)
	Median	2.0	2.0
	Min, max	(2, 3)	(1, 5)
2	Fever (≥38.0°C)		
	n[a]	9	5
	Mean (SD)	2.6 (1.74)	3.8 (2.39)
	Median	2.0	4.0
	Min, max	(1, 7)	(1, 7)
	Fatigue		
	n[a]	24	12
	Mean (SD)	2.3 (1.40)	2.3 (1.37)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 6)
	Headache		
	n[a]	18	12
	Mean (SD)	2.6 (1.69)	3.9 (2.31)
	Median	2.0	4.0
	Min, max	(1, 7)	(1, 7)
	Chills		
	n[a]	14	4
	Mean (SD)	2.9 (1.61)	4.3 (2.63)
	Median	2.0	4.0

14.80. Onset Days for Systemic Events (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
	Min, max	(2, 7)	(2, 7)
	Vomiting		
	n[a]	2	2
	Mean (SD)	1.5 (0.71)	2.0 (1.41)
	Median	1.5	2.0
	Min, max	(1, 2)	(1, 3)
	Diarrhea		
	n[a]	4	9
	Mean (SD)	3.8 (2.50)	3.1 (1.96)
	Median	3.5	3.0
	Min, max	(1, 7)	(1, 7)
	New or worsened muscle pain		
	n[a]	10	5
	Mean (SD)	1.9 (0.57)	3.8 (2.49)
	Median	2.0	2.0
	Min, max	(1, 3)	(2, 7)
	New or worsened joint pain		
	n[a]	10	5
	Mean (SD)	3.1 (2.23)	4.6 (2.07)
	Median	2.0	5.0
	Min, max	(1, 7)	(2, 7)
	Any systemic event[b]		
	n[a]	36	23
	Mean (SD)	2.5 (1.63)	2.2 (1.37)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 5)
	Use of antipyretic or pain medication		
	n[a]	16	7
	Mean (SD)	2.6 (1.71)	4.1 (2.12)
	Median	2.0	5.0
	Min, max	(1, 7)	(2, 7)

14.80. Onset Days for Systemic Events (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**

Abbreviations: HIV = human immunodeficiency virus; 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: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_s060_se_onset_hiv_p3_saf

14.81. Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
1	Fever (≥38.0°C)		
	n[a]	1	4
	Mean (SD)	1.0 (NE)	1.8 (0.96)
	Median	1.0	1.5
	Min, max	(1, 1)	(1, 3)
	Fatigue		
	n[a]	22	15
	Mean (SD)	2.5 (2.11)	3.0 (2.07)
	Median	1.5	3.0
	Min, max	(1, 9)	(1, 7)
	Headache		
	n[a]	11	18
	Mean (SD)	3.0 (2.65)	2.9 (2.50)
	Median	1.0	2.0
	Min, max	(1, 7)	(1, 7)
	Unknown[b]	0	1
	Chills		
	n[a]	6	5
	Mean (SD)	2.2 (2.68)	1.8 (0.50)
	Median	1.0	2.0
	Min, max	(1, 7)	(1, 2)
	Unknown[b]	1	1
	Vomiting		
	n[a]	1	3
	Mean (SD)	1.0 (NE)	2.0 (1.00)
	Median	1.0	2.0
	Min, max	(1, 1)	(1, 3)
	Diarrhea		
	n[a]	5	8
	Mean (SD)	2.0 (1.73)	1.5 (0.76)
	Median	1.0	1.0
	Min, max	(1, 5)	(1, 3)
	New or worsened muscle pain		
	n[a]	9	10

14.81. Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
	Mean (SD)	1.3 (0.50)	1.8 (1.93)
	Median	1.0	1.0
	Min, max	(1, 2)	(1, 7)
	New or worsened joint pain		
	n[a]	5	7
	Mean (SD)	1.4 (0.55)	2.0 (1.91)
	Median	1.0	1.0
	Min, max	(1, 2)	(1, 6)
	Use of antipyretic or pain medication		
	n[a]	7	8
	Mean (SD)	2.4 (2.15)	2.3 (1.91)
	Median	1.0	1.0
	Min, max	(1, 6)	(1, 6)
2	Fever (≥38.0°C)		
	n[a]	9	5
	Mean (SD)	1.4 (0.88)	1.8 (1.30)
	Median	1.0	1.0
	Min, max	(1, 3)	(1, 4)
	Fatigue		
	n[a]	24	12
	Mean (SD)	3.3 (2.63)	2.9 (1.92)
	Median	2.0	2.0
	Min, max	(1, 10)	(1, 6)
	Unknown[b]	0	1
	Headache		
	n[a]	18	12
	Mean (SD)	2.1 (1.45)	2.3 (1.56)
	Median	1.5	2.0
	Min, max	(1, 5)	(1, 5)
	Unknown[b]	0	1
	Chills		
	n[a]	14	4
	Mean (SD)	1.2 (0.43)	1.3 (0.50)
	Median	1.0	1.0
	Min, max	(1, 2)	(1, 2)

14.81. Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
	Vomiting		
	n[a]	2	2
	Mean (SD)	1.0 (0.00)	5.5 (2.12)
	Median	1.0	5.5
	Min, max	(1, 1)	(4, 7)
	Diarrhea		
	n[a]	4	9
	Mean (SD)	2.3 (2.50)	2.1 (2.26)
	Median	1.0	1.0
	Min, max	(1, 6)	(1, 8)
	New or worsened muscle pain		
	n[a]	10	5
	Mean (SD)	1.9 (1.60)	2.2 (1.64)
	Median	1.0	2.0
	Min, max	(1, 6)	(1, 5)
	New or worsened joint pain		
	n[a]	10	5
	Mean (SD)	1.5 (0.97)	1.2 (0.45)
	Median	1.0	1.0
	Min, max	(1, 4)	(1, 2)
	Use of antipyretic or pain medication		
	n[a]	16	7
	Mean (SD)	2.0 (2.00)	1.6 (1.51)
	Median	1.0	1.0
	Min, max	(1, 6)	(1, 5)

Abbreviations: HIV = human immunodeficiency virus; 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. For symptoms that are ongoing at the time of the next dose, stop date is computed as the next dose date.
Note: Events and use of antipyretic or pain medication were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each 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.
b. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adcevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adce s040 se dur hiv p3 saf

Adverse Events

14.82. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12995)	Placebo (N[a]=13026)
Adverse Event	n[b] (%)	n[b] (%)
Any event	4233 (32.6)	1871 (14.4)
Related[c]	3480 (26.8)	882 (6.8)
Severe	154 (1.2)	74 (0.6)
Life-threatening	8 (0.1)	11 (0.1)
Any serious adverse event	52 (0.4)	49 (0.4)
Related[c]	2 (0.0)	0
Severe	27 (0.2)	31 (0.2)
Life-threatening	8 (0.1)	11 (0.1)
Any adverse event leading to withdrawal	19 (0.1)	20 (0.2)
Related[c]	9 (0.1)	7 (0.1)
Severe	5 (0.0)	4 (0.0)
Life-threatening	0	3 (0.0)
Death	0	2 (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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s091_age_pd2_p3_saf

14.83. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=8931)	Placebo (N[a]=8895)
Adverse Event	n[b] (%)	n[b] (%)
Any event	2384 (26.7)	1177 (13.2)
Related[c]	1761 (19.7)	429 (4.8)
Severe	108 (1.2)	76 (0.9)
Life-threatening	13 (0.1)	15 (0.2)
Any serious adverse event	75 (0.8)	67 (0.8)
Related[c]	1 (0.0)	0
Severe	44 (0.5)	35 (0.4)
Life-threatening	13 (0.1)	15 (0.2)
Any adverse event leading to withdrawal	13 (0.1)	16 (0.2)
Related[c]	4 (0.0)	4 (0.0)
Severe	5 (0.1)	6 (0.1)
Life-threatening	3 (0.0)	4 (0.0)
Death	3 (0.0)	3 (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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s091_age_pd2_p3_saf

14.84. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=100) n[b] (%)	Placebo (N[a]=100) n[b] (%)
Any event	26 (26.0)	13 (13.0)
Related[c]	19 (19.0)	3 (3.0)
Severe	1 (1.0)	0
Life-threatening	0	0
Any serious adverse event	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Any adverse event leading to withdrawal	1 (1.0)	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

Abbreviation: HIV = human immunodeficiency virus.
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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s091_all_hiv_p3_saf

14.85. Tier 2 Adverse Events Reported From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)		Difference	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	%[d]	(95% CI[c])
GASTROINTESTINAL DISORDERS						
Nausea	274 (1.2)	(1.1, 1.4)	87 (0.4)	(0.3, 0.5)	0.9	(0.7, 1.0)
Diarrhoea	248 (1.1)	(1.0, 1.3)	188 (0.9)	(0.7, 1.0)	0.3	(0.1, 0.5)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS						
Injection site pain	2915 (13.3)	(12.8, 13.8)	397 (1.8)	(1.6, 2.0)	11.5	(11.0, 12.0)
Pyrexia	1517 (6.9)	(6.6, 7.3)	77 (0.4)	(0.3, 0.4)	6.6	(6.2, 6.9)
Fatigue	1463 (6.7)	(6.3, 7.0)	379 (1.7)	(1.6, 1.9)	4.9	(4.6, 5.3)
Chills	1365 (6.2)	(5.9, 6.6)	120 (0.5)	(0.5, 0.7)	5.7	(5.3, 6.0)
Pain	628 (2.9)	(2.6, 3.1)	61 (0.3)	(0.2, 0.4)	2.6	(2.4, 2.8)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS						
Myalgia	1239 (5.7)	(5.3, 6.0)	168 (0.8)	(0.7, 0.9)	4.9	(4.6, 5.2)
Arthralgia	268 (1.2)	(1.1, 1.4)	102 (0.5)	(0.4, 0.6)	0.8	(0.6, 0.9)
NERVOUS SYSTEM DISORDERS						
Headache	1339 (6.1)	(5.8, 6.4)	424 (1.9)	(1.8, 2.1)	4.2	(3.8, 4.5)

14.85. Tier 2 Adverse Events Reported From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)		Difference	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	%[d]	(95% CI[e])

Note: MedDRA (v23.1) coding dictionary applied.
Note: Tier 2 events are "common" adverse events with an incidence rate ≥1.0% in any vaccine group (preferred term level). No Tier 1 events were identified at this stage for this program.
Note: The 95% confidence interval quantifies the precision of the risk difference estimate. Confidence intervals are not adjusted for multiplicity. They should only be used to identify potentially important adverse events.
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 adverse event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Difference in proportions, expressed as a percentage (BNT162b2 [30 µg] - placebo).
e. 2-Sided CI, based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_vax_tier2_p3_saf

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	4233 (32.6)	(31.8, 33.4)	1871 (14.4)	(13.8, 15.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	80 (0.6)	(0.5, 0.8)	10 (0.1)	(0.0, 0.1)
Lymphadenopathy	67 (0.5)	(0.4, 0.7)	4 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaemia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Lymph node pain	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood loss anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Neutropenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypochromic anaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Leukopenia	0	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy mediastinal	0	(0.0, 0.0)	0	(0.0, 0.0)
Lymphopenia	0	(0.0, 0.0)	0	(0.0, 0.0)
Splenomegaly	0	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	27 (0.2)	(0.1, 0.3)	24 (0.2)	(0.1, 0.3)
Palpitations	3 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Tachycardia	10 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Atrial fibrillation	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute myocardial infarction	2 (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)
Cardiac failure congestive	0	(0.0, 0.0)	0	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Angina unstable	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)
Left ventricular hypertrophy	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)
Angina pectoris	0	(0.0, 0.0)	0	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Aortic valve incompetence	0	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arteriospasm coronary	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac arrest	0	(0.0, 0.0)	0	(0.0, 0.0)
Mitral valve prolapse	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial ischaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tricuspid valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular extrasystoles	0	(0.0, 0.0)	0	(0.0, 0.0)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Atrioventricular block complete	0	(0.0, 0.0)	0	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block left	0	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure acute	0	(0.0, 0.0)	0	(0.0, 0.0)
Cardiovascular disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	0	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Junctional ectopic tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left atrial enlargement	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left ventricular dysfunction	0	(0.0, 0.0)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Pericarditis	0	(0.0, 0.0)	0	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular arrhythmia	0	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Congenital bladder neck obstruction	0	(0.0, 0.0)	0	(0.0, 0.0)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Heart disease congenital	0	(0.0, 0.0)	0	(0.0, 0.0)
Type V hyperlipidaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	36 (0.3)	(0.2, 0.4)	20 (0.2)	(0.1, 0.2)
Vertigo	10 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Ear pain	9 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tinnitus	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Vertigo positional	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerumen impaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meniere's disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergic otitis media	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness	0	(0.0, 0.0)	0	(0.0, 0.0)
Deafness neurosensory	0	(0.0, 0.0)	0	(0.0, 0.0)
Ear pruritus	0	(0.0, 0.0)	0	(0.0, 0.0)
Eustachian tube dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sudden hearing loss	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	7 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypothyroidism	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypogonadism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid mass	0	(0.0, 0.0)	0	(0.0, 0.0)
Autoimmune thyroiditis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Goitre	0	(0.0, 0.0)	0	(0.0, 0.0)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	34 (0.3)	(0.2, 0.4)	22 (0.2)	(0.1, 0.3)
Cataract	0	(0.0, 0.0)	0	(0.0, 0.0)
Eye pain	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Eye irritation	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vision blurred	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chalazion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vitreous detachment	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blepharitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctivitis allergic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Keratitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ocular hyperaemia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Glaucoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Retinal detachment	0	(0.0, 0.0)	0	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenopia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blepharospasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amaurosis fugax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Conjunctival hyperaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dacryostenosis acquired	0	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic retinopathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Episcleritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye inflammation	0	(0.0, 0.0)	0	(0.0, 0.0)
Eye swelling	0	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid haematoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Iritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Ocular discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Scleral discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulcerative keratitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual acuity reduced	0	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	440 (3.4)	(3.1, 3.7)	288 (2.2)	(2.0, 2.5)
Diarrhoea	157 (1.2)	(1.0, 1.4)	117 (0.9)	(0.7, 1.1)
Nausea	184 (1.4)	(1.2, 1.6)	61 (0.5)	(0.4, 0.6)
Vomiting	54 (0.4)	(0.3, 0.5)	22 (0.2)	(0.1, 0.3)
Toothache	14 (0.1)	(0.1, 0.2)	16 (0.1)	(0.1, 0.2)
Abdominal pain upper	18 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.1)
Abdominal pain	11 (0.1)	(0.0, 0.2)	14 (0.1)	(0.1, 0.2)
Gastrooesophageal reflux disease	5 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Dyspepsia	7 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Odynophagia	9 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Constipation	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dental caries	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Gastritis	2 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Haemorrhoids	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Aphthous ulcer	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal discomfort	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal distension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flatulence	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Irritable bowel syndrome	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dry mouth	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Large intestine polyp	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abdominal pain lower	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dysphagia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Inguinal hernia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Stomatitis	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Diverticulum	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gastrointestinal disorder	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hiatus hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cheilitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food poisoning	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lip swelling	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rectal haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Swollen tongue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Umbilical hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis microscopic	0	(0.0, 0.0)	0	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glossodynia	0	(0.0, 0.0)	0	(0.0, 0.0)
Haematochezia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parotid duct obstruction	0	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal adhesions	0	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal rigidity	0	(0.0, 0.0)	0	(0.0, 0.0)
Abnormal faeces	0	(0.0, 0.0)	0	(0.0, 0.0)
Acute abdomen	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anal pruritus	0	(0.0, 0.0)	0	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Angular cheilitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Appendix disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic gastritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Colitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Colitis ulcerative	0	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal haemorrhagic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Epiploic appendagitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Femoral hernia	0	(0.0, 0.0)	0	(0.0, 0.0)
Frequent bowel movements	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastric polyps	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastric ulcer	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal mucosa hyperaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Impaired gastric emptying	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 obstruction	0	(0.0, 0.0)	0	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal spasm	0	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal ulcer	0	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal varices haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophagitis	0	(0.0, 0.0)	0	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Oral discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Oral lichenoid reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peptic ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Proctalgia	0	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland mucocoele	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Teething	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discolouration	0	(0.0, 0.0)	0	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue oedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Tongue pruritus	0	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	0	(0.0, 0.0)	0	(0.0, 0.0)
Tooth disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Varices oesophageal	0	(0.0, 0.0)	0	(0.0, 0.0)
Volvulus	0	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3161 (24.3)	(23.6, 25.1)	681 (5.2)	(4.9, 5.6)
Injection site pain	1929 (14.8)	(14.2, 15.5)	284 (2.2)	(1.9, 2.4)
Fatigue	1012 (7.8)	(7.3, 8.3)	270 (2.1)	(1.8, 2.3)
Pyrexia	1117 (8.6)	(8.1, 9.1)	54 (0.4)	(0.3, 0.5)
Chills	966 (7.4)	(7.0, 7.9)	77 (0.6)	(0.5, 0.7)
Pain	430 (3.3)	(3.0, 3.6)	40 (0.3)	(0.2, 0.4)
Injection site erythema	119 (0.9)	(0.8, 1.1)	18 (0.1)	(0.1, 0.2)
Injection site swelling	86 (0.7)	(0.5, 0.8)	12 (0.1)	(0.0, 0.2)
Malaise	86 (0.7)	(0.5, 0.8)	11 (0.1)	(0.0, 0.2)
Asthenia	46 (0.4)	(0.3, 0.5)	18 (0.1)	(0.1, 0.2)
Injection site pruritus	23 (0.2)	(0.1, 0.3)	4 (0.0)	(0.0, 0.1)
Injection site bruising	8 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Influenza like illness	15 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Chest pain	10 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Injection site warmth	8 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Axillary pain	9 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site induration	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site oedema	10 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Oedema peripheral	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Peripheral swelling	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Chest discomfort	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Feeling hot	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site discomfort	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site reaction	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site mass	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling abnormal	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discolouration	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site nodule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sensation of foreign body	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Face oedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Medical device pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sluggishness	0	(0.0, 0.0)	0	(0.0, 0.0)
Thirst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Application site pruritus	0	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Capsular contracture associated with breast implant	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Drug withdrawal syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
Effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Gait disturbance	0	(0.0, 0.0)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Induration	0	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site irritation	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site urticaria	0	(0.0, 0.0)	0	(0.0, 0.0)
Mass	0	(0.0, 0.0)	0	(0.0, 0.0)
Medical device site granuloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mucosal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temperature intolerance	0	(0.0, 0.0)	0	(0.0, 0.0)
Therapeutic response unexpected	0	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site swelling	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)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cholelithiasis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cholecystitis acute	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Biliary colic	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 dyskinesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Cirrhosis alcoholic	0	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Nonalcoholic fatty liver disease	0	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	19 (0.1)	(0.1, 0.2)	15 (0.1)	(0.1, 0.2)
Seasonal allergy	7 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Drug hypersensitivity	7 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Food allergy	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Hypersensitivity	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Allergy to arthropod bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	0	(0.0, 0.0)
Milk allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	190 (1.5)	(1.3, 1.7)	218 (1.7)	(1.5, 1.9)
Urinary tract infection	32 (0.2)	(0.2, 0.3)	25 (0.2)	(0.1, 0.3)
Tooth infection	9 (0.1)	(0.0, 0.1)	18 (0.1)	(0.1, 0.2)
Sinusitis	8 (0.1)	(0.0, 0.1)	15 (0.1)	(0.1, 0.2)
Cellulitis	7 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Herpes zoster	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Ear infection	6 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Conjunctivitis	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Hordeolum	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Cystitis	2 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Gastroenteritis	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Rhinitis	5 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Tooth abscess	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diverticulitis	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Otitis externa	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Otitis media	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Appendicitis	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gingivitis	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Oral herpes	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute sinusitis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Pneumonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin infection	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vaginal infection	0	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Onychomycosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Periodontitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Folliculitis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Furuncle	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Localised infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Nasopharyngitis	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Otitis media acute	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Paronychia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Genital herpes	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Herpes simplex	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Influenza	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea versicolour	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bacterial vulvovaginitis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bronchitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Chronic sinusitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye infection	0	(0.0, 0.0)	0	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gingival abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Impetigo	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Infected bite	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parotitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pustule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Abscess	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acarodermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anal abscess	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial vaginosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
COVID-19	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctivitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Erysipelas	0	(0.0, 0.0)	0	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Kidney infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Labyrinthitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Laryngitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Ophthalmic herpes zoster	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral candidiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Papilloma viral infection	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peritonsillar abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash pustular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sialoadenitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinusitis bacterial	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Trichomoniasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vulvovaginitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess intestinal	0	(0.0, 0.0)	0	(0.0, 0.0)
Abscess jaw	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abscess neck	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal fistula infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial blepharitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial sepsis	0	(0.0, 0.0)	0	(0.0, 0.0)
Balanitis candida	0	(0.0, 0.0)	0	(0.0, 0.0)
Bartholin's abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bartholinitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blister infected	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Campylobacter infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Carbuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cellulitis orbital	0	(0.0, 0.0)	0	(0.0, 0.0)
Clostridium difficile infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Coxsackie viral infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental fistula	0	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis infected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device related infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Empyema	0	(0.0, 0.0)	0	(0.0, 0.0)
Eye infection bacterial	0	(0.0, 0.0)	0	(0.0, 0.0)
Genital herpes simplex	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gonorrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Groin abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Helicobacter infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Hepatitis A	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis C	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Lyme disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nail infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Oral infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Orchitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Otitis media bacterial	0	(0.0, 0.0)	0	(0.0, 0.0)
Parasitic gastroenteritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic inflammatory disease	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)
Peritonitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary tuberculosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Puncture site infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	0	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory tract infection viral	0	(0.0, 0.0)	0	(0.0, 0.0)
Sepsis	0	(0.0, 0.0)	0	(0.0, 0.0)
Shigella sepsis	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin bacterial infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Soft tissue infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Subacute endocarditis	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)
Syphilis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varicella	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	113 (0.9)	(0.7, 1.0)	140 (1.1)	(0.9, 1.3)
Fall	17 (0.1)	(0.1, 0.2)	13 (0.1)	(0.1, 0.2)
Ligament sprain	10 (0.1)	(0.0, 0.1)	15 (0.1)	(0.1, 0.2)
Skin laceration	8 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Contusion	8 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Exposure during pregnancy	10 (0.1)	(0.0, 0.1)	19 (0.1)	(0.1, 0.2)
Muscle strain	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Road traffic accident	8 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Skin abrasion	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Arthropod bite	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Limb injury	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Foot fracture	2 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Joint injury	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tooth fracture	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Procedural pain	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Meniscus injury	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Animal bite	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Arthropod sting	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint dislocation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ankle fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Concussion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscle rupture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Wound	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Corneal abrasion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ligament rupture	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Thermal burn	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vaccination complication	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epicondylitis	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Fibula 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)
Head injury	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Overdose	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Wrist fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Bone contusion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Muscle injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Spinal compression fracture	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)
Administration related reaction	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)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ligament injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Skin injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Stress fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Tendon injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcohol poisoning	0	(0.0, 0.0)	0	(0.0, 0.0)
Anaemia postoperative	0	(0.0, 0.0)	0	(0.0, 0.0)
Brain contusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Burn oral cavity	0	(0.0, 0.0)	0	(0.0, 0.0)
Burns first degree	0	(0.0, 0.0)	0	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental restoration failure	0	(0.0, 0.0)	0	(0.0, 0.0)
Ear canal abrasion	0	(0.0, 0.0)	0	(0.0, 0.0)
Ear injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Exposure to communicable disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Femur fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foreign body	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Foreign body aspiration	0	(0.0, 0.0)	0	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Foreign body in eye	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	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during breast feeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngeal perforation	0	(0.0, 0.0)	0	(0.0, 0.0)
Post concussion syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural swelling	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)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural hypotension	0	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory fume inhalation disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Scapula fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Scar	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Soft tissue injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal column injury	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)	0	(0.0, 0.0)
Stab wound	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stoma site rash	0	(0.0, 0.0)	0	(0.0, 0.0)
Subdural haematoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Sunburn	0	(0.0, 0.0)	0	(0.0, 0.0)
Tibia fracture	0	(0.0, 0.0)	0	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic haemothorax	0	(0.0, 0.0)	0	(0.0, 0.0)
Traumatic intracranial haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Venom poisoning	0	(0.0, 0.0)	0	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	105 (0.8)	(0.7, 1.0)	21 (0.2)	(0.1, 0.2)
Body temperature increased	80 (0.6)	(0.5, 0.8)	10 (0.1)	(0.0, 0.1)
Blood pressure increased	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Blood glucose increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart rate increased	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blood cholesterol increased	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood thyroid stimulating hormone increased	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Weight decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	0	(0.0, 0.0)
High density lipoprotein increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Mammogram abnormal	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostatic specific antigen increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Alanine aminotransferase increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood chloride decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood creatinine increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose fluctuation	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure diastolic increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood pressure systolic increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood sodium decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood triglycerides increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cardiac stress test abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fractional exhaled nitric oxide increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Glomerular filtration rate decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis C antibody positive	0	(0.0, 0.0)	0	(0.0, 0.0)
Herpes simplex test positive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intraocular pressure increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Mean cell volume decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Monocyte count increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Platelet count increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory rate increased	0	(0.0, 0.0)	0	(0.0, 0.0)
SARS-CoV-2 antibody test positive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid function test abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
Troponin increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Urine ketone body present	0	(0.0, 0.0)	0	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
White blood cell count increased	0	(0.0, 0.0)	0	(0.0, 0.0)
White blood cells urine positive	0	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	59 (0.5)	(0.3, 0.6)	42 (0.3)	(0.2, 0.4)
Decreased appetite	26 (0.2)	(0.1, 0.3)	6 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Vitamin D deficiency	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Hyperlipidaemia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypokalaemia	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dyslipidaemia	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Gout	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dehydration	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hyperglycaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Glucose tolerance impaired	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Vitamin B12 deficiency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Insulin resistance	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obesity	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	0	(0.0, 0.0)	0	(0.0, 0.0)
Folate deficiency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperkalaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypernatraemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hyperuricaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypomagnesaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hyponatraemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypovolaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	0	(0.0, 0.0)
Iron deficiency	0	(0.0, 0.0)	0	(0.0, 0.0)
Lactic acidosis	0	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1201 (9.2)	(8.7, 9.8)	303 (2.3)	(2.1, 2.6)
Myalgia	871 (6.7)	(6.3, 7.1)	104 (0.8)	(0.7, 1.0)
Arthralgia	176 (1.4)	(1.2, 1.6)	54 (0.4)	(0.3, 0.5)
Pain in extremity	98 (0.8)	(0.6, 0.9)	22 (0.2)	(0.1, 0.3)
Back pain	57 (0.4)	(0.3, 0.6)	56 (0.4)	(0.3, 0.6)
Neck pain	19 (0.1)	(0.1, 0.2)	21 (0.2)	(0.1, 0.2)
Muscle spasms	12 (0.1)	(0.0, 0.2)	6 (0.0)	(0.0, 0.1)
Osteoarthritis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tendonitis	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Bursitis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Muscular weakness	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	9 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Muscle contracture	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Plantar fasciitis	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Arthritis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Exostosis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flank pain	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint swelling	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint stiffness	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Costochondritis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle twitching	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Musculoskeletal pain	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)
Intervertebral disc degeneration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Synovial cyst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Bone pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tendon disorder	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Torticollis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arthropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Axillary mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coccydynia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fibromyalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metatarsalgia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Mobility decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Osteitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psoriatic arthropathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spondylitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Trigger finger	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthritis reactive	0	(0.0, 0.0)	0	(0.0, 0.0)
Bone swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dupuytren's contracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Intervertebral disc disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint instability	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondrosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteopenia	0	(0.0, 0.0)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rheumatoid arthritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Scoliosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Systemic lupus erythematosus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	14 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.2)
Basal cell carcinoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Lipoma	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Uterine leiomyoma	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Colon adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	0	(0.0, 0.0)
Acrochordon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Fibroadenoma of breast	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Squamous cell carcinoma of skin	0	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma pancreas	0	(0.0, 0.0)	0	(0.0, 0.0)
Adenoma benign	0	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	0	(0.0, 0.0)	0	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign pancreatic neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary cancer metastatic	0	(0.0, 0.0)	0	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	0	(0.0, 0.0)
Infected naevus	0	(0.0, 0.0)	0	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	0	(0.0, 0.0)
Invasive ductal breast carcinoma	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)
Lymphoproliferative disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Malignant melanoma of eyelid	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)
Metastases to liver	0	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian germ cell teratoma benign	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatic carcinoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	0	(0.0, 0.0)	0	(0.0, 0.0)
Penile squamous cell carcinoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer metastatic	0	(0.0, 0.0)	0	(0.0, 0.0)
Seborrhoeic keratosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cancer	0	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	1067 (8.2)	(7.7, 8.7)	393 (3.0)	(2.7, 3.3)
Headache	930 (7.2)	(6.7, 7.6)	290 (2.2)	(2.0, 2.5)
Dizziness	46 (0.4)	(0.3, 0.5)	33 (0.3)	(0.2, 0.4)
Paraesthesia	17 (0.1)	(0.1, 0.2)	14 (0.1)	(0.1, 0.2)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12995) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=13026) n[b] (%)	 (95% CI[c])
Migraine	21 (0.2)	(0.1, 0.2)	9 (0.1)	(0.0, 0.1)
Lethargy	7 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Syncope	9 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Sciatica	8 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Dysgeusia	9 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Somnolence	5 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Tension headache	7 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Presyncope	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Hypoaesthesia	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tremor	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burning sensation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Parosmia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Carpal tunnel syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
Cervical radiculopathy	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Disturbance in attention	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperaesthesia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neuropathy peripheral	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sinus headache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerebrovascular accident	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness postural	0	(0.0, 0.0)	0	(0.0, 0.0)
Facial paralysis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Radiculopathy	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	0	(0.0, 0.0)	0	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post herpetic neuralgia	0	(0.0, 0.0)	0	(0.0, 0.0)
Restless legs syndrome	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Transient ischaemic attack	0	(0.0, 0.0)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amyotrophic lateral sclerosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Balance disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Cerebellar infarction	0	(0.0, 0.0)	0	(0.0, 0.0)
Cerebral atrophy	0	(0.0, 0.0)	0	(0.0, 0.0)
Cerebral capillary telangiectasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	0	(0.0, 0.0)
Cervicogenic headache	0	(0.0, 0.0)	0	(0.0, 0.0)
Depressed level of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic neuropathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Drug withdrawal headache	0	(0.0, 0.0)	0	(0.0, 0.0)
Dyskinesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial paresis	0	(0.0, 0.0)	0	(0.0, 0.0)
Generalised tonic-clonic seizure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	0	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypersomnia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myoclonus	0	(0.0, 0.0)	0	(0.0, 0.0)
Nystagmus	0	(0.0, 0.0)	0	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parkinsonism	0	(0.0, 0.0)	0	(0.0, 0.0)
Periodic limb movement disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Piriformis syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
Sciatic nerve neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord compression	0	(0.0, 0.0)	0	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Transient global amnesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	0	(0.0, 0.0)	0	(0.0, 0.0)
VIth nerve paralysis	0	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abortion spontaneous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PRODUCT ISSUES	0	(0.0, 0.0)	0	(0.0, 0.0)
Device breakage	0	(0.0, 0.0)	0	(0.0, 0.0)
Device connection issue	0	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	64 (0.5)	(0.4, 0.6)	55 (0.4)	(0.3, 0.5)
Anxiety	17 (0.1)	(0.1, 0.2)	20 (0.2)	(0.1, 0.2)
Insomnia	17 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Depression	13 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.1)
Attention deficit hyperactivity disorder	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Irritability	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Panic attack	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anxiety disorder	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Disorientation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abnormal dreams	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Depressed mood	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)
Alcohol withdrawal syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bruxism	1 (0.0)	(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)	0	(0.0, 0.0)
Nightmare	0	(0.0, 0.0)	0	(0.0, 0.0)
Confusional state	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Generalised anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Libido decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Libido increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Listless	0	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	0	(0.0, 0.0)
Panic disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranoia	0	(0.0, 0.0)	0	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	0	(0.0, 0.0)	0	(0.0, 0.0)
Schizophrenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Substance abuse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	13 (0.1)	(0.1, 0.2)	15 (0.1)	(0.1, 0.2)
Nephrolithiasis	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dysuria	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Haematuria	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Acute kidney injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pollakiuria	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Renal colic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Urinary retention	0	(0.0, 0.0)	0	(0.0, 0.0)
Bladder spasm	0	(0.0, 0.0)	0	(0.0, 0.0)
Chronic kidney disease	0	(0.0, 0.0)	0	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hydronephrosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Micturition urgency	0	(0.0, 0.0)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	0	(0.0, 0.0)
Obstructive nephropathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Oedematous kidney	0	(0.0, 0.0)	0	(0.0, 0.0)
Perinephric oedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Renal atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Renal cyst haemorrhage	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)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary tract obstruction	0	(0.0, 0.0)	0	(0.0, 0.0)
Urine odour abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	31 (0.2)	(0.2, 0.3)	31 (0.2)	(0.2, 0.3)
Dysmenorrhoea	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Erectile dysfunction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ovarian cyst	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pelvic pain	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Amenorrhoea	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	0	(0.0, 0.0)	0	(0.0, 0.0)
Breast pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast mass	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Prostatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Genital erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhagic ovarian cyst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Menstruation irregular	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metrorrhagia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus genital	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Testicular pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine haemorrhage	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Adenomyosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast calcifications	0	(0.0, 0.0)	0	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical polyp	0	(0.0, 0.0)	0	(0.0, 0.0)
Dysfunctional uterine bleeding	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)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Haematospermia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mammary duct ectasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menometrorrhagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nipple pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	0	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Polycystic ovaries	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatomegaly	0	(0.0, 0.0)	0	(0.0, 0.0)
Scrotal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uterine inflammation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	0	(0.0, 0.0)	0	(0.0, 0.0)
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal pruritus	0	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	111 (0.9)	(0.7, 1.0)	121 (0.9)	(0.8, 1.1)
Oropharyngeal pain	24 (0.2)	(0.1, 0.3)	23 (0.2)	(0.1, 0.3)
Nasal congestion	14 (0.1)	(0.1, 0.2)	28 (0.2)	(0.1, 0.3)
Cough	13 (0.1)	(0.1, 0.2)	11 (0.1)	(0.0, 0.2)
Rhinorrhoea	11 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Rhinitis allergic	11 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.1)
Asthma	7 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dyspnoea	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Throat irritation	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Epistaxis	1 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Sinus congestion	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysphonia	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bronchospasm	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea exertional	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Respiratory tract congestion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sleep apnoea syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wheezing	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	0	(0.0, 0.0)	0	(0.0, 0.0)
Asthma exercise induced	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dry throat	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Allergic sinusitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthmatic crisis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Interstitial lung disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Reflux laryngitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atelectasis	0	(0.0, 0.0)	0	(0.0, 0.0)
Emphysema	0	(0.0, 0.0)	0	(0.0, 0.0)
Haemoptysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hiccups	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lung infiltration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal polyps	0	(0.0, 0.0)	0	(0.0, 0.0)
Nasal septum deviation	0	(0.0, 0.0)	0	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	0	(0.0, 0.0)
Paranasal sinus hypersecretion	0	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	0	(0.0, 0.0)	0	(0.0, 0.0)
Pleuritic pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	0	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pulmonary hypertension	0	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary oedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinalgia	0	(0.0, 0.0)	0	(0.0, 0.0)
Rhinitis perennial	0	(0.0, 0.0)	0	(0.0, 0.0)
Sinus disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	124 (1.0)	(0.8, 1.1)	88 (0.7)	(0.5, 0.8)
Rash	32 (0.2)	(0.2, 0.3)	23 (0.2)	(0.1, 0.3)
Pruritus	9 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.2)
Hyperhidrosis	18 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Dermatitis contact	7 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Urticaria	11 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Night sweats	9 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Rash pruritic	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Erythema	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Alopecia	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eczema	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Skin lesion	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Rash maculo-papular	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dermatitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis allergic	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Angioedema	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dermal cyst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Actinic keratosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Blister	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ecchymosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hand dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psoriasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash papular	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Acne	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cold sweat	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)
Drug eruption	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Macule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain of skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pityriasis rosea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Rosacea	0	(0.0, 0.0)	0	(0.0, 0.0)
Seborrhoeic dermatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Skin mass	0	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis acneiform	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis bullous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis exfoliative	0	(0.0, 0.0)	0	(0.0, 0.0)
Dyshidrotic eczema	0	(0.0, 0.0)	0	(0.0, 0.0)
Fixed eruption	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hidradenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Onychomadesis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pseudofolliculitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin discolouration	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stasis dermatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Urticaria contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria papular	0	(0.0, 0.0)	0	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Menopause	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
High risk sexual behaviour	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	11 (0.1)	(0.0, 0.2)	14 (0.1)	(0.1, 0.2)
Tooth extraction	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dental implantation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Wisdom teeth removal	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dental care	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Endodontic procedure	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abortion induced	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Apicectomy	0	(0.0, 0.0)	0	(0.0, 0.0)
Botulinum toxin injection	0	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac pacemaker replacement	0	(0.0, 0.0)	0	(0.0, 0.0)
Carpal tunnel decompression	0	(0.0, 0.0)	0	(0.0, 0.0)
Cataract operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug titration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facet joint block	0	(0.0, 0.0)	0	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia repair	0	(0.0, 0.0)	0	(0.0, 0.0)
Lacrimal duct procedure	0	(0.0, 0.0)	0	(0.0, 0.0)
Lens extraction	0	(0.0, 0.0)	0	(0.0, 0.0)
Medical device implantation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Open reduction of fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative care	0	(0.0, 0.0)	0	(0.0, 0.0)
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin neoplasm excision	0	(0.0, 0.0)	0	(0.0, 0.0)
Toe operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vasectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound drainage	0	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	42 (0.3)	(0.2, 0.4)	39 (0.3)	(0.2, 0.4)
Hypertension	19 (0.1)	(0.1, 0.2)	22 (0.2)	(0.1, 0.3)
Hot flush	5 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Flushing	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deep vein thrombosis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.86. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Haematoma	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypotension	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	0	(0.0, 0.0)
Varicose vein	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.0)	0	(0.0, 0.0)
Arteriosclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive crisis	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)
Accelerated hypertension	0	(0.0, 0.0)	0	(0.0, 0.0)
Aortic dilatation	0	(0.0, 0.0)	0	(0.0, 0.0)
Aortic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diastolic hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphorrhoea	0	(0.0, 0.0)	0	(0.0, 0.0)
Pallor	0	(0.0, 0.0)	0	(0.0, 0.0)
Phlebolith	0	(0.0, 0.0)	0	(0.0, 0.0)
Raynaud's phenomenon	0	(0.0, 0.0)	0	(0.0, 0.0)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 age pd2 p3 saf

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2384 (26.7)	(25.8, 27.6)	1177 (13.2)	(12.5, 14.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	25 (0.3)	(0.2, 0.4)	9 (0.1)	(0.0, 0.2)
Lymphadenopathy	16 (0.2)	(0.1, 0.3)	3 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Anaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lymph node pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood loss anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thrombocytopenia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypochromic anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymphadenitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy mediastinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymphopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Splenomegaly	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	29 (0.3)	(0.2, 0.5)	26 (0.3)	(0.2, 0.4)
Palpitations	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tachycardia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Atrial fibrillation	6 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Coronary artery disease	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cardiac failure congestive	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Angina unstable	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bradycardia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Left ventricular hypertrophy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mitral valve incompetence	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Aortic valve incompetence	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	0	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cardiac arrest	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mitral valve prolapse	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)
Sinus tachycardia	0	(0.0, 0.0)	0	(0.0, 0.0)
Supraventricular tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tricuspid valve incompetence	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ventricular extrasystoles	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute left ventricular failure	0	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	0	(0.0, 0.0)	0	(0.0, 0.0)
Atrioventricular block complete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Atrioventricular block first degree	0	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block left	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bundle branch block right	0	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cardiovascular disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Junctional ectopic tachycardia	0	(0.0, 0.0)	0	(0.0, 0.0)
Left atrial enlargement	0	(0.0, 0.0)	0	(0.0, 0.0)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pericarditis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ventricular tachycardia	0	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Congenital bladder neck obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Congenital cystic kidney disease	0	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Type V hyperlipidaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	29 (0.3)	(0.2, 0.5)	23 (0.3)	(0.2, 0.4)
Vertigo	15 (0.2)	(0.1, 0.3)	9 (0.1)	(0.0, 0.2)
Ear pain	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tinnitus	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Vertigo positional	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Cerumen impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ear disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Meniere's disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Allergic otitis media	0	(0.0, 0.0)	0	(0.0, 0.0)
Deafness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Deafness neurosensory	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eustachian tube dysfunction	0	(0.0, 0.0)	0	(0.0, 0.0)
Hyperacusis	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	0	(0.0, 0.0)
Otorrhoea	0	(0.0, 0.0)	0	(0.0, 0.0)
Sudden hearing loss	0	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	0	(0.0, 0.0)
ENDOCRINE DISORDERS	6 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypothyroidism	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hypogonadism	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thyroid mass	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Autoimmune thyroiditis	0	(0.0, 0.0)	0	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperprolactinaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cyst	0	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	26 (0.3)	(0.2, 0.4)	28 (0.3)	(0.2, 0.5)
Cataract	6 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Eye pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eye irritation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Vision blurred	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Chalazion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vitreous detachment	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blepharitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conjunctival haemorrhage	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Conjunctivitis allergic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Keratitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Glaucoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Lacrimation increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Photophobia	0	(0.0, 0.0)	0	(0.0, 0.0)
Retinal detachment	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vitreous floaters	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Asthenopia	0	(0.0, 0.0)	0	(0.0, 0.0)
Blepharospasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye pruritus	0	(0.0, 0.0)	0	(0.0, 0.0)
Amaurosis fugax	0	(0.0, 0.0)	0	(0.0, 0.0)
Choroidal neovascularisation	0	(0.0, 0.0)	0	(0.0, 0.0)
Conjunctival hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctival oedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Corneal irritation	0	(0.0, 0.0)	0	(0.0, 0.0)
Dacryostenosis acquired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diabetic retinopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Episcleritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	0	(0.0, 0.0)
Eye inflammation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eyelid haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eyelid oedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Eyelids pruritus	0	(0.0, 0.0)	0	(0.0, 0.0)
Iritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ocular discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Scleral discolouration	0	(0.0, 0.0)	0	(0.0, 0.0)
Swelling of eyelid	0	(0.0, 0.0)	0	(0.0, 0.0)
Ulcerative keratitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Visual acuity reduced	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	259 (2.9)	(2.6, 3.3)	176 (2.0)	(1.7, 2.3)
Diarrhoea	91 (1.0)	(0.8, 1.2)	71 (0.8)	(0.6, 1.0)
Nausea	90 (1.0)	(0.8, 1.2)	26 (0.3)	(0.2, 0.4)
Vomiting	12 (0.1)	(0.1, 0.2)	10 (0.1)	(0.1, 0.2)
Toothache	10 (0.1)	(0.1, 0.2)	11 (0.1)	(0.1, 0.2)
Abdominal pain upper	7 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)
Abdominal pain	8 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Gastrooesophageal reflux disease	7 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Dyspepsia	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Odynophagia	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Constipation	4 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Dental caries	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gastritis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Haemorrhoids	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Aphthous ulcer	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal discomfort	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Abdominal distension	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flatulence	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Irritable bowel syndrome	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry mouth	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Large intestine polyp	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal pain lower	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dysphagia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Stomatitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulum	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hiatus hernia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Retching	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cheilitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Faeces soft	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Food poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gingival pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lip swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rectal haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Swollen tongue	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tooth impacted	0	(0.0, 0.0)	0	(0.0, 0.0)
Umbilical hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis microscopic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eructation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gingival discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Glossodynia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematochezia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Noninfective gingivitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Oral pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pancreatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Parotid duct obstruction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal adhesions	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal faeces	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute abdomen	0	(0.0, 0.0)	0	(0.0, 0.0)
Anal pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angular cheilitis	0	(0.0, 0.0)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Appendix disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Chronic gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colitis ulcerative	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	0	(0.0, 0.0)
Diverticulum intestinal haemorrhagic	0	(0.0, 0.0)	0	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Femoral hernia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Frequent bowel movements	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastric polyps	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastric ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastric ulcer haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis erosive	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal mucosa hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastrointestinal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	0	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	0	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia teeth	0	(0.0, 0.0)	0	(0.0, 0.0)
Impaired gastric emptying	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Incarcerated inguinal hernia	0	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lip oedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	0	(0.0, 0.0)
Obstructive pancreatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oesophageal ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oesophageal varices haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Oesophagitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oral discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Oral lichenoid reaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatic failure	0	(0.0, 0.0)	0	(0.0, 0.0)
Peptic ulcer	0	(0.0, 0.0)	0	(0.0, 0.0)
Proctalgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Salivary gland mucocoele	0	(0.0, 0.0)	0	(0.0, 0.0)
Teething	0	(0.0, 0.0)	0	(0.0, 0.0)
Tongue discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tongue discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Tongue oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tooth disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Varices oesophageal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Volvulus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1564 (17.5)	(16.7, 18.3)	312 (3.5)	(3.1, 3.9)
Injection site pain	986 (11.0)	(10.4, 11.7)	113 (1.3)	(1.0, 1.5)
Fatigue	451 (5.0)	(4.6, 5.5)	109 (1.2)	(1.0, 1.5)
Pyrexia	400 (4.5)	(4.1, 4.9)	23 (0.3)	(0.2, 0.4)
Chills	399 (4.5)	(4.0, 4.9)	43 (0.5)	(0.4, 0.7)
Pain	198 (2.2)	(1.9, 2.5)	21 (0.2)	(0.1, 0.4)
Injection site erythema	66 (0.7)	(0.6, 0.9)	10 (0.1)	(0.1, 0.2)
Injection site swelling	54 (0.6)	(0.5, 0.8)	11 (0.1)	(0.1, 0.2)
Malaise	44 (0.5)	(0.4, 0.7)	11 (0.1)	(0.1, 0.2)
Asthenia	30 (0.3)	(0.2, 0.5)	7 (0.1)	(0.0, 0.2)
Injection site pruritus	15 (0.2)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Injection site bruising	5 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Influenza like illness	8 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Chest pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site warmth	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Axillary pain	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site induration	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Non-cardiac chest pain	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Oedema peripheral	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Peripheral swelling	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chest discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Swelling face	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site haemorrhage	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site reaction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site mass	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Swelling	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Adverse drug reaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Cyst	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Feeling abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site nodule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site papule	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sensation of foreign body	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Face oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling cold	0	(0.0, 0.0)	0	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	0	(0.0, 0.0)
Medical device pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sluggishness	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Thirst	0	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vessel puncture site haematoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Application site erythema	0	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Application site rash	0	(0.0, 0.0)	0	(0.0, 0.0)
Application site reaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Capsular contracture associated with breast implant	0	(0.0, 0.0)	0	(0.0, 0.0)
Death	0	(0.0, 0.0)	0	(0.0, 0.0)
Discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Effusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Exercise tolerance decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gait disturbance	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Illness	0	(0.0, 0.0)	0	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Inflammation	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site lymphadenopathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site urticaria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Medical device site granuloma	0	(0.0, 0.0)	0	(0.0, 0.0)
Mucosal disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	0	(0.0, 0.0)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Therapeutic response unexpected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vaccination site induration	0	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vascular stent occlusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	9 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Cholelithiasis	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Biliary colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bile duct stone	0	(0.0, 0.0)	0	(0.0, 0.0)
Biliary dyskinesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Nonalcoholic fatty liver disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)	10 (0.1)	(0.1, 0.2)
Seasonal allergy	1 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Drug hypersensitivity	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Food allergy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypersensitivity	0	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to arthropod bite	0	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to arthropod sting	0	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic reaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Milk allergy	0	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	147 (1.6)	(1.4, 1.9)	147 (1.7)	(1.4, 1.9)
Urinary tract infection	26 (0.3)	(0.2, 0.4)	27 (0.3)	(0.2, 0.4)
Tooth infection	15 (0.2)	(0.1, 0.3)	11 (0.1)	(0.1, 0.2)
Sinusitis	10 (0.1)	(0.1, 0.2)	12 (0.1)	(0.1, 0.2)
Cellulitis	5 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Herpes zoster	6 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Ear infection	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Conjunctivitis	4 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Hordeolum	5 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cystitis	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Gastroenteritis	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Rhinitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Tooth abscess	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Diverticulitis	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Otitis externa	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Otitis media	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Appendicitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gingivitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oral herpes	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Acute sinusitis	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Pneumonia	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Skin infection	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vaginal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fungal skin infection	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Onychomycosis	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Periodontitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Folliculitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Furuncle	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Localised infection	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nasopharyngitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Otitis media acute	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paronychia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tonsillitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Genital herpes	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Herpes simplex	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Influenza	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tinea versicolour	0	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial vulvovaginitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Bronchitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Chronic sinusitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye infection	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gingival abscess	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Impetigo	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Infected bite	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parotitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pustule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tinea infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acarodermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anal abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bacterial vaginosis	0	(0.0, 0.0)	0	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctivitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Erysipelas	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Escherichia urinary tract infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastroenteritis viral	0	(0.0, 0.0)	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)
Laryngitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ophthalmic herpes zoster	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral candidiasis	0	(0.0, 0.0)	0	(0.0, 0.0)
Papilloma viral infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pharyngotonsillitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Rash pustular	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sialoadenitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinusitis bacterial	0	(0.0, 0.0)	0	(0.0, 0.0)
Trichomoniasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vulvovaginitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess jaw	0	(0.0, 0.0)	0	(0.0, 0.0)
Abscess neck	0	(0.0, 0.0)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Anal fistula infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial blepharitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bacterial sepsis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Balanitis candida	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bartholin's abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Bartholinitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Blister infected	0	(0.0, 0.0)	0	(0.0, 0.0)
Bone abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Campylobacter infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Carbuncle	0	(0.0, 0.0)	0	(0.0, 0.0)
Cellulitis orbital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Clostridium difficile infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coxsackie viral infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Dental fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dermatitis infected	0	(0.0, 0.0)	0	(0.0, 0.0)
Device related infection	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)
Eye infection bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Genital herpes simplex	0	(0.0, 0.0)	0	(0.0, 0.0)
Gonorrhoea	0	(0.0, 0.0)	0	(0.0, 0.0)
Groin abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Helicobacter infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hepatitis A	0	(0.0, 0.0)	0	(0.0, 0.0)
Hepatitis C	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lyme disease	0	(0.0, 0.0)	0	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	0	(0.0, 0.0)
Nail infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Oral infection	0	(0.0, 0.0)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Orchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Otitis media bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Parasitic gastroenteritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic inflammatory disease	0	(0.0, 0.0)	0	(0.0, 0.0)
Peritoneal abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pharyngitis bacterial	0	(0.0, 0.0)	0	(0.0, 0.0)
Pilonidal cyst	0	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary tuberculosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Puncture site infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis acute	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)
Sepsis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Shigella sepsis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Soft tissue infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subacute endocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Suspected COVID-19	0	(0.0, 0.0)	0	(0.0, 0.0)
Syphilis	0	(0.0, 0.0)	0	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillitis bacterial	0	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	0	(0.0, 0.0)
Varicella	0	(0.0, 0.0)	0	(0.0, 0.0)
Viral infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Viral upper respiratory tract infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Wound infection	0	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	102 (1.1)	(0.9, 1.4)	129 (1.5)	(1.2, 1.7)
Fall	31 (0.3)	(0.2, 0.5)	38 (0.4)	(0.3, 0.6)
Ligament sprain	9 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.2)
Skin laceration	6 (0.1)	(0.0, 0.1)	14 (0.2)	(0.1, 0.3)
Contusion	4 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Exposure during pregnancy	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle strain	8 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Road traffic accident	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Skin abrasion	5 (0.1)	(0.0, 0.1)	11 (0.1)	(0.1, 0.2)
Arthropod bite	9 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Limb injury	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Foot fracture	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint injury	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tooth fracture	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Procedural pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Meniscus injury	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Animal bite	0	(0.0, 0.0)	5 (0.1)	(0.0, 0.1)
Arthropod sting	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint dislocation	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rib fracture	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ankle fracture	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Concussion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscle rupture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Wound	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Chest injury	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Corneal abrasion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ligament rupture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thermal burn	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vaccination complication	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epicondylitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fibula fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hand fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Head injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Humerus fracture	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Overdose	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tendon rupture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Wrist fracture	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bone contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Craniocerebral injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Maternal exposure during pregnancy	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle injury	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Spinal compression fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ulna fracture	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Administration related reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burns second degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ligament injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Procedural dizziness	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stress fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Tendon injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Upper limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Alcohol poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaemia postoperative	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain contusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burns first degree	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Clavicle fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Dental restoration failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ear canal abrasion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ear injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Exposure to communicable disease	0	(0.0, 0.0)	0	(0.0, 0.0)
Eye contusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Flail chest	0	(0.0, 0.0)	0	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Foreign body	0	(0.0, 0.0)	0	(0.0, 0.0)
Foreign body aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Foreign body in eye	0	(0.0, 0.0)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hip fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Limb fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Limb traumatic amputation	0	(0.0, 0.0)	0	(0.0, 0.0)
Lip injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Maternal exposure during breast feeding	0	(0.0, 0.0)	0	(0.0, 0.0)
Mouth injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Multiple injuries	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pelvic fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Penis injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngeal perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Post concussion syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post procedural discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural swelling	0	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative ileus	0	(0.0, 0.0)	0	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Procedural hypotension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory fume inhalation disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Scapula fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Scar	0	(0.0, 0.0)	0	(0.0, 0.0)
Soft tissue injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Spinal column injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spinal cord injury cervical	0	(0.0, 0.0)	0	(0.0, 0.0)
Spinal fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stab wound	0	(0.0, 0.0)	0	(0.0, 0.0)
Stoma site rash	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subdural haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sunburn	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tibia fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Traumatic haemothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Venom poisoning	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vulvovaginal injury	0	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	67 (0.8)	(0.6, 1.0)	16 (0.2)	(0.1, 0.3)
Body temperature increased	40 (0.4)	(0.3, 0.6)	2 (0.0)	(0.0, 0.1)
Blood pressure increased	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blood glucose increased	8 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Heart rate increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood cholesterol increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Blood thyroid stimulating hormone increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Weight decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hepatic enzyme increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
High density lipoprotein increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Mammogram abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
Prostatic specific antigen increased	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Alanine aminotransferase increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood chloride decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood creatinine decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood creatinine increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood potassium decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure diastolic increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure systolic increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood sodium decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood testosterone decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood triglycerides increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Body temperature	0	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
C-reactive protein	0	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Electrocardiogram QT prolonged	0	(0.0, 0.0)	0	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	0	(0.0, 0.0)
Hepatitis C antibody positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Herpes simplex test positive	0	(0.0, 0.0)	0	(0.0, 0.0)
Intraocular pressure increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Mean cell volume decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Monocyte count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Platelet count increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SARS-CoV-2 antibody test positive	0	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid function test abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Troponin increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urine ketone body present	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Weight increased	0	(0.0, 0.0)	0	(0.0, 0.0)
White blood cell count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
White blood cells urine positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	41 (0.5)	(0.3, 0.6)	31 (0.3)	(0.2, 0.5)
Decreased appetite	13 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	4 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Vitamin D deficiency	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hyperlipidaemia	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypokalaemia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dyslipidaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gout	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dehydration	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hyperglycaemia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Glucose tolerance impaired	0	(0.0, 0.0)	0	(0.0, 0.0)
Vitamin B12 deficiency	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Diabetes mellitus inadequate control	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypoglycaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Insulin resistance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypocalcaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypocholesterolaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Obesity	0	(0.0, 0.0)	0	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diabetes mellitus	0	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic ketoacidosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Folate deficiency	0	(0.0, 0.0)	0	(0.0, 0.0)
Food intolerance	0	(0.0, 0.0)	0	(0.0, 0.0)
Hyperkalaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypernatraemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperuricaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypomagnesaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyponatraemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypovolaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Impaired fasting glucose	0	(0.0, 0.0)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lactic acidosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	603 (6.8)	(6.2, 7.3)	224 (2.5)	(2.2, 2.9)
Myalgia	368 (4.1)	(3.7, 4.6)	64 (0.7)	(0.6, 0.9)
Arthralgia	92 (1.0)	(0.8, 1.3)	48 (0.5)	(0.4, 0.7)
Pain in extremity	87 (1.0)	(0.8, 1.2)	22 (0.2)	(0.2, 0.4)
Back pain	40 (0.4)	(0.3, 0.6)	29 (0.3)	(0.2, 0.5)
Neck pain	10 (0.1)	(0.1, 0.2)	12 (0.1)	(0.1, 0.2)
Muscle spasms	15 (0.2)	(0.1, 0.3)	9 (0.1)	(0.0, 0.2)
Osteoarthritis	9 (0.1)	(0.0, 0.2)	14 (0.2)	(0.1, 0.3)
Musculoskeletal stiffness	9 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Tendonitis	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bursitis	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Muscular weakness	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle contracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Plantar fasciitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arthritis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Exostosis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Flank pain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Joint swelling	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Joint stiffness	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Osteoporosis	0	(0.0, 0.0)	5 (0.1)	(0.0, 0.1)
Costochondritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle twitching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Intervertebral disc degeneration	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Limb discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain in jaw	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Synovial cyst	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tenosynovitis stenosans	0	(0.0, 0.0)	0	(0.0, 0.0)
Bone pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Tendon disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Torticollis	0	(0.0, 0.0)	0	(0.0, 0.0)
Arthropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Axillary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coccydynia	0	(0.0, 0.0)	0	(0.0, 0.0)
Fibromyalgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metatarsalgia	0	(0.0, 0.0)	0	(0.0, 0.0)
Mobility decreased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Osteitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Periarthritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Spinal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spondylitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Synovitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Trigger finger	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arthritis reactive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bone swelling	0	(0.0, 0.0)	0	(0.0, 0.0)
Dupuytren's contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intervertebral disc disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Joint instability	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle tightness	0	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondrosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Osteopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	0	(0.0, 0.0)
Rheumatoid arthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Scoliosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Spinal disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Systemic lupus erythematosus	0	(0.0, 0.0)	0	(0.0, 0.0)
Tendon pain	0	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	18 (0.2)	(0.1, 0.3)	24 (0.3)	(0.2, 0.4)
Basal cell carcinoma	3 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Lipoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Uterine leiomyoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Colon adenoma	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Malignant melanoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Breast cancer	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Prostate cancer	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acrochordon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fibroadenoma of breast	0	(0.0, 0.0)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Squamous cell carcinoma of skin	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Adenocarcinoma gastric	0	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenoma benign	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)
Benign breast neoplasm	0	(0.0, 0.0)	0	(0.0, 0.0)
Benign pancreatic neoplasm	0	(0.0, 0.0)	0	(0.0, 0.0)
Biliary cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Chondroma	0	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Infected naevus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Leydig cell tumour of the testis	0	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoproliferative disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Meningioma	0	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	0	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to liver	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ovarian germ cell teratoma benign	0	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatic carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Penile neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Penile squamous cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostate cancer metastatic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Squamous cell carcinoma	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)
NERVOUS SYSTEM DISORDERS	498 (5.6)	(5.1, 6.1)	207 (2.3)	(2.0, 2.7)
Headache	409 (4.6)	(4.2, 5.0)	134 (1.5)	(1.3, 1.8)
Dizziness	32 (0.4)	(0.2, 0.5)	27 (0.3)	(0.2, 0.4)
Paraesthesia	5 (0.1)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)
Migraine	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lethargy	18 (0.2)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Syncope	2 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Sciatica	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dysgeusia	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Somnolence	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tension headache	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Presyncope	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tremor	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Burning sensation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Parosmia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Cervical radiculopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Disturbance in attention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperaesthesia	1 (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)
Sinus headache	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Aphasia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dizziness postural	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Facial paralysis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine without aura	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Radiculopathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Head discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Mental impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Migraine with aura	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Post herpetic neuralgia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Restless legs syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Trigeminal neuralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ageusia	0	(0.0, 0.0)	0	(0.0, 0.0)
Amyotrophic lateral sclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Balance disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebellar infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebral atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebral capillary telangiectasia	0	(0.0, 0.0)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cervicogenic headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Depressed level of consciousness	0	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic neuropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug withdrawal headache	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	0	(0.0, 0.0)
Facial paresis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Generalised tonic-clonic seizure	0	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hemiplegic migraine	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypersomnia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	0	(0.0, 0.0)
Idiopathic intracranial hypertension	0	(0.0, 0.0)	0	(0.0, 0.0)
Motor dysfunction	0	(0.0, 0.0)	0	(0.0, 0.0)
Myoclonus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Nystagmus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Paraparesis	0	(0.0, 0.0)	0	(0.0, 0.0)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peripheral sensory neuropathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Piriformis syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sciatic nerve neuropathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Seizure	0	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord compression	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)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
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)
VIth nerve paralysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	0	(0.0, 0.0)
Abortion spontaneous	0	(0.0, 0.0)	0	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	0	(0.0, 0.0)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Device breakage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Device connection issue	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	33 (0.4)	(0.3, 0.5)	20 (0.2)	(0.1, 0.3)
Anxiety	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Insomnia	8 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Depression	4 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Attention deficit hyperactivity disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Irritability	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Panic attack	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Anxiety disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disorientation	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep disorder	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Depressed mood	0	(0.0, 0.0)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Alcohol withdrawal syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bruxism	0	(0.0, 0.0)	0	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mental status changes	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nightmare	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Confusional state	0	(0.0, 0.0)	0	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	0	(0.0, 0.0)
Dysphemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Generalised anxiety disorder	0	(0.0, 0.0)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Libido decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Libido increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Listless	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	0	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Panic disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Paranoia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Post-traumatic stress disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Schizophrenia	0	(0.0, 0.0)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	0	(0.0, 0.0)
Substance abuse	0	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	21 (0.2)	(0.1, 0.4)	19 (0.2)	(0.1, 0.3)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Dysuria	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Haematuria	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Acute kidney injury	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Pollakiuria	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Renal colic	0	(0.0, 0.0)	0	(0.0, 0.0)
Urinary retention	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bladder spasm	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Costovertebral angle tenderness	0	(0.0, 0.0)	0	(0.0, 0.0)
Hydronephrosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Obstructive nephropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oedematous kidney	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Perinephric oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Renal atrophy	0	(0.0, 0.0)	0	(0.0, 0.0)
Renal cyst haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Subcapsular renal haematoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Urethral discharge	0	(0.0, 0.0)	0	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	0	(0.0, 0.0)
Urinary tract obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	14 (0.2)	(0.1, 0.3)	8 (0.1)	(0.0, 0.2)
Dysmenorrhoea	0	(0.0, 0.0)	0	(0.0, 0.0)
Erectile dysfunction	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)
Pelvic pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Amenorrhoea	0	(0.0, 0.0)	0	(0.0, 0.0)
Benign prostatic hyperplasia	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Breast pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Menorrhagia	0	(0.0, 0.0)	0	(0.0, 0.0)
Prostatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaginal haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast cyst	0	(0.0, 0.0)	0	(0.0, 0.0)
Genital erythema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhagic ovarian cyst	0	(0.0, 0.0)	0	(0.0, 0.0)
Menstruation delayed	0	(0.0, 0.0)	0	(0.0, 0.0)
Menstruation irregular	0	(0.0, 0.0)	0	(0.0, 0.0)
Metrorrhagia	0	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Testicular pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Adenomyosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Breast calcifications	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast hyperplasia	0	(0.0, 0.0)	0	(0.0, 0.0)
Cervical dysplasia	0	(0.0, 0.0)	0	(0.0, 0.0)
Cervical polyp	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysfunctional uterine bleeding	0	(0.0, 0.0)	0	(0.0, 0.0)
Endometriosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Haematospermia	0	(0.0, 0.0)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Mammary duct ectasia	0	(0.0, 0.0)	0	(0.0, 0.0)
Menometrorrhagia	0	(0.0, 0.0)	0	(0.0, 0.0)
Nipple pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Penile vein thrombosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Polycystic ovaries	0	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
Prostatomegaly	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Scrotal pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Uterine inflammation	0	(0.0, 0.0)	0	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaginal discharge	0	(0.0, 0.0)	0	(0.0, 0.0)
Vulvovaginal pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	83 (0.9)	(0.7, 1.2)	47 (0.5)	(0.4, 0.7)
Oropharyngeal pain	12 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.2)
Nasal congestion	11 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Cough	10 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Rhinorrhoea	9 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)
Rhinitis allergic	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Asthma	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dyspnoea	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Throat irritation	5 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Epistaxis	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sinus congestion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pulmonary embolism	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Sneezing	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dysphonia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bronchospasm	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dyspnoea exertional	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory tract congestion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep apnoea syndrome	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Wheezing	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute respiratory failure	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Asthma exercise induced	0	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Allergic sinusitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Asthmatic crisis	0	(0.0, 0.0)	0	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oropharyngeal discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Reflux laryngitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Snoring	0	(0.0, 0.0)	0	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	0	(0.0, 0.0)
Atelectasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Emphysema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemoptysis	0	(0.0, 0.0)	0	(0.0, 0.0)
Hiccups	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	0	(0.0, 0.0)
Lung infiltration	0	(0.0, 0.0)	0	(0.0, 0.0)
Nasal discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	0	(0.0, 0.0)	0	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasal septum deviation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pleuritic pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pulmonary hypertension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pulmonary pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	0	(0.0, 0.0)
Rhinalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rhinitis perennial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tonsillar hypertrophy	0	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	100 (1.1)	(0.9, 1.4)	70 (0.8)	(0.6, 1.0)
Rash	22 (0.2)	(0.2, 0.4)	18 (0.2)	(0.1, 0.3)
Pruritus	14 (0.2)	(0.1, 0.3)	6 (0.1)	(0.0, 0.1)
Hyperhidrosis	13 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Dermatitis contact	7 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)
Urticaria	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Night sweats	8 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Rash pruritic	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Erythema	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Alopecia	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eczema	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Skin lesion	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Rash maculo-papular	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dermatitis	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dermatitis allergic	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Angioedema	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermal cyst	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Actinic keratosis	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Blister	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ecchymosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hand dermatitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Papule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash papular	0	(0.0, 0.0)	0	(0.0, 0.0)
Acne	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Alopecia areata	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cold sweat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diabetic foot	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Drug eruption	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Macule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pityriasis rosea	0	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	0	(0.0, 0.0)
Rosacea	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Seborrhoeic dermatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin mass	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis acneiform	0	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis bullous	0	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyshidrotic eczema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fixed eruption	0	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	0	(0.0, 0.0)	0	(0.0, 0.0)
Hidradenitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.0)	0	(0.0, 0.0)
Livedo reticularis	0	(0.0, 0.0)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	0	(0.0, 0.0)
Onychomadesis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pityriasis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pseudofolliculitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin irritation	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin ulcer	0	(0.0, 0.0)	0	(0.0, 0.0)
Stasis dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urticaria contact	0	(0.0, 0.0)	0	(0.0, 0.0)
Urticaria papular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Menopause	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
High risk sexual behaviour	0	(0.0, 0.0)	0	(0.0, 0.0)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
SURGICAL AND MEDICAL PROCEDURES	17 (0.2)	(0.1, 0.3)	5 (0.1)	(0.0, 0.1)
Tooth extraction	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dental implantation	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Wisdom teeth removal	0	(0.0, 0.0)	0	(0.0, 0.0)
Dental care	0	(0.0, 0.0)	0	(0.0, 0.0)
Endodontic procedure	0	(0.0, 0.0)	0	(0.0, 0.0)
Abortion induced	0	(0.0, 0.0)	0	(0.0, 0.0)
Apicectomy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Botulinum toxin injection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac pacemaker replacement	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cataract operation	0	(0.0, 0.0)	0	(0.0, 0.0)
Drug titration	0	(0.0, 0.0)	0	(0.0, 0.0)
Facet joint block	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gingival operation	0	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lens extraction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Medical device implantation	0	(0.0, 0.0)	0	(0.0, 0.0)
Open reduction of fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rhinoplasty	0	(0.0, 0.0)	0	(0.0, 0.0)
Sclerotherapy	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin neoplasm excision	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Toe operation	0	(0.0, 0.0)	0	(0.0, 0.0)
Vasectomy	0	(0.0, 0.0)	0	(0.0, 0.0)
Wound drainage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VASCULAR DISORDERS	41 (0.5)	(0.3, 0.6)	43 (0.5)	(0.4, 0.7)
Hypertension	23 (0.3)	(0.2, 0.4)	24 (0.3)	(0.2, 0.4)
Hot flush	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flushing	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Deep vein thrombosis	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Haematoma	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.87. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypotension	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Orthostatic hypotension	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Varicose vein	0	(0.0, 0.0)	0	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive crisis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypertensive urgency	0	(0.0, 0.0)	0	(0.0, 0.0)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Aortic dilatation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aortic stenosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Diastolic hypertension	0	(0.0, 0.0)	0	(0.0, 0.0)
Essential hypertension	0	(0.0, 0.0)	0	(0.0, 0.0)
Intermittent claudication	0	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pallor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Phlebolith	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Raynaud's phenomenon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Subgaleal haematoma	0	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 age pd2 p3 saf

14.88. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	3152 (14.4)	(13.9, 14.8)	1170 (5.3)	(5.0, 5.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	18 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Lymphadenopathy	17 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Blood loss anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iron deficiency anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymph node pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	8 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Tachycardia	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Palpitations	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Atrial fibrillation	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute myocardial infarction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block left	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	14 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Vertigo	8 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Ear pain	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinnitus	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vertigo positional	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypothyroidism	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	17 (0.1)	(0.0, 0.1)	14 (0.1)	(0.0, 0.1)
Eye irritation	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Eye pain	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctivitis allergic	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ocular hyperaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.88. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Asthenopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cataract	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chalazion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Keratitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vision blurred	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitreous floaters	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	238 (1.1)	(1.0, 1.2)	178 (0.8)	(0.7, 0.9)
Diarrhoea	122 (0.6)	(0.5, 0.7)	99 (0.5)	(0.4, 0.5)
Nausea	61 (0.3)	(0.2, 0.4)	45 (0.2)	(0.1, 0.3)
Vomiting	17 (0.1)	(0.0, 0.1)	17 (0.1)	(0.0, 0.1)
Abdominal pain upper	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Abdominal pain	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Constipation	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Abdominal discomfort	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental caries	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspepsia	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrooesophageal reflux disease	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Toothache	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal distension	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aphthous ulcer	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry mouth	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Flatulence	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoids	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Odynophagia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.88. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abdominal pain lower	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colitis microscopic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticulum	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Faeces soft	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hiatus hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Irritable bowel syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Large intestine polyp	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Proctalgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stomatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2495 (11.4)	(11.0, 11.8)	575 (2.6)	(2.4, 2.8)
Injection site pain	1960 (8.9)	(8.6, 9.3)	236 (1.1)	(0.9, 1.2)
Fatigue	523 (2.4)	(2.2, 2.6)	225 (1.0)	(0.9, 1.2)
Chills	256 (1.2)	(1.0, 1.3)	65 (0.3)	(0.2, 0.4)
Pyrexia	260 (1.2)	(1.0, 1.3)	33 (0.2)	(0.1, 0.2)

14.88. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pain	125 (0.6)	(0.5, 0.7)	22 (0.1)	(0.1, 0.2)
Injection site erythema	86 (0.4)	(0.3, 0.5)	13 (0.1)	(0.0, 0.1)
Injection site swelling	74 (0.3)	(0.3, 0.4)	12 (0.1)	(0.0, 0.1)
Malaise	48 (0.2)	(0.2, 0.3)	9 (0.0)	(0.0, 0.1)
Asthenia	23 (0.1)	(0.1, 0.2)	9 (0.0)	(0.0, 0.1)
Injection site bruising	8 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Injection site pruritus	13 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Injection site induration	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site oedema	8 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site warmth	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Chest pain	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Feeling hot	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Influenza like illness	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site discomfort	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chest discomfort	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Oedema peripheral	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Injection site haemorrhage	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Injection site reaction	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral swelling	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Axillary pain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site papule	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sensation of foreign body	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site bruise	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.88. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gait disturbance	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site nodule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sluggishness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholelithiasis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	4 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Drug hypersensitivity	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Seasonal allergy	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Food allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	55 (0.3)	(0.2, 0.3)	72 (0.3)	(0.3, 0.4)
Urinary tract infection	8 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Sinusitis	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Tooth infection	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Conjunctivitis	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Cellulitis	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear infection	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Cystitis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Herpes zoster	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)

14.88. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hordeolum	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Otitis externa	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper respiratory tract infection	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute sinusitis	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Gastroenteritis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Otitis media	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tooth abscess	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vulvovaginal mycotic infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diverticulitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Oral herpes	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periodontitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngitis streptococcal	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial vulvovaginitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bartholin's abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye infection bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Furuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingivitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex	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)
Localised infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasopharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Onychomycosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media bacterial	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	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.88. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pustule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Syphilis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vulvovaginal candidiasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	32 (0.1)	(0.1, 0.2)	45 (0.2)	(0.1, 0.3)
Fall	6 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Exposure during pregnancy	2 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Contusion	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Muscle strain	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ligament sprain	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Meniscus injury	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Skin laceration	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Arthropod bite	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arthropod sting	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Facial bones fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ligament rupture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Limb injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radius fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Skin abrasion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Wound	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Animal bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ankle fracture	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)
Corneal abrasion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.88. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Epicondylitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fibula fracture	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)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during breast feeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth injury	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)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural discomfort	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)
Rib fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal compression fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stoma site rash	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)
Thermal burn	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination complication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	41 (0.2)	(0.1, 0.3)	9 (0.0)	(0.0, 0.1)
Body temperature increased	30 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.0)
Blood pressure increased	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Heart rate increased	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blood glucose increased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood cholesterol increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure systolic increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex test positive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Low density lipoprotein increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostatic specific antigen increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Troponin increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.88. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Weight increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	20 (0.1)	(0.1, 0.1)	13 (0.1)	(0.0, 0.1)
Decreased appetite	10 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Hyperlipidaemia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vitamin D deficiency	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dehydration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyslipidaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypokalaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Insulin resistance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Type 2 diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitamin B12 deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	521 (2.4)	(2.2, 2.6)	180 (0.8)	(0.7, 0.9)
Myalgia	331 (1.5)	(1.4, 1.7)	82 (0.4)	(0.3, 0.5)
Arthralgia	75 (0.3)	(0.3, 0.4)	40 (0.2)	(0.1, 0.2)
Pain in extremity	88 (0.4)	(0.3, 0.5)	12 (0.1)	(0.0, 0.1)
Back pain	20 (0.1)	(0.1, 0.1)	23 (0.1)	(0.1, 0.2)
Muscle spasms	8 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Neck pain	4 (0.0)	(0.0, 0.0)	8 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tendonitis	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Joint range of motion decreased	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bursitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Flank pain	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Muscular weakness	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint stiffness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.88. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Muscle contracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fibromyalgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intervertebral disc protrusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint instability	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle fatigue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Plantar fasciitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psoriatic arthropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spondylitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Synovitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	7 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Basal cell carcinoma	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Colon adenoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acrochordon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intraductal proliferative breast lesion	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	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.88. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
NERVOUS SYSTEM DISORDERS	512 (2.3)	(2.1, 2.5)	275 (1.3)	(1.1, 1.4)
Headache	439 (2.0)	(1.8, 2.2)	218 (1.0)	(0.9, 1.1)
Dizziness	20 (0.1)	(0.1, 0.1)	29 (0.1)	(0.1, 0.2)
Paraesthesia	10 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Lethargy	10 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Migraine	9 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Dysgeusia	8 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Somnolence	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Tremor	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Hypoaesthesia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Presyncope	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syncope	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tension headache	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dizziness postural	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine without aura	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parosmia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diabetic neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Disturbance in attention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nystagmus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	24 (0.1)	(0.1, 0.2)	16 (0.1)	(0.0, 0.1)
Insomnia	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Anxiety	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Depression	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.88. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abnormal dreams	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Disorientation	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Irritability	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Panic attack	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bruxism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nightmare	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	8 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Dysuria	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haematuria	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pollakiuria	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute kidney injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	13 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Erectile dysfunction	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pelvic pain	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast mass	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian cyst	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Testicular pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysmenorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.88. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Scrotal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	63 (0.3)	(0.2, 0.4)	52 (0.2)	(0.2, 0.3)
Oropharyngeal pain	13 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Nasal congestion	11 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Rhinorrhoea	9 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Cough	8 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dyspnoea	2 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Throat irritation	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Asthma	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Rhinitis allergic	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Productive cough	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sneezing	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper-airway cough syndrome	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Epistaxis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bronchospasm	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sinus congestion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper respiratory tract congestion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic sinusitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea exertional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sleep apnoea syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Wheezing	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	68 (0.3)	(0.2, 0.4)	52 (0.2)	(0.2, 0.3)
Rash	16 (0.1)	(0.0, 0.1)	14 (0.1)	(0.0, 0.1)

14.88. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pruritus	7 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Hyperhidrosis	11 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Urticaria	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dermatitis contact	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Rash pruritic	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Erythema	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Night sweats	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rash erythematous	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alopecia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis allergic	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Actinic keratosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angioedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blister	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermal cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eczema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis rosea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.88. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
VASCULAR DISORDERS	17 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Hypertension	8 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Hot flush	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Flushing	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haematoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_d17d_p3_saf

14.89. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	4247 (19.7)	(19.2, 20.2)	889 (4.1)	(3.9, 4.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	61 (0.3)	(0.2, 0.4)	9 (0.0)	(0.0, 0.1)
Lymphadenopathy	56 (0.3)	(0.2, 0.3)	3 (0.0)	(0.0, 0.0)
Lymph node pain	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iron deficiency anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Splenomegaly	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	22 (0.1)	(0.1, 0.2)	9 (0.0)	(0.0, 0.1)
Tachycardia	8 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Palpitations	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Atrial fibrillation	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute myocardial infarction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	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	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus tachycardia	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)
EAR AND LABYRINTH DISORDERS	21 (0.1)	(0.1, 0.1)	13 (0.1)	(0.0, 0.1)

14.89. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Vertigo	9 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Tinnitus	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Ear pain	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo positional	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear discomfort	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerumen impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness neurosensory	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypothyroidism	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	17 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Vision blurred	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cataract	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Eye irritation	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Eye pain	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenopia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye inflammation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glaucoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swelling of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.89. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Vitreous detachment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	352 (1.6)	(1.5, 1.8)	125 (0.6)	(0.5, 0.7)
Nausea	205 (1.0)	(0.8, 1.1)	25 (0.1)	(0.1, 0.2)
Diarrhoea	110 (0.5)	(0.4, 0.6)	66 (0.3)	(0.2, 0.4)
Vomiting	45 (0.2)	(0.2, 0.3)	5 (0.0)	(0.0, 0.1)
Abdominal pain	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Abdominal pain upper	10 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Toothache	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Dyspepsia	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Abdominal discomfort	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Odynophagia	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphthous ulcer	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Constipation	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flatulence	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Abdominal pain lower	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Gastrooesophageal reflux disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retching	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abnormal faeces	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)
Dental caries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Frequent bowel movements	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.89. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Haemorrhoids	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral lichenoid reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Stomatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3550 (16.5)	(16.0, 17.0)	437 (2.0)	(1.8, 2.2)
Injection site pain	1703 (7.9)	(7.5, 8.3)	180 (0.8)	(0.7, 1.0)
Pyrexia	1342 (6.2)	(5.9, 6.6)	35 (0.2)	(0.1, 0.2)
Fatigue	1109 (5.1)	(4.9, 5.4)	173 (0.8)	(0.7, 0.9)
Chills	1177 (5.5)	(5.2, 5.8)	52 (0.2)	(0.2, 0.3)
Pain	525 (2.4)	(2.2, 2.6)	32 (0.1)	(0.1, 0.2)
Injection site erythema	101 (0.5)	(0.4, 0.6)	13 (0.1)	(0.0, 0.1)
Malaise	88 (0.4)	(0.3, 0.5)	10 (0.0)	(0.0, 0.1)
Injection site swelling	78 (0.4)	(0.3, 0.5)	8 (0.0)	(0.0, 0.1)
Asthenia	51 (0.2)	(0.2, 0.3)	9 (0.0)	(0.0, 0.1)
Injection site pruritus	24 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.0)
Influenza like illness	17 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site bruising	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Injection site warmth	10 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Axillary pain	10 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site induration	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site mass	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site oedema	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.89. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Adverse drug reaction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chest pain	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Feeling hot	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site haemorrhage	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site nodule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oedema peripheral	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chest discomfort	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Face oedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling abnormal	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site papule	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site reaction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peripheral swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Medical device pain	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)
Sluggishness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Therapeutic response unexpected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.89. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Thirst	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	3 (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)
Biliary dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholelithiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Seasonal allergy	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Drug hypersensitivity	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	45 (0.2)	(0.2, 0.3)	46 (0.2)	(0.2, 0.3)
Urinary tract infection	10 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Tooth infection	0	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Rhinitis	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Cellulitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctivitis	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinusitis	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hordeolum	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cystitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ear infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Herpes zoster	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Onychomycosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parotitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tooth abscess	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper respiratory tract infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vulvovaginal candidiasis	2 (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)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.89. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diverticulitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Folliculitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Furuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastroenteritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingivitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gonorrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impetigo	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Influenza	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ophthalmic herpes zoster	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral candidiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Otitis media acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papilloma viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parasitic gastroenteritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paronychia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary tuberculosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pustule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subcutaneous 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)
Tonsillitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	33 (0.2)	(0.1, 0.2)	24 (0.1)	(0.1, 0.2)
Fall	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Exposure during pregnancy	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Joint dislocation	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Procedural pain	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth fracture	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination complication	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ligament sprain	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Meniscus injury	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

14.89. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Muscle strain	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Skin laceration	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibula fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthropod bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthropod sting	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chest injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Concussion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	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)
Joint injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ligament rupture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin abrasion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal compression fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon injury	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)
Venom poisoning	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	103 (0.5)	(0.4, 0.6)	10 (0.0)	(0.0, 0.1)
Body temperature increased	83 (0.4)	(0.3, 0.5)	7 (0.0)	(0.0, 0.1)
Blood pressure increased	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart rate increased	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose increased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.89. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Blood pressure diastolic increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Low density lipoprotein increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mammogram abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	39 (0.2)	(0.1, 0.2)	13 (0.1)	(0.0, 0.1)
Decreased appetite	28 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.0)
Vitamin D deficiency	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyslipidaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hyperglycaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Polydipsia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Type 2 diabetes mellitus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitamin B12 deficiency	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dehydration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocalcaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1244 (5.8)	(5.5, 6.1)	135 (0.6)	(0.5, 0.7)
Myalgia	1004 (4.7)	(4.4, 4.9)	68 (0.3)	(0.2, 0.4)
Arthralgia	166 (0.8)	(0.7, 0.9)	25 (0.1)	(0.1, 0.2)
Pain in extremity	84 (0.4)	(0.3, 0.5)	11 (0.1)	(0.0, 0.1)
Back pain	25 (0.1)	(0.1, 0.2)	16 (0.1)	(0.0, 0.1)
Neck pain	10 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Muscle spasms	8 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Musculoskeletal stiffness	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)

14.89. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Muscular weakness	7 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint stiffness	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bursitis	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle fatigue	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle twitching	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoarthritis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bone pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Costochondritis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint range of motion decreased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tendonitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthritis reactive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Axillary mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exostosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metatarsalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mobility decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibroadenoma of breast	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.89. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostate cancer metastatic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	1115 (5.2)	(4.9, 5.5)	198 (0.9)	(0.8, 1.1)
Headache	1014 (4.7)	(4.4, 5.0)	151 (0.7)	(0.6, 0.8)
Dizziness	47 (0.2)	(0.2, 0.3)	16 (0.1)	(0.0, 0.1)
Lethargy	18 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Paraesthesia	6 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Migraine	12 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Somnolence	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dysgeusia	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Hypoaesthesia	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Syncope	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Disturbance in attention	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Tension headache	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tremor	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyperaesthesia	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burning sensation	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Head discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parosmia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Presyncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus headache	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Balance disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Carpal tunnel syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical radiculopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial paralysis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Generalised tonic-clonic seizure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.89. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypersomnia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuropathy peripheral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radiculopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restless legs syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	24 (0.1)	(0.1, 0.2)	19 (0.1)	(0.1, 0.1)
Insomnia	11 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Anxiety	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Depression	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Irritability	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Disorientation	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Attention deficit hyperactivity disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	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 fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic attack	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranoia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	8 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Dysuria	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nephrolithiasis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pollakiuria	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haematuria	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bladder spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.89. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Micturition urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oedematous kidney	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Perinephric oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal cyst haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Metrorrhagia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Genital erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	51 (0.2)	(0.2, 0.3)	27 (0.1)	(0.1, 0.2)
Oropharyngeal pain	14 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Nasal congestion	9 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Rhinorrhoea	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Cough	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Asthma	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus congestion	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper respiratory tract congestion	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper-airway cough syndrome	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory tract congestion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Throat irritation	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthma exercise induced	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthmatic crisis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bronchospasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.89. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dysphonia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Epistaxis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Productive cough	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Reflux laryngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinitis allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	88 (0.4)	(0.3, 0.5)	36 (0.2)	(0.1, 0.2)
Rash	18 (0.1)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Hyperhidrosis	18 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Night sweats	13 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pruritus	11 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Erythema	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urticaria	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alopecia	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rash pruritic	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin lesion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angioedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blister	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dermatitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis contact	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eczema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Papule	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rash papular	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermal cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug eruption	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fixed eruption	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.89. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hand dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rosacea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endodontic procedure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facet joint block	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	20 (0.1)	(0.1, 0.1)	16 (0.1)	(0.0, 0.1)
Hypertension	5 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Flushing	9 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Hot flush	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Subjects who did not receive Dose 2 or who received a different vaccine at Dose 1 and Dose 2 were excluded from this table.
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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 29MAR2021 (04:19)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adae s130 d27d p3 saf

14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2093 (16.1)	(15.5, 16.7)	768 (5.9)	(5.5, 6.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	14 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Lymphadenopathy	13 (0.1)	(0.1, 0.2)	1 (0.0)	(0.0, 0.0)
Blood loss anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iron deficiency anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymph node pain	0	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tachycardia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Palpitations	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	0	(0.0, 0.0)
Acute coronary syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
Acute myocardial infarction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block left	0	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Vertigo	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ear pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tinnitus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo positional	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)
Hypothyroidism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Goitre	0	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	12 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)
Eye irritation	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Conjunctivitis allergic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)

14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ocular hyperaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cataract	0	(0.0, 0.0)	0	(0.0, 0.0)
Chalazion	0	(0.0, 0.0)	0	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Keratitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lacrimation increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Vision blurred	0	(0.0, 0.0)	0	(0.0, 0.0)
Vitreous floaters	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	157 (1.2)	(1.0, 1.4)	117 (0.9)	(0.7, 1.1)
Diarrhoea	82 (0.6)	(0.5, 0.8)	64 (0.5)	(0.4, 0.6)
Nausea	42 (0.3)	(0.2, 0.4)	29 (0.2)	(0.1, 0.3)
Vomiting	16 (0.1)	(0.1, 0.2)	11 (0.1)	(0.0, 0.2)
Abdominal pain upper	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal pain	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Constipation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gastritis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Abdominal discomfort	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dental caries	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dyspepsia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrooesophageal reflux disease	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Toothache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal distension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aphthous ulcer	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Flatulence	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Odynophagia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.0)	0	(0.0, 0.0)

14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Umbilical hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal pain lower	0	(0.0, 0.0)	0	(0.0, 0.0)
Colitis microscopic	0	(0.0, 0.0)	0	(0.0, 0.0)
Diverticulum	0	(0.0, 0.0)	0	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Faeces soft	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Gingival pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossodynia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hiatus hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Irritable bowel syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Large intestine polyp	0	(0.0, 0.0)	0	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Oral pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	0	(0.0, 0.0)
Proctalgia	0	(0.0, 0.0)	0	(0.0, 0.0)
Retching	0	(0.0, 0.0)	0	(0.0, 0.0)
Stomatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	0	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1707 (13.1)	(12.6, 13.7)	402 (3.1)	(2.8, 3.4)
Injection site pain	1326 (10.2)	(9.7, 10.7)	169 (1.3)	(1.1, 1.5)
Fatigue	369 (2.8)	(2.6, 3.1)	162 (1.2)	(1.1, 1.4)

14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Chills	198 (1.5)	(1.3, 1.7)	43 (0.3)	(0.2, 0.4)
Pyrexia	209 (1.6)	(1.4, 1.8)	27 (0.2)	(0.1, 0.3)
Pain	88 (0.7)	(0.5, 0.8)	13 (0.1)	(0.1, 0.2)
Injection site erythema	57 (0.4)	(0.3, 0.6)	10 (0.1)	(0.0, 0.1)
Injection site swelling	49 (0.4)	(0.3, 0.5)	5 (0.0)	(0.0, 0.1)
Malaise	36 (0.3)	(0.2, 0.4)	4 (0.0)	(0.0, 0.1)
Asthenia	13 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Injection site bruising	5 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Injection site pruritus	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site induration	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site oedema	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site warmth	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Chest pain	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Feeling hot	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Influenza like illness	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site discomfort	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chest discomfort	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Oedema peripheral	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Injection site haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peripheral swelling	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Axillary pain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site papule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sensation of foreign body	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling face	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cyst	0	(0.0, 0.0)	0	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Gait disturbance	0	(0.0, 0.0)	0	(0.0, 0.0)
Induration	0	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site nodule	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site paraesthesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mass	0	(0.0, 0.0)	0	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sluggishness	0	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholelithiasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Drug hypersensitivity	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Seasonal allergy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	27 (0.2)	(0.1, 0.3)	45 (0.3)	(0.3, 0.5)
Urinary tract infection	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Sinusitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Tooth infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Conjunctivitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ear infection	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12995) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=13026) n[b] (%)	 (95% CI[c])
Cystitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Herpes zoster	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hordeolum	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis externa	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper respiratory tract infection	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute sinusitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Gastroenteritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tooth abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal mycotic infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Diverticulitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Oral herpes	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periodontitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial vulvovaginitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bartholin's abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Eye infection bacterial	0	(0.0, 0.0)	0	(0.0, 0.0)
Furuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Gingivitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex	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)
Localised infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasopharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Onychomycosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Otitis media bacterial	0	(0.0, 0.0)	0	(0.0, 0.0)

14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
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	0	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pustule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Syphilis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vulvovaginal candidiasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	20 (0.2)	(0.1, 0.2)	22 (0.2)	(0.1, 0.3)
Fall	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Exposure during pregnancy	2 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Contusion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle strain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ligament sprain	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Meniscus injury	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Skin laceration	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)
Arthropod sting	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Facial bones fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Ligament rupture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Limb injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Radius fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin abrasion	0	(0.0, 0.0)	0	(0.0, 0.0)
Wound	0	(0.0, 0.0)	0	(0.0, 0.0)
Administration related reaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Animal bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ankle fracture	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)

14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Corneal abrasion	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)
Epicondylitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Fibula fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during breast feeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural discomfort	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)
Rib fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Spinal compression fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Stoma site rash	0	(0.0, 0.0)	0	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thermal burn	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Upper limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination complication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	22 (0.2)	(0.1, 0.3)	7 (0.1)	(0.0, 0.1)
Body temperature increased	17 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Blood pressure increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart rate increased	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Blood glucose increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood cholesterol increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure systolic increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Glomerular filtration rate decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex test positive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Low density lipoprotein increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostatic specific antigen increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Troponin increased	0	(0.0, 0.0)	0	(0.0, 0.0)

14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	15 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Decreased appetite	7 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hyperlipidaemia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitamin D deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dehydration	0	(0.0, 0.0)	0	(0.0, 0.0)
Dyslipidaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypokalaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	0	(0.0, 0.0)
Insulin resistance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Iron deficiency	0	(0.0, 0.0)	0	(0.0, 0.0)
Type 2 diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitamin B12 deficiency	0	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	357 (2.7)	(2.5, 3.0)	102 (0.8)	(0.6, 0.9)
Myalgia	245 (1.9)	(1.7, 2.1)	55 (0.4)	(0.3, 0.5)
Arthralgia	56 (0.4)	(0.3, 0.6)	20 (0.2)	(0.1, 0.2)
Pain in extremity	47 (0.4)	(0.3, 0.5)	3 (0.0)	(0.0, 0.1)
Back pain	13 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.2)
Muscle spasms	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Neck pain	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tendonitis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Joint range of motion decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bursitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flank pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscular weakness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Joint stiffness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fibromyalgia	0	(0.0, 0.0)	0	(0.0, 0.0)
Intervertebral disc protrusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint effusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Joint instability	0	(0.0, 0.0)	0	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle fatigue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Plantar fasciitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Psoriatic arthropathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal stenosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Spondylitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Synovitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Basal cell carcinoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Colon adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acrochordon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intraductal proliferative breast lesion	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	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	0	(0.0, 0.0)	0	(0.0, 0.0)

14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12995) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=13026) n[b] (%)	 (95% CI[c])
Squamous cell carcinoma	0	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	360 (2.8)	(2.5, 3.1)	187 (1.4)	(1.2, 1.7)
Headache	314 (2.4)	(2.2, 2.7)	150 (1.2)	(1.0, 1.3)
Dizziness	12 (0.1)	(0.0, 0.2)	19 (0.1)	(0.1, 0.2)
Paraesthesia	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Lethargy	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Migraine	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dysgeusia	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Somnolence	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tremor	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Presyncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syncope	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tension headache	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness postural	0	(0.0, 0.0)	0	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetic neuropathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Disturbance in attention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyskinesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental impairment	0	(0.0, 0.0)	0	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nystagmus	0	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	19 (0.1)	(0.1, 0.2)	10 (0.1)	(0.0, 0.1)
Insomnia	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Anxiety	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Depression	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Irritability	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Panic attack	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bruxism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	0	(0.0, 0.0)
Nightmare	0	(0.0, 0.0)	0	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dysuria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematuria	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pollakiuria	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Acute kidney injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	0	(0.0, 0.0)
Urine odour abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	7 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Erectile dysfunction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Testicular pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	0	(0.0, 0.0)	0	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysmenorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scrotal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uterine prolapse	0	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	35 (0.3)	(0.2, 0.4)	36 (0.3)	(0.2, 0.4)
Oropharyngeal pain	9 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Nasal congestion	6 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Rhinorrhoea	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Cough	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dyspnoea	2 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Throat irritation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Asthma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Rhinitis allergic	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Productive cough	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sneezing	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper-airway cough syndrome	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Epistaxis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bronchospasm	0	(0.0, 0.0)	0	(0.0, 0.0)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sinus congestion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic sinusitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	0	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea exertional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus hypersecretion	0	(0.0, 0.0)	0	(0.0, 0.0)
Rhinalgia	0	(0.0, 0.0)	0	(0.0, 0.0)
Sleep apnoea syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
Wheezing	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	35 (0.3)	(0.2, 0.4)	35 (0.3)	(0.2, 0.4)
Rash	7 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Pruritus	1 (0.0)	(0.0, 0.0)	10 (0.1)	(0.0, 0.1)
Hyperhidrosis	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Urticaria	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dermatitis contact	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Rash pruritic	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Erythema	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Night sweats	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alopecia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis allergic	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hand dermatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Actinic keratosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Angioedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Blister	0	(0.0, 0.0)	0	(0.0, 0.0)
Cold sweat	0	(0.0, 0.0)	0	(0.0, 0.0)
Dermal cyst	0	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis exfoliative	0	(0.0, 0.0)	0	(0.0, 0.0)
Ecchymosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Eczema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Macule	0	(0.0, 0.0)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis rosea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative care	0	(0.0, 0.0)	0	(0.0, 0.0)

14.90. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	8 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Hypertension	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hot flush	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Flushing	0	(0.0, 0.0)	0	(0.0, 0.0)
Haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arteriosclerosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (14:41)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s091 d17d age p3 saf

14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1059 (11.9)	(11.2, 12.5)	402 (4.5)	(4.1, 5.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lymphadenopathy	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood loss anaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Iron deficiency anaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Lymph node pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Palpitations	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Atrial fibrillation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute myocardial infarction	0	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block left	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cardiac disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	8 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Vertigo	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ear pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tinnitus	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vertigo positional	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
ENDOCRINE DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypothyroidism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Goitre	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EYE DISORDERS	5 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Eye irritation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Eye pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Conjunctivitis allergic	0	(0.0, 0.0)	0	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctival haemorrhage	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Photophobia	0	(0.0, 0.0)	0	(0.0, 0.0)

14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8931) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8895) n[b] (%)	 (95% CI[c])
Asthenopia	0	(0.0, 0.0)	0	(0.0, 0.0)
Cataract	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chalazion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Corneal irritation	0	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	0	(0.0, 0.0)
Keratitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vision blurred	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vitreous floaters	0	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	81 (0.9)	(0.7, 1.1)	61 (0.7)	(0.5, 0.9)
Diarrhoea	40 (0.4)	(0.3, 0.6)	35 (0.4)	(0.3, 0.5)
Nausea	19 (0.2)	(0.1, 0.3)	16 (0.2)	(0.1, 0.3)
Vomiting	1 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Abdominal pain upper	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal pain	1 (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)	1 (0.0)	(0.0, 0.1)
Abdominal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dental caries	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspepsia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Toothache	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal distension	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aphthous ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry mouth	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	0	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhoids	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Odynophagia	0	(0.0, 0.0)	0	(0.0, 0.0)
Small intestinal obstruction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Umbilical hernia	0	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	0	(0.0, 0.0)

14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8931) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8895) n[b] (%)	 (95% CI[c])
Abdominal pain lower	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Colitis microscopic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulum	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	0	(0.0, 0.0)
Faeces soft	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastric ulcer haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gingival pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	0	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hiatus hernia	0	(0.0, 0.0)	0	(0.0, 0.0)
Irritable bowel syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
Large intestine polyp	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lip oedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Lip swelling	0	(0.0, 0.0)	0	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	0	(0.0, 0.0)
Noninfective gingivitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Proctalgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stomatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	788 (8.8)	(8.2, 9.4)	173 (1.9)	(1.7, 2.3)
Injection site pain	634 (7.1)	(6.6, 7.7)	67 (0.8)	(0.6, 1.0)
Fatigue	154 (1.7)	(1.5, 2.0)	63 (0.7)	(0.5, 0.9)
Chills	58 (0.6)	(0.5, 0.8)	22 (0.2)	(0.2, 0.4)
Pyrexia	51 (0.6)	(0.4, 0.8)	6 (0.1)	(0.0, 0.1)

14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pain	37 (0.4)	(0.3, 0.6)	9 (0.1)	(0.0, 0.2)
Injection site erythema	29 (0.3)	(0.2, 0.5)	3 (0.0)	(0.0, 0.1)
Injection site swelling	25 (0.3)	(0.2, 0.4)	7 (0.1)	(0.0, 0.2)
Malaise	12 (0.1)	(0.1, 0.2)	5 (0.1)	(0.0, 0.1)
Asthenia	10 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Injection site bruising	3 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Injection site pruritus	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site induration	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site warmth	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Feeling hot	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Oedema peripheral	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peripheral swelling	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Axillary pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site papule	0	(0.0, 0.0)	0	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sensation of foreign body	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Swelling face	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site erythema	0	(0.0, 0.0)	0	(0.0, 0.0)
Application site pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	0	(0.0, 0.0)
Application site reaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Death	0	(0.0, 0.0)	0	(0.0, 0.0)

14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Exercise tolerance decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gait disturbance	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Induration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Inflammation	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site nodule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site rash	0	(0.0, 0.0)	0	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	0	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Medical device pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	0	(0.0, 0.0)
Sluggishness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vaccination site pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Drug hypersensitivity	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Seasonal allergy	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Food allergy	0	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	28 (0.3)	(0.2, 0.5)	27 (0.3)	(0.2, 0.4)
Urinary tract infection	5 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Sinusitis	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tooth infection	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Conjunctivitis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cystitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Herpes zoster	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)

14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8931) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8895) n[b] (%)	 (95% CI[c])
Hordeolum	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Otitis externa	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute sinusitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastroenteritis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Otitis media	0	(0.0, 0.0)	0	(0.0, 0.0)
Tooth abscess	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Oral herpes	0	(0.0, 0.0)	0	(0.0, 0.0)
Periodontitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tinea infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	0	(0.0, 0.0)
Appendicitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bacterial vulvovaginitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Bartholin's abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Eye infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye infection bacterial	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Furuncle	0	(0.0, 0.0)	0	(0.0, 0.0)
Gingival abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingivitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Herpes simplex	0	(0.0, 0.0)	0	(0.0, 0.0)
Infected bite	0	(0.0, 0.0)	0	(0.0, 0.0)
Localised infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Nasopharyngitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Onychomycosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oral fungal infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Otitis media bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritoneal abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Peritonsillar abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8931) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8895) n[b] (%)	 (95% CI[c])
Pharyngitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngotonsillitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pustule	0	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Rhinitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Syphilis	0	(0.0, 0.0)	0	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillitis bacterial	0	(0.0, 0.0)	0	(0.0, 0.0)
Vulvovaginal candidiasis	0	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	12 (0.1)	(0.1, 0.2)	23 (0.3)	(0.2, 0.4)
Fall	4 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.2)
Exposure during pregnancy	0	(0.0, 0.0)	0	(0.0, 0.0)
Contusion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscle strain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ligament sprain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Meniscus injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin laceration	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Arthropod bite	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arthropod sting	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)
Humerus fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ligament rupture	0	(0.0, 0.0)	0	(0.0, 0.0)
Limb injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	0	(0.0, 0.0)	0	(0.0, 0.0)
Radius fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin abrasion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Wound	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Administration related reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Animal bite	0	(0.0, 0.0)	0	(0.0, 0.0)
Ankle fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burns second degree	0	(0.0, 0.0)	0	(0.0, 0.0)
Corneal abrasion	0	(0.0, 0.0)	0	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	0	(0.0, 0.0)

14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8931) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8895) n[b] (%)	 (95% CI[c])
Epicondylitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fibula fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Foot fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Limb traumatic amputation	0	(0.0, 0.0)	0	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Maternal exposure during breast feeding	0	(0.0, 0.0)	0	(0.0, 0.0)
Mouth injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle rupture	0	(0.0, 0.0)	0	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Post procedural discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Procedural pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spinal compression fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stoma site rash	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	0	(0.0, 0.0)
Thermal burn	0	(0.0, 0.0)	0	(0.0, 0.0)
Tooth fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper limb fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination complication	0	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	19 (0.2)	(0.1, 0.3)	2 (0.0)	(0.0, 0.1)
Body temperature increased	13 (0.1)	(0.1, 0.2)	0	(0.0, 0.0)
Blood pressure increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Heart rate increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood cholesterol increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood pressure systolic increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	0	(0.0, 0.0)
Herpes simplex test positive	0	(0.0, 0.0)	0	(0.0, 0.0)
Low density lipoprotein increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Prostatic specific antigen increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Troponin increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Weight decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Weight increased	0	(0.0, 0.0)	0	(0.0, 0.0)

14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
METABOLISM AND NUTRITION DISORDERS	5 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.2)
Decreased appetite	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hyperlipidaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vitamin D deficiency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dehydration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dyslipidaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Food intolerance	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypertriglyceridaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Impaired fasting glucose	0	(0.0, 0.0)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Insulin resistance	0	(0.0, 0.0)	0	(0.0, 0.0)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	0	(0.0, 0.0)	0	(0.0, 0.0)
Vitamin B12 deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	164 (1.8)	(1.6, 2.1)	78 (0.9)	(0.7, 1.1)
Myalgia	86 (1.0)	(0.8, 1.2)	27 (0.3)	(0.2, 0.4)
Arthralgia	19 (0.2)	(0.1, 0.3)	20 (0.2)	(0.1, 0.3)
Pain in extremity	41 (0.5)	(0.3, 0.6)	9 (0.1)	(0.0, 0.2)
Back pain	7 (0.1)	(0.0, 0.2)	11 (0.1)	(0.1, 0.2)
Muscle spasms	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Neck pain	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Tendonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Joint range of motion decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bursitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flank pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscular weakness	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Osteoarthritis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Groin pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint stiffness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Musculoskeletal chest pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pain in jaw	0	(0.0, 0.0)	0	(0.0, 0.0)
Fibromyalgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intervertebral disc protrusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint instability	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint swelling	0	(0.0, 0.0)	0	(0.0, 0.0)
Limb discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle fatigue	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle twitching	0	(0.0, 0.0)	0	(0.0, 0.0)
Periarthritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Plantar fasciitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Psoriatic arthropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rhabdomyolysis	0	(0.0, 0.0)	0	(0.0, 0.0)
Spinal stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spondylitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Synovitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Tenosynovitis stenosans	0	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	4 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Basal cell carcinoma	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Colon adenoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acrochordon	0	(0.0, 0.0)	0	(0.0, 0.0)
Benign breast neoplasm	0	(0.0, 0.0)	0	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Leydig cell tumour of the testis	0	(0.0, 0.0)	0	(0.0, 0.0)
Lipoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Meningioma	0	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Squamous cell carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	152 (1.7)	(1.4, 2.0)	88 (1.0)	(0.8, 1.2)

14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8931) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8895) n[b] (%)	 (95% CI[c])
Headache	125 (1.4)	(1.2, 1.7)	68 (0.8)	(0.6, 1.0)
Dizziness	8 (0.1)	(0.0, 0.2)	10 (0.1)	(0.1, 0.2)
Paraesthesia	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Lethargy	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Migraine	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dysgeusia	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Somnolence	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tremor	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Presyncope	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Syncope	0	(0.0, 0.0)	0	(0.0, 0.0)
Tension headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Carpal tunnel syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dizziness postural	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diabetic neuropathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disturbance in attention	0	(0.0, 0.0)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	0	(0.0, 0.0)
Mental impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Nerve compression	0	(0.0, 0.0)	0	(0.0, 0.0)
Neuropathy peripheral	0	(0.0, 0.0)	0	(0.0, 0.0)
Nystagmus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peripheral sensory neuropathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	5 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Insomnia	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)
Depression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abnormal dreams	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8931) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8895) n[b] (%)	 (95% CI[c])
Disorientation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Irritability	0	(0.0, 0.0)	0	(0.0, 0.0)
Panic attack	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	0	(0.0, 0.0)
Anxiety disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Bruxism	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Nightmare	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dysuria	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haematuria	0	(0.0, 0.0)	0	(0.0, 0.0)
Nephrolithiasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pollakiuria	0	(0.0, 0.0)	0	(0.0, 0.0)
Acute kidney injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	6 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Erectile dysfunction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pelvic pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Testicular pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	0	(0.0, 0.0)
Cervical dysplasia	0	(0.0, 0.0)	0	(0.0, 0.0)
Dysmenorrhoea	0	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
Scrotal pain	0	(0.0, 0.0)	0	(0.0, 0.0)

14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Uterine prolapse	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	28 (0.3)	(0.2, 0.5)	16 (0.2)	(0.1, 0.3)
Oropharyngeal pain	4 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Nasal congestion	5 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Rhinorrhoea	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cough	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dyspnoea	0	(0.0, 0.0)	0	(0.0, 0.0)
Throat irritation	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Asthma	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rhinitis allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sneezing	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epistaxis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bronchospasm	1 (0.0)	(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, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	0	(0.0, 0.0)
Sinus congestion	0	(0.0, 0.0)	0	(0.0, 0.0)
Upper respiratory tract congestion	0	(0.0, 0.0)	0	(0.0, 0.0)
Allergic sinusitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea exertional	0	(0.0, 0.0)	0	(0.0, 0.0)
Nasal discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	0	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rhinalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sleep apnoea syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Wheezing	0	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	33 (0.4)	(0.3, 0.5)	17 (0.2)	(0.1, 0.3)
Rash	9 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Pruritus	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hyperhidrosis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Urticaria	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermatitis contact	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Rash pruritic	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Erythema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Night sweats	0	(0.0, 0.0)	0	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alopecia	0	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis allergic	0	(0.0, 0.0)	0	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash maculo-papular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Actinic keratosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Angioedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blister	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermal cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermatitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eczema	0	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	0	(0.0, 0.0)	0	(0.0, 0.0)
Livedo reticularis	0	(0.0, 0.0)	0	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	0	(0.0, 0.0)
Papule	0	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis rosea	0	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin lesion	0	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rhinoplasty	0	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	9 (0.1)	(0.0, 0.2)	5 (0.1)	(0.0, 0.1)

14.91. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 7 Days After Dose 1, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypertension	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hot flush	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flushing	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Haematoma	1 (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)
Hypotension	0	(0.0, 0.0)	0	(0.0, 0.0)
Intermittent claudication	0	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (14:41)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s091_d17d_age_p3_saf

14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12727)		Placebo (N[a]=12757)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	2810 (22.1)	(21.4, 22.8)	561 (4.4)	(4.0, 4.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	54 (0.4)	(0.3, 0.6)	3 (0.0)	(0.0, 0.1)
Lymphadenopathy	50 (0.4)	(0.3, 0.5)	1 (0.0)	(0.0, 0.0)
Lymph node pain	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iron deficiency anaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Splenomegaly	0	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	12 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)
Tachycardia	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Palpitations	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute coronary syndrome	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)
Acute myocardial infarction	0	(0.0, 0.0)	0	(0.0, 0.0)
Angina pectoris	0	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	0	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia	0	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	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	0	(0.0, 0.0)	0	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular arrhythmia	0	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular extrasystoles	0	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	12 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.1)
Vertigo	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)

14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12727)		Placebo (N[a]=12757)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tinnitus	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Ear pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vertigo positional	0	(0.0, 0.0)	0	(0.0, 0.0)
Ear discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerumen impaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Deafness neurosensory	0	(0.0, 0.0)	0	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypothyroidism	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	12 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Vision blurred	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cataract	0	(0.0, 0.0)	0	(0.0, 0.0)
Eye irritation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eye pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenopia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	0	(0.0, 0.0)
Eye inflammation	0	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glaucoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Ocular discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Swelling of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitreous detachment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	228 (1.8)	(1.6, 2.0)	86 (0.7)	(0.5, 0.8)

14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12727)		Placebo (N[a]=12757)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Nausea	138 (1.1)	(0.9, 1.3)	21 (0.2)	(0.1, 0.3)
Diarrhoea	64 (0.5)	(0.4, 0.6)	43 (0.3)	(0.2, 0.5)
Vomiting	36 (0.3)	(0.2, 0.4)	3 (0.0)	(0.0, 0.1)
Abdominal pain	7 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Abdominal pain upper	7 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Toothache	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dyspepsia	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal discomfort	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Odynophagia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aphthous ulcer	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Constipation	0	(0.0, 0.0)	0	(0.0, 0.0)
Flatulence	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Abdominal pain lower	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parotid duct obstruction	0	(0.0, 0.0)	0	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abnormal faeces	0	(0.0, 0.0)	0	(0.0, 0.0)
Colitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Dental caries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Frequent bowel movements	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastric ulcer	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Glossodynia	0	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12727)		Placebo (N[a]=12757)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal spasm	0	(0.0, 0.0)	0	(0.0, 0.0)
Oral lichenoid reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	0	(0.0, 0.0)	0	(0.0, 0.0)
Stomatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discolouration	0	(0.0, 0.0)	0	(0.0, 0.0)
Tongue oedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Tongue pruritus	0	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2390 (18.8)	(18.1, 19.5)	294 (2.3)	(2.1, 2.6)
Injection site pain	1107 (8.7)	(8.2, 9.2)	127 (1.0)	(0.8, 1.2)
Pyrexia	977 (7.7)	(7.2, 8.2)	23 (0.2)	(0.1, 0.3)
Fatigue	765 (6.0)	(5.6, 6.4)	121 (0.9)	(0.8, 1.1)
Chills	827 (6.5)	(6.1, 6.9)	32 (0.3)	(0.2, 0.4)
Pain	356 (2.8)	(2.5, 3.1)	23 (0.2)	(0.1, 0.3)
Injection site erythema	64 (0.5)	(0.4, 0.6)	8 (0.1)	(0.0, 0.1)
Malaise	52 (0.4)	(0.3, 0.5)	5 (0.0)	(0.0, 0.1)
Injection site swelling	45 (0.4)	(0.3, 0.5)	4 (0.0)	(0.0, 0.1)
Asthenia	32 (0.3)	(0.2, 0.4)	6 (0.0)	(0.0, 0.1)
Injection site pruritus	15 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Influenza like illness	9 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site bruising	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Injection site warmth	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Axillary pain	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site induration	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site mass	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site oedema	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12727)		Placebo (N[a]=12757)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Feeling hot	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site nodule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oedema peripheral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chest discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Face oedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Feeling abnormal	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling cold	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site papule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site rash	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peripheral swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	0	(0.0, 0.0)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site irritation	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site urticaria	0	(0.0, 0.0)	0	(0.0, 0.0)
Medical device pain	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)
Sluggishness	0	(0.0, 0.0)	0	(0.0, 0.0)
Temperature intolerance	0	(0.0, 0.0)	0	(0.0, 0.0)
Therapeutic response unexpected	0	(0.0, 0.0)	0	(0.0, 0.0)
Thirst	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)

14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12727) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12757) n[b] (%)	 (95% CI[c])
HEPATOBILIARY DISORDERS	0	(0.0, 0.0)	0	(0.0, 0.0)
Biliary colic	0	(0.0, 0.0)	0	(0.0, 0.0)
Biliary dyskinesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Cholelithiasis	0	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Seasonal allergy	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Drug hypersensitivity	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	26 (0.2)	(0.1, 0.3)	27 (0.2)	(0.1, 0.3)
Urinary tract infection	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth infection	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Rhinitis	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Conjunctivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinusitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hordeolum	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cystitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ear infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes zoster	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Onychomycosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Parotitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tooth abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Upper respiratory tract infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	0	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial sepsis	0	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Diverticulitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Folliculitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Furuncle	0	(0.0, 0.0)	0	(0.0, 0.0)

14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12727) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=12757) n[b] (%)	 (95% CI[c])
Gastroenteritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingivitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gonorrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impetigo	0	(0.0, 0.0)	0	(0.0, 0.0)
Influenza	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Ophthalmic herpes zoster	0	(0.0, 0.0)	0	(0.0, 0.0)
Oral candidiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Otitis media acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papilloma viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parasitic gastroenteritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paronychia	0	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonia	0	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary tuberculosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pustule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous 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)
Tonsillitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	17 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.2)
Fall	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exposure during pregnancy	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Joint dislocation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Procedural pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tooth fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vaccination complication	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ligament sprain	1 (0.0)	(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 strain	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin laceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fibula fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12727)		Placebo (N[a]=12757)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Limb injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthropod bite	0	(0.0, 0.0)	0	(0.0, 0.0)
Arthropod sting	0	(0.0, 0.0)	0	(0.0, 0.0)
Chest injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Concussion	0	(0.0, 0.0)	0	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hand fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Joint injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Ligament rupture	0	(0.0, 0.0)	0	(0.0, 0.0)
Lip injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle rupture	0	(0.0, 0.0)	0	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin abrasion	0	(0.0, 0.0)	0	(0.0, 0.0)
Spinal compression fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tibia fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Venom poisoning	0	(0.0, 0.0)	0	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	70 (0.6)	(0.4, 0.7)	8 (0.1)	(0.0, 0.1)
Body temperature increased	59 (0.5)	(0.4, 0.6)	6 (0.0)	(0.0, 0.1)
Blood pressure increased	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Heart rate increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose fluctuation	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure diastolic increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone increased	0	(0.0, 0.0)	0	(0.0, 0.0)

14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12727)		Placebo (N[a]=12757)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Body temperature	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
Low density lipoprotein increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Mammogram abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory rate increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	23 (0.2)	(0.1, 0.3)	9 (0.1)	(0.0, 0.1)
Decreased appetite	17 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Vitamin D deficiency	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyslipidaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hyperglycaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Type 2 diabetes mellitus	0	(0.0, 0.0)	0	(0.0, 0.0)
Vitamin B12 deficiency	0	(0.0, 0.0)	0	(0.0, 0.0)
Dehydration	0	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocalcaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	852 (6.7)	(6.3, 7.1)	78 (0.6)	(0.5, 0.8)
Myalgia	707 (5.6)	(5.2, 6.0)	42 (0.3)	(0.2, 0.4)
Arthralgia	109 (0.9)	(0.7, 1.0)	15 (0.1)	(0.1, 0.2)
Pain in extremity	44 (0.3)	(0.3, 0.5)	7 (0.1)	(0.0, 0.1)
Back pain	16 (0.1)	(0.1, 0.2)	7 (0.1)	(0.0, 0.1)
Neck pain	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscle spasms	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal stiffness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscular weakness	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint stiffness	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12727)		Placebo (N[a]=12757)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bursitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intervertebral disc protrusion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Bone pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Costochondritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthritis reactive	0	(0.0, 0.0)	0	(0.0, 0.0)
Axillary mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exostosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Intervertebral disc degeneration	0	(0.0, 0.0)	0	(0.0, 0.0)
Metatarsalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mobility decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Periarthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Breast cancer	0	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibroadenoma of breast	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	0	(0.0, 0.0)
Malignant melanoma of eyelid	0	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer metastatic	0	(0.0, 0.0)	0	(0.0, 0.0)

14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12727)		Placebo (N[a]=12757)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
NERVOUS SYSTEM DISORDERS	755 (5.9)	(5.5, 6.4)	134 (1.1)	(0.9, 1.2)
Headache	693 (5.4)	(5.1, 5.9)	105 (0.8)	(0.7, 1.0)
Dizziness	26 (0.2)	(0.1, 0.3)	7 (0.1)	(0.0, 0.1)
Lethargy	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Paraesthesia	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Migraine	11 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Somnolence	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dysgeusia	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disturbance in attention	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Tension headache	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tremor	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperaesthesia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burning sensation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Head discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nerve compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parosmia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Presyncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus headache	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Balance disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Carpal tunnel syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
Cervical radiculopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial paralysis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Generalised tonic-clonic seizure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypersomnia	0	(0.0, 0.0)	0	(0.0, 0.0)
Ischaemic stroke	0	(0.0, 0.0)	0	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12727)		Placebo (N[a]=12757)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuropathy peripheral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post herpetic neuralgia	0	(0.0, 0.0)	0	(0.0, 0.0)
Radiculopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restless legs syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	12 (0.1)	(0.0, 0.2)	13 (0.1)	(0.1, 0.2)
Insomnia	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Anxiety	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Depression	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Irritability	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Attention deficit hyperactivity disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Dysphemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Generalised anxiety disorder	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 fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic attack	0	(0.0, 0.0)	0	(0.0, 0.0)
Paranoia	0	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	0	(0.0, 0.0)	0	(0.0, 0.0)
Sleep disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Dysuria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nephrolithiasis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pollakiuria	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haematuria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bladder spasm	0	(0.0, 0.0)	0	(0.0, 0.0)
Micturition urgency	0	(0.0, 0.0)	0	(0.0, 0.0)
Oedematous kidney	0	(0.0, 0.0)	0	(0.0, 0.0)
Perinephric oedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Renal cyst haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)

14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12727)		Placebo (N[a]=12757)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Metrorrhagia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus genital	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Genital erythema	0	(0.0, 0.0)	0	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	32 (0.3)	(0.2, 0.4)	20 (0.2)	(0.1, 0.2)
Oropharyngeal pain	10 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Nasal congestion	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Rhinorrhoea	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Cough	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Asthma	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinus congestion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper respiratory tract congestion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper-airway cough syndrome	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Respiratory tract congestion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Throat irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthma exercise induced	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthmatic crisis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bronchospasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysphonia	0	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea exertional	0	(0.0, 0.0)	0	(0.0, 0.0)
Epistaxis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal polyps	0	(0.0, 0.0)	0	(0.0, 0.0)

14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12727)		Placebo (N[a]=12757)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Nasal turbinate hypertrophy	0	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	0	(0.0, 0.0)	0	(0.0, 0.0)
Productive cough	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Reflux laryngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinitis allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	49 (0.4)	(0.3, 0.5)	19 (0.1)	(0.1, 0.2)
Rash	12 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Hyperhidrosis	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Night sweats	7 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erythema	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urticaria	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Alopecia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psoriasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash pruritic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Skin lesion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blister	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis contact	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eczema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Papule	0	(0.0, 0.0)	0	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash papular	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermal cyst	0	(0.0, 0.0)	0	(0.0, 0.0)
Drug eruption	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fixed eruption	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hand dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain of skin	0	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.92. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12727)		Placebo (N[a]=12757)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rosacea	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin discolouration	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endodontic procedure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facet joint block	0	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	12 (0.1)	(0.0, 0.2)	7 (0.1)	(0.0, 0.1)
Hypertension	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Flushing	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hot flush	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypotension	0	(0.0, 0.0)	0	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphorrhoea	0	(0.0, 0.0)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	0	(0.0, 0.0)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Subjects who did not receive Dose 2 or who received a different vaccine at Dose 1 and Dose 2 were excluded from this table.
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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 29MAR2021 (04:19)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s091 d27d age p3 saf

14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8844)		Placebo (N[a]=8792)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1437 (16.2)	(15.5, 17.0)	328 (3.7)	(3.3, 4.1)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	7 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Lymphadenopathy	6 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Lymph node pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Iron deficiency anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Leukocytosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Splenomegaly	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thrombocytosis	0	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	10 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Tachycardia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Palpitations	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Atrial fibrillation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bradycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Angina unstable	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arrhythmia supraventricular	0	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	0	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Atrioventricular block first degree	0	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block right	0	(0.0, 0.0)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	0	(0.0, 0.0)
Sinus tachycardia	0	(0.0, 0.0)	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)
EAR AND LABYRINTH DISORDERS	9 (0.1)	(0.0, 0.2)	4 (0.0)	(0.0, 0.1)
Vertigo	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tinnitus	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8844)		Placebo (N[a]=8792)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ear pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo positional	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ear discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Cerumen impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Deafness neurosensory	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deafness unilateral	0	(0.0, 0.0)	0	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Hyperacusis	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	0	(0.0, 0.0)
Otorrhoea	0	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	0	(0.0, 0.0)
ENDOCRINE DISORDERS	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypothyroidism	0	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	5 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Vision blurred	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cataract	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Eye irritation	0	(0.0, 0.0)	0	(0.0, 0.0)
Eye pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lacrimation increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Asthenopia	0	(0.0, 0.0)	0	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Diplopia	0	(0.0, 0.0)	0	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye inflammation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eyelid oedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Glaucoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ocular discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ocular hyperaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Photophobia	0	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Swelling of eyelid	0	(0.0, 0.0)	0	(0.0, 0.0)
Vitreous detachment	0	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	124 (1.4)	(1.2, 1.7)	39 (0.4)	(0.3, 0.6)
Nausea	67 (0.8)	(0.6, 1.0)	4 (0.0)	(0.0, 0.1)

14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8844)		Placebo (N[a]=8792)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Diarrhoea	46 (0.5)	(0.4, 0.7)	23 (0.3)	(0.2, 0.4)
Vomiting	9 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Abdominal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal pain upper	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Toothache	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dyspepsia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal discomfort	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Odynophagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Aphthous ulcer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Constipation	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flatulence	0	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain lower	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrooesophageal reflux disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Retching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tooth impacted	0	(0.0, 0.0)	0	(0.0, 0.0)
Abnormal faeces	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dental caries	0	(0.0, 0.0)	0	(0.0, 0.0)
Faeces soft	0	(0.0, 0.0)	0	(0.0, 0.0)
Frequent bowel movements	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gastric ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis erosive	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	0	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glossodynia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypoaesthesia oral	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia teeth	0	(0.0, 0.0)	0	(0.0, 0.0)

14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8844)		Placebo (N[a]=8792)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lip swelling	0	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	0	(0.0, 0.0)
Noninfective gingivitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral lichenoid reaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Stomatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Tongue discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tongue oedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1160 (13.1)	(12.4, 13.8)	143 (1.6)	(1.4, 1.9)
Injection site pain	596 (6.7)	(6.2, 7.3)	53 (0.6)	(0.5, 0.8)
Pyrexia	365 (4.1)	(3.7, 4.6)	12 (0.1)	(0.1, 0.2)
Fatigue	344 (3.9)	(3.5, 4.3)	52 (0.6)	(0.4, 0.8)
Chills	350 (4.0)	(3.6, 4.4)	20 (0.2)	(0.1, 0.4)
Pain	169 (1.9)	(1.6, 2.2)	9 (0.1)	(0.0, 0.2)
Injection site erythema	37 (0.4)	(0.3, 0.6)	5 (0.1)	(0.0, 0.1)
Malaise	36 (0.4)	(0.3, 0.6)	5 (0.1)	(0.0, 0.1)
Injection site swelling	33 (0.4)	(0.3, 0.5)	4 (0.0)	(0.0, 0.1)
Asthenia	19 (0.2)	(0.1, 0.3)	3 (0.0)	(0.0, 0.1)
Injection site pruritus	9 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Influenza like illness	8 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Injection site bruising	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site warmth	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Axillary pain	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site induration	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site mass	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site oedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Adverse drug reaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Chest pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Feeling hot	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8844)		Placebo (N[a]=8792)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site nodule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site paraesthesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Oedema peripheral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Face oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discomfort	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site haematoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site papule	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peripheral swelling	0	(0.0, 0.0)	0	(0.0, 0.0)
Swelling face	0	(0.0, 0.0)	0	(0.0, 0.0)
Application site pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Illness	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site lymphadenopathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site urticaria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Medical device pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	0	(0.0, 0.0)	0	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Therapeutic response unexpected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thirst	0	(0.0, 0.0)	0	(0.0, 0.0)
Vascular stent occlusion	0	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8844)		Placebo (N[a]=8792)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Biliary colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Biliary dyskinesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholelithiasis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Seasonal allergy	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Drug hypersensitivity	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	19 (0.2)	(0.1, 0.3)	19 (0.2)	(0.1, 0.3)
Urinary tract infection	6 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Tooth infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Rhinitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Cellulitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Conjunctivitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sinusitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Fungal skin infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hordeolum	0	(0.0, 0.0)	0	(0.0, 0.0)
Cystitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Ear infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Herpes simplex	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Herpes zoster	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Onychomycosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Parotitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	0	(0.0, 0.0)	0	(0.0, 0.0)
Tooth abscess	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Vulvovaginal candidiasis	0	(0.0, 0.0)	0	(0.0, 0.0)
Abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	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)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diverticulitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Folliculitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Furuncle	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastroenteritis	0	(0.0, 0.0)	0	(0.0, 0.0)

14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8844)		Placebo (N[a]=8792)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gingivitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Gonorrhoea	0	(0.0, 0.0)	0	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Impetigo	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Influenza	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ophthalmic herpes zoster	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral candidiasis	0	(0.0, 0.0)	0	(0.0, 0.0)
Otitis media acute	0	(0.0, 0.0)	0	(0.0, 0.0)
Papilloma viral infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Parasitic gastroenteritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Paronychia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pulmonary tuberculosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pustule	0	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Subcutaneous abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	0	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Viral infection	0	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	16 (0.2)	(0.1, 0.3)	12 (0.1)	(0.1, 0.2)
Fall	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Exposure during pregnancy	0	(0.0, 0.0)	0	(0.0, 0.0)
Joint dislocation	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Procedural pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tooth fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaccination complication	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ligament sprain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Meniscus injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Muscle strain	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Skin laceration	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Fibula fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Limb injury	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8844) n[b] (%)	(95% CI[c])	Placebo (N[a]=8792) n[b] (%)	(95% CI[c])
Administration related reaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Arthropod bite	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arthropod sting	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Concussion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Craniocerebral injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Hand fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ligament rupture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lip injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Penis injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Radius fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin abrasion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Spinal compression fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Tendon injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Tibia fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Venom poisoning	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Vulvovaginal injury	0	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	33 (0.4)	(0.3, 0.5)	2 (0.0)	(0.0, 0.1)
Body temperature increased	24 (0.3)	(0.2, 0.4)	1 (0.0)	(0.0, 0.1)
Blood pressure increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart rate increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood glucose abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood glucose increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood creatinine decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood pressure diastolic increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Body temperature	0	(0.0, 0.0)	0	(0.0, 0.0)

14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8844)		Placebo (N[a]=8792)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
C-reactive protein	0	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mammogram abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Weight decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	16 (0.2)	(0.1, 0.3)	4 (0.0)	(0.0, 0.1)
Decreased appetite	11 (0.1)	(0.1, 0.2)	0	(0.0, 0.0)
Vitamin D deficiency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyslipidaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	0	(0.0, 0.0)
Hyperglycaemia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Type 2 diabetes mellitus	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Vitamin B12 deficiency	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dehydration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diabetes mellitus	0	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus inadequate control	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypocalcaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypocholesterolaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	392 (4.4)	(4.0, 4.9)	57 (0.6)	(0.5, 0.8)
Myalgia	297 (3.4)	(3.0, 3.8)	26 (0.3)	(0.2, 0.4)
Arthralgia	57 (0.6)	(0.5, 0.8)	10 (0.1)	(0.1, 0.2)
Pain in extremity	40 (0.5)	(0.3, 0.6)	4 (0.0)	(0.0, 0.1)
Back pain	9 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Neck pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscle spasms	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscular weakness	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint stiffness	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bursitis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8844)		Placebo (N[a]=8792)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle twitching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteoarthritis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bone pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Costochondritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Joint range of motion decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Limb discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rotator cuff syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tendonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arthritis reactive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Axillary mass	0	(0.0, 0.0)	0	(0.0, 0.0)
Exostosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metatarsalgia	0	(0.0, 0.0)	0	(0.0, 0.0)
Mobility decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle contracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle tightness	0	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Periarthritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Spinal stenosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Chronic myeloid leukaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Fibroadenoma of breast	0	(0.0, 0.0)	0	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostate cancer	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)
NERVOUS SYSTEM DISORDERS	360 (4.1)	(3.7, 4.5)	64 (0.7)	(0.6, 0.9)

14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8844)		Placebo (N[a]=8792)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Headache	321 (3.6)	(3.2, 4.0)	46 (0.5)	(0.4, 0.7)
Dizziness	21 (0.2)	(0.1, 0.4)	9 (0.1)	(0.0, 0.2)
Lethargy	15 (0.2)	(0.1, 0.3)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Migraine	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Somnolence	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dysgeusia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Disturbance in attention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	0	(0.0, 0.0)
Tension headache	0	(0.0, 0.0)	0	(0.0, 0.0)
Tremor	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hyperaesthesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Burning sensation	0	(0.0, 0.0)	0	(0.0, 0.0)
Head discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Migraine with aura	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Nerve compression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parosmia	0	(0.0, 0.0)	0	(0.0, 0.0)
Presyncope	0	(0.0, 0.0)	0	(0.0, 0.0)
Sinus headache	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	0	(0.0, 0.0)
Amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aphasia	0	(0.0, 0.0)	0	(0.0, 0.0)
Balance disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Carpal tunnel syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cervical radiculopathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Facial paralysis	0	(0.0, 0.0)	0	(0.0, 0.0)
Generalised tonic-clonic seizure	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypersomnia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mental impairment	0	(0.0, 0.0)	0	(0.0, 0.0)
Motor dysfunction	0	(0.0, 0.0)	0	(0.0, 0.0)

14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8844)		Placebo (N[a]=8792)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Neuropathy peripheral	0	(0.0, 0.0)	0	(0.0, 0.0)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Radiculopathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Restless legs syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	12 (0.1)	(0.1, 0.2)	6 (0.1)	(0.0, 0.1)
Insomnia	7 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Anxiety	0	(0.0, 0.0)	0	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Irritability	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Disorientation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anxiety disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Attention deficit hyperactivity disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dysphemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Generalised anxiety disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Mental disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	0	(0.0, 0.0)
Panic attack	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Paranoia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	7 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Dysuria	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nephrolithiasis	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pollakiuria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematuria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bladder spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oedematous kidney	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Perinephric oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Renal cyst haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Urethral discharge	0	(0.0, 0.0)	0	(0.0, 0.0)

14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8844)		Placebo (N[a]=8792)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Menstruation delayed	0	(0.0, 0.0)	0	(0.0, 0.0)
Metrorrhagia	0	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Genital erythema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Menstruation irregular	0	(0.0, 0.0)	0	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Prostatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Vaginal discharge	0	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	19 (0.2)	(0.1, 0.3)	7 (0.1)	(0.0, 0.2)
Oropharyngeal pain	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Nasal congestion	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rhinorrhoea	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cough	2 (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)
Dyspnoea	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus congestion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper-airway cough syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory tract congestion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Snoring	0	(0.0, 0.0)	0	(0.0, 0.0)
Throat irritation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Allergic respiratory disease	0	(0.0, 0.0)	0	(0.0, 0.0)
Asthma exercise induced	0	(0.0, 0.0)	0	(0.0, 0.0)
Asthmatic crisis	0	(0.0, 0.0)	0	(0.0, 0.0)
Bronchospasm	0	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	0	(0.0, 0.0)	0	(0.0, 0.0)
Dysphonia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epistaxis	0	(0.0, 0.0)	0	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8844) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8792) n[b] (%)	 (95% CI[c])
Oropharyngeal discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Productive cough	0	(0.0, 0.0)	0	(0.0, 0.0)
Reflux laryngitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Rhinitis allergic	0	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillar hypertrophy	0	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	39 (0.4)	(0.3, 0.6)	17 (0.2)	(0.1, 0.3)
Rash	6 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Hyperhidrosis	10 (0.1)	(0.1, 0.2)	1 (0.0)	(0.0, 0.1)
Night sweats	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pruritus	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Erythema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urticaria	0	(0.0, 0.0)	0	(0.0, 0.0)
Alopecia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Psoriasis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash pruritic	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Angioedema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blister	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dermatitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dermatitis contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eczema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Papule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rash papular	0	(0.0, 0.0)	0	(0.0, 0.0)
Cold sweat	0	(0.0, 0.0)	0	(0.0, 0.0)
Dermal cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug eruption	0	(0.0, 0.0)	0	(0.0, 0.0)
Fixed eruption	0	(0.0, 0.0)	0	(0.0, 0.0)
Hand dermatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	0	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	0	(0.0, 0.0)
Rosacea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.93. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 2 to 7 Days After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8844)		Placebo (N[a]=8792)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Skin discolouration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin ulcer	0	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Endodontic procedure	0	(0.0, 0.0)	0	(0.0, 0.0)
Facet joint block	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VASCULAR DISORDERS	8 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.2)
Hypertension	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Flushing	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hot flush	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Essential hypertension	0	(0.0, 0.0)	0	(0.0, 0.0)
Haematoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Subgaleal haematoma	0	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Subjects who did not receive Dose 2 or who received a different vaccine at Dose 1 and Dose 2 were excluded from this table.
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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 29MAR2021 (04:19)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s091 d27d age p3 saf

14.94. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=100)		Placebo (N[a]=100)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	26 (26.0)	(17.7, 35.7)	13 (13.0)	(7.1, 21.2)
EYE DISORDERS	0	(0.0, 3.6)	3 (3.0)	(0.6, 8.5)
Vitreous detachment	0	(0.0, 3.6)	2 (2.0)	(0.2, 7.0)
Meibomianitis	0	(0.0, 3.6)	1 (1.0)	(0.0, 5.4)
Retinal haemorrhage	0	(0.0, 3.6)	1 (1.0)	(0.0, 5.4)
GASTROINTESTINAL DISORDERS	3 (3.0)	(0.6, 8.5)	4 (4.0)	(1.1, 9.9)
Diarrhoea	0	(0.0, 3.6)	2 (2.0)	(0.2, 7.0)
Dyspepsia	0	(0.0, 3.6)	1 (1.0)	(0.0, 5.4)
Gastritis	1 (1.0)	(0.0, 5.4)	0	(0.0, 3.6)
Gastrooesophageal reflux disease	1 (1.0)	(0.0, 5.4)	0	(0.0, 3.6)
Mouth ulceration	0	(0.0, 3.6)	1 (1.0)	(0.0, 5.4)
Nausea	1 (1.0)	(0.0, 5.4)	0	(0.0, 3.6)
Stomatitis	0	(0.0, 3.6)	1 (1.0)	(0.0, 5.4)
Vomiting	1 (1.0)	(0.0, 5.4)	0	(0.0, 3.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	19 (19.0)	(11.8, 28.1)	2 (2.0)	(0.2, 7.0)
Injection site pain	11 (11.0)	(5.6, 18.8)	0	(0.0, 3.6)
Fatigue	7 (7.0)	(2.9, 13.9)	1 (1.0)	(0.0, 5.4)
Chills	6 (6.0)	(2.2, 12.6)	1 (1.0)	(0.0, 5.4)
Pyrexia	7 (7.0)	(2.9, 13.9)	0	(0.0, 3.6)
Injection site erythema	2 (2.0)	(0.2, 7.0)	0	(0.0, 3.6)
Injection site swelling	1 (1.0)	(0.0, 5.4)	0	(0.0, 3.6)
Malaise	0	(0.0, 3.6)	1 (1.0)	(0.0, 5.4)
INFECTIONS AND INFESTATIONS	2 (2.0)	(0.2, 7.0)	2 (2.0)	(0.2, 7.0)
Conjunctivitis	1 (1.0)	(0.0, 5.4)	1 (1.0)	(0.0, 5.4)
Abscess limb	0	(0.0, 3.6)	1 (1.0)	(0.0, 5.4)
Folliculitis	1 (1.0)	(0.0, 5.4)	0	(0.0, 3.6)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (1.0)	(0.0, 5.4)	1 (1.0)	(0.0, 5.4)
Exposure during pregnancy	1 (1.0)	(0.0, 5.4)	0	(0.0, 3.6)
Foot fracture	0	(0.0, 3.6)	1 (1.0)	(0.0, 5.4)

14.94. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥ 16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=100) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=100) n[b] (%)	 (95% CI[c])
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	6 (6.0)	(2.2, 12.6)	3 (3.0)	(0.6, 8.5)
Myalgia	6 (6.0)	(2.2, 12.6)	2 (2.0)	(0.2, 7.0)
Arthralgia	1 (1.0)	(0.0, 5.4)	0	(0.0, 3.6)
Back pain	0	(0.0, 3.6)	1 (1.0)	(0.0, 5.4)
NERVOUS SYSTEM DISORDERS	5 (5.0)	(1.6, 11.3)	0	(0.0, 3.6)
Headache	3 (3.0)	(0.6, 8.5)	0	(0.0, 3.6)
Dizziness	1 (1.0)	(0.0, 5.4)	0	(0.0, 3.6)
Hypoaesthesia	1 (1.0)	(0.0, 5.4)	0	(0.0, 3.6)
PSYCHIATRIC DISORDERS	1 (1.0)	(0.0, 5.4)	0	(0.0, 3.6)
Insomnia	1 (1.0)	(0.0, 5.4)	0	(0.0, 3.6)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 3.6)	1 (1.0)	(0.0, 5.4)
Rhinorrhoea	0	(0.0, 3.6)	1 (1.0)	(0.0, 5.4)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 3.6)	1 (1.0)	(0.0, 5.4)
Urticaria	0	(0.0, 3.6)	1 (1.0)	(0.0, 5.4)

Abbreviation: HIV = human immunodeficiency virus.
Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_all_pd2_hiv_p3_saf

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	5241 (23.9)	(23.3, 24.5)	1311 (6.0)	(5.7, 6.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	68 (0.3)	(0.2, 0.4)	5 (0.0)	(0.0, 0.1)
Lymphadenopathy	62 (0.3)	(0.2, 0.4)	4 (0.0)	(0.0, 0.0)
Lymph node pain	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Lymphopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	13 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Tachycardia	10 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Palpitations	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Supraventricular tachycardia	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)
EAR AND LABYRINTH DISORDERS	15 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Vertigo	8 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Deafness unilateral	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo positional	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Otorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinnitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	17 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Eye irritation	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Eye pain	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vision blurred	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lacrimation increased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ocular hyperaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Asthenopia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Swelling of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	479 (2.2)	(2.0, 2.4)	215 (1.0)	(0.9, 1.1)
Diarrhoea	209 (1.0)	(0.8, 1.1)	136 (0.6)	(0.5, 0.7)
Nausea	247 (1.1)	(1.0, 1.3)	58 (0.3)	(0.2, 0.3)
Vomiting	55 (0.3)	(0.2, 0.3)	15 (0.1)	(0.0, 0.1)
Abdominal pain upper	11 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Abdominal pain	5 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Abdominal discomfort	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Dyspepsia	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Aphthous ulcer	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry mouth	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Paraesthesia oral	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Retching	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glossodynia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Odynophagia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toothache	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal distension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cheilitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Swollen tongue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4650 (21.2)	(20.7, 21.8)	883 (4.0)	(3.8, 4.3)
Injection site pain	2913 (13.3)	(12.8, 13.7)	391 (1.8)	(1.6, 2.0)
Fatigue	1435 (6.5)	(6.2, 6.9)	351 (1.6)	(1.4, 1.8)
Pyrexia	1510 (6.9)	(6.6, 7.2)	66 (0.3)	(0.2, 0.4)
Chills	1359 (6.2)	(5.9, 6.5)	111 (0.5)	(0.4, 0.6)
Pain	623 (2.8)	(2.6, 3.1)	52 (0.2)	(0.2, 0.3)
Injection site erythema	185 (0.8)	(0.7, 1.0)	25 (0.1)	(0.1, 0.2)
Injection site swelling	139 (0.6)	(0.5, 0.7)	22 (0.1)	(0.1, 0.2)
Malaise	129 (0.6)	(0.5, 0.7)	17 (0.1)	(0.0, 0.1)
Asthenia	69 (0.3)	(0.2, 0.4)	11 (0.1)	(0.0, 0.1)
Injection site pruritus	38 (0.2)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Injection site bruising	12 (0.1)	(0.0, 0.1)	17 (0.1)	(0.0, 0.1)
Influenza like illness	23 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.0)
Injection site warmth	14 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Injection site induration	10 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Axillary pain	9 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site oedema	12 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site discomfort	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site haemorrhage	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Injection site reaction	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site haematoma	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Injection site mass	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Peripheral swelling	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chest discomfort	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chest pain	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site discolouration	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site nodule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site rash	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Application site pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling abnormal	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gait disturbance	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sensation of foreign body	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)
Thirst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Drug hypersensitivity	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	7 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Cystitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Herpes zoster	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rhinitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Conjunctivitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral candidiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral herpes	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Otitis media acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pustule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	14 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vaccination complication	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Contusion	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural pain	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Administration related reaction	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	127 (0.6)	(0.5, 0.7)	13 (0.1)	(0.0, 0.1)
Body temperature increased	115 (0.5)	(0.4, 0.6)	9 (0.0)	(0.0, 0.1)
Heart rate increased	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose increased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure diastolic increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood pressure systolic increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraocular pressure increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SARS-CoV-2 antibody test positive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	38 (0.2)	(0.1, 0.2)	9 (0.0)	(0.0, 0.1)
Decreased appetite	35 (0.2)	(0.1, 0.2)	8 (0.0)	(0.0, 0.1)
Polydipsia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gout	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1527 (7.0)	(6.6, 7.3)	207 (0.9)	(0.8, 1.1)
Myalgia	1217 (5.6)	(5.3, 5.9)	144 (0.7)	(0.6, 0.8)
Arthralgia	204 (0.9)	(0.8, 1.1)	38 (0.2)	(0.1, 0.2)
Pain in extremity	158 (0.7)	(0.6, 0.8)	14 (0.1)	(0.0, 0.1)
Back pain	23 (0.1)	(0.1, 0.2)	8 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	10 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Neck pain	9 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Muscle spasms	8 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Muscular weakness	7 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal discomfort	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint stiffness	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle fatigue	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb discomfort	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle twitching	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flank pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendonitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthritis reactive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Axillary mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bursitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Costochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Joint effusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mobility decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psoriatic arthropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	1376 (6.3)	(6.0, 6.6)	376 (1.7)	(1.5, 1.9)
Headache	1267 (5.8)	(5.5, 6.1)	319 (1.5)	(1.3, 1.6)
Dizziness	53 (0.2)	(0.2, 0.3)	29 (0.1)	(0.1, 0.2)
Lethargy	24 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Paraesthesia	10 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Dysgeusia	10 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Somnolence	9 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Migraine	9 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Tremor	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Hypoaesthesia	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Presyncope	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Disturbance in attention	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tension headache	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperaesthesia	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parosmia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness postural	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial paralysis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Head discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine without aura	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinus headache	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Taste disorder	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burning sensation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypersomnia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nerve compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nystagmus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	30 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Insomnia	17 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Anxiety	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abnormal dreams	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Disorientation	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Irritability	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depression	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nightmare	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paranoia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bladder spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pollakiuria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scrotal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	61 (0.3)	(0.2, 0.4)	39 (0.2)	(0.1, 0.2)
Oropharyngeal pain	16 (0.1)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Nasal congestion	14 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Rhinorrhoea	8 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Cough	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Throat irritation	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper respiratory tract congestion	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper-airway cough syndrome	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Asthma	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Sinus congestion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sneezing	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea	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)
Epistaxis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Productive cough	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	105 (0.5)	(0.4, 0.6)	44 (0.2)	(0.1, 0.3)
Rash	23 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.1)
Hyperhidrosis	27 (0.1)	(0.1, 0.2)	7 (0.0)	(0.0, 0.1)
Night sweats	17 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pruritus	7 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Urticaria	8 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Erythema	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Rash pruritic	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin lesion	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alopecia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cold sweat	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Papule	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug eruption	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eczema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fixed eruption	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis rosea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psoriasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash papular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	17 (0.1)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Flushing	10 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Hot flush	4 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Hypertension	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypotension	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 1md2 rel p3 saf

14.96. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	3480 (26.8)	(26.0, 27.5)	882 (6.8)	(6.3, 7.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	56 (0.4)	(0.3, 0.6)	2 (0.0)	(0.0, 0.1)
Lymphadenopathy	52 (0.4)	(0.3, 0.5)	2 (0.0)	(0.0, 0.1)
Lymph node pain	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lymphopenia	0	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	9 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Tachycardia	7 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Palpitations	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular arrhythmia	0	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	7 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Vertigo	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo positional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Otorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinnitus	0	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	12 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)
Eye irritation	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eye pain	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vision blurred	0	(0.0, 0.0)	0	(0.0, 0.0)
Photophobia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenopia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.96. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Swelling of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	322 (2.5)	(2.2, 2.8)	140 (1.1)	(0.9, 1.3)
Diarrhoea	135 (1.0)	(0.9, 1.2)	87 (0.7)	(0.5, 0.8)
Nausea	168 (1.3)	(1.1, 1.5)	41 (0.3)	(0.2, 0.4)
Vomiting	45 (0.3)	(0.3, 0.5)	9 (0.1)	(0.0, 0.1)
Abdominal pain upper	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal pain	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Abdominal discomfort	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dyspepsia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aphthous ulcer	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glossodynia	0	(0.0, 0.0)	0	(0.0, 0.0)
Odynophagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toothache	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal distension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cheilitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)

14.96. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Swollen tongue	0	(0.0, 0.0)	0	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue pruritus	0	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	0	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3118 (24.0)	(23.3, 24.7)	608 (4.7)	(4.3, 5.0)
Injection site pain	1927 (14.8)	(14.2, 15.5)	280 (2.1)	(1.9, 2.4)
Fatigue	991 (7.6)	(7.2, 8.1)	254 (1.9)	(1.7, 2.2)
Pyrexia	1114 (8.6)	(8.1, 9.1)	50 (0.4)	(0.3, 0.5)
Chills	965 (7.4)	(7.0, 7.9)	71 (0.5)	(0.4, 0.7)
Pain	429 (3.3)	(3.0, 3.6)	36 (0.3)	(0.2, 0.4)
Injection site erythema	119 (0.9)	(0.8, 1.1)	17 (0.1)	(0.1, 0.2)
Injection site swelling	86 (0.7)	(0.5, 0.8)	11 (0.1)	(0.0, 0.2)
Malaise	85 (0.7)	(0.5, 0.8)	7 (0.1)	(0.0, 0.1)
Asthenia	42 (0.3)	(0.2, 0.4)	7 (0.1)	(0.0, 0.1)
Injection site pruritus	23 (0.2)	(0.1, 0.3)	4 (0.0)	(0.0, 0.1)
Injection site bruising	8 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Influenza like illness	15 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Injection site warmth	8 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Injection site induration	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Axillary pain	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site oedema	10 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site discomfort	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site reaction	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site mass	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peripheral swelling	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Adverse drug reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest discomfort	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Chest pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.96. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12995) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=13026) n[b] (%)	 (95% CI[c])
Injection site discolouration	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site nodule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Application site pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling abnormal	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling cold	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sluggishness	0	(0.0, 0.0)	0	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	0	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gait disturbance	0	(0.0, 0.0)	0	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Induration	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site irritation	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site urticaria	0	(0.0, 0.0)	0	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sensation of foreign body	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)
Thirst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.96. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Drug hypersensitivity	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cystitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Herpes zoster	0	(0.0, 0.0)	0	(0.0, 0.0)
Rhinitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Conjunctivitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Oral candidiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral herpes	0	(0.0, 0.0)	0	(0.0, 0.0)
Otitis media	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Otitis media acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pustule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	10 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vaccination complication	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Contusion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	87 (0.7)	(0.5, 0.8)	11 (0.1)	(0.0, 0.2)
Body temperature increased	79 (0.6)	(0.5, 0.8)	8 (0.1)	(0.0, 0.1)
Heart rate increased	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Blood glucose increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure diastolic increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood pressure systolic increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraocular pressure increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory rate increased	0	(0.0, 0.0)	0	(0.0, 0.0)
SARS-CoV-2 antibody test positive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.96. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	26 (0.2)	(0.1, 0.3)	6 (0.0)	(0.0, 0.1)
Decreased appetite	24 (0.2)	(0.1, 0.3)	6 (0.0)	(0.0, 0.1)
Polydipsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gout	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1053 (8.1)	(7.6, 8.6)	128 (1.0)	(0.8, 1.2)
Myalgia	858 (6.6)	(6.2, 7.0)	96 (0.7)	(0.6, 0.9)
Arthralgia	142 (1.1)	(0.9, 1.3)	23 (0.2)	(0.1, 0.3)
Pain in extremity	84 (0.6)	(0.5, 0.8)	4 (0.0)	(0.0, 0.1)
Back pain	18 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Neck pain	7 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Muscle spasms	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscular weakness	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint stiffness	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal chest pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Limb discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle twitching	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flank pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tendonitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Arthritis reactive	0	(0.0, 0.0)	0	(0.0, 0.0)
Axillary mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bursitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Costochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.96. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12995) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=13026) n[b] (%)	 (95% CI[c])
Joint effusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mobility decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psoriatic arthropathy	0	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	945 (7.3)	(6.8, 7.7)	262 (2.0)	(1.8, 2.3)
Headache	877 (6.7)	(6.3, 7.2)	221 (1.7)	(1.5, 1.9)
Dizziness	32 (0.2)	(0.2, 0.3)	19 (0.1)	(0.1, 0.2)
Lethargy	7 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Paraesthesia	9 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Dysgeusia	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Somnolence	5 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Migraine	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tremor	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Presyncope	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Disturbance in attention	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tension headache	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperaesthesia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness postural	0	(0.0, 0.0)	0	(0.0, 0.0)
Facial paralysis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Head discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine without aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinus headache	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burning sensation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyskinesia	0	(0.0, 0.0)	0	(0.0, 0.0)

14.96. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypersomnia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nerve compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nystagmus	0	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post herpetic neuralgia	0	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	16 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Insomnia	10 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anxiety	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abnormal dreams	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Irritability	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nightmare	0	(0.0, 0.0)	0	(0.0, 0.0)
Paranoia	0	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	0	(0.0, 0.0)	0	(0.0, 0.0)
Sleep disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bladder spasm	0	(0.0, 0.0)	0	(0.0, 0.0)
Micturition urgency	0	(0.0, 0.0)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	0	(0.0, 0.0)
Pollakiuria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Erectile dysfunction	0	(0.0, 0.0)	0	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menstruation irregular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scrotal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.96. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=12995) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=13026) n[b] (%)	 (95% CI[c])
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	37 (0.3)	(0.2, 0.4)	27 (0.2)	(0.1, 0.3)
Oropharyngeal pain	11 (0.1)	(0.0, 0.2)	6 (0.0)	(0.0, 0.1)
Nasal congestion	8 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Rhinorrhoea	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cough	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Throat irritation	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Upper-airway cough syndrome	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Asthma	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sinus congestion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sneezing	0	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dyspnoea exertional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Epistaxis	0	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Productive cough	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	0	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	63 (0.5)	(0.4, 0.6)	28 (0.2)	(0.1, 0.3)
Rash	17 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Hyperhidrosis	15 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Night sweats	9 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Urticaria	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Erythema	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Rash pruritic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin lesion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Alopecia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.96. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Papule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	0	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug eruption	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ecchymosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Eczema	0	(0.0, 0.0)	0	(0.0, 0.0)
Fixed eruption	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Macule	0	(0.0, 0.0)	0	(0.0, 0.0)
Pain of skin	0	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis rosea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psoriasis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash papular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin discolouration	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	10 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Flushing	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hot flush	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Hypertension	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 1md2 rel age p3 saf

14.97. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1761 (19.7)	(18.9, 20.6)	429 (4.8)	(4.4, 5.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	12 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Lymphadenopathy	10 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Lymph node pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lymphopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tachycardia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Palpitations	0	(0.0, 0.0)	0	(0.0, 0.0)
Sinus tachycardia	0	(0.0, 0.0)	0	(0.0, 0.0)
Supraventricular tachycardia	0	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	8 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Vertigo	5 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo positional	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ear discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Otorrhoea	0	(0.0, 0.0)	0	(0.0, 0.0)
Tinnitus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Eye irritation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Eye pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vision blurred	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Photophobia	0	(0.0, 0.0)	0	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ocular hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Asthenopia	0	(0.0, 0.0)	0	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Dry eye	0	(0.0, 0.0)	0	(0.0, 0.0)
Swelling of eyelid	0	(0.0, 0.0)	0	(0.0, 0.0)

14.97. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
GASTROINTESTINAL DISORDERS	157 (1.8)	(1.5, 2.1)	75 (0.8)	(0.7, 1.1)
Diarrhoea	74 (0.8)	(0.7, 1.0)	49 (0.6)	(0.4, 0.7)
Nausea	79 (0.9)	(0.7, 1.1)	17 (0.2)	(0.1, 0.3)
Vomiting	10 (0.1)	(0.1, 0.2)	6 (0.1)	(0.0, 0.1)
Abdominal pain upper	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Abdominal discomfort	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dyspepsia	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Aphthous ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry mouth	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Flatulence	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Retching	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Faeces soft	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingival pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Glossodynia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Odynophagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Toothache	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal distension	0	(0.0, 0.0)	0	(0.0, 0.0)
Cheilitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dysphagia	0	(0.0, 0.0)	0	(0.0, 0.0)
Eructation	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	0	(0.0, 0.0)
Gingival discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Gingival swelling	0	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypoaesthesia teeth	0	(0.0, 0.0)	0	(0.0, 0.0)
Lip swelling	0	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	0	(0.0, 0.0)
Noninfective gingivitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swollen tongue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.97. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tongue discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1532 (17.2)	(16.4, 18.0)	275 (3.1)	(2.7, 3.5)
Injection site pain	986 (11.0)	(10.4, 11.7)	111 (1.2)	(1.0, 1.5)
Fatigue	444 (5.0)	(4.5, 5.4)	97 (1.1)	(0.9, 1.3)
Pyrexia	396 (4.4)	(4.0, 4.9)	16 (0.2)	(0.1, 0.3)
Chills	394 (4.4)	(4.0, 4.9)	40 (0.4)	(0.3, 0.6)
Pain	194 (2.2)	(1.9, 2.5)	16 (0.2)	(0.1, 0.3)
Injection site erythema	66 (0.7)	(0.6, 0.9)	8 (0.1)	(0.0, 0.2)
Injection site swelling	53 (0.6)	(0.4, 0.8)	11 (0.1)	(0.1, 0.2)
Malaise	44 (0.5)	(0.4, 0.7)	10 (0.1)	(0.1, 0.2)
Asthenia	27 (0.3)	(0.2, 0.4)	4 (0.0)	(0.0, 0.1)
Injection site pruritus	15 (0.2)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Injection site bruising	4 (0.0)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Influenza like illness	8 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Injection site warmth	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site induration	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Axillary pain	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site haemorrhage	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site reaction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site mass	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Peripheral swelling	0	(0.0, 0.0)	0	(0.0, 0.0)
Adverse drug reaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Chest discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Chest pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.97. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site nodule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site papule	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Swelling face	0	(0.0, 0.0)	0	(0.0, 0.0)
Application site pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Feeling abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	0	(0.0, 0.0)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sluggishness	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Application site erythema	0	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	0	(0.0, 0.0)
Application site reaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Exercise tolerance decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
Gait disturbance	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Illness	0	(0.0, 0.0)	0	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site dermatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site lymphadenopathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Injection site urticaria	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Medical device pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Sensation of foreign body	0	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	0	(0.0, 0.0)	0	(0.0, 0.0)
Thirst	0	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site bruise	0	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Drug hypersensitivity	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.97. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INFECTIONS AND INFESTATIONS	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Cystitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Herpes zoster	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Rhinitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Conjunctivitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Influenza	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral candidiasis	0	(0.0, 0.0)	0	(0.0, 0.0)
Oral herpes	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Otitis media	0	(0.0, 0.0)	0	(0.0, 0.0)
Otitis media acute	0	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pustule	0	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vaccination complication	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Contusion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Procedural pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Administration related reaction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INVESTIGATIONS	40 (0.4)	(0.3, 0.6)	2 (0.0)	(0.0, 0.1)
Body temperature increased	36 (0.4)	(0.3, 0.6)	1 (0.0)	(0.0, 0.1)
Heart rate increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood pressure increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure diastolic increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure systolic increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Body temperature	0	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	0	(0.0, 0.0)
Intraocular pressure increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Respiratory rate increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SARS-CoV-2 antibody test positive	0	(0.0, 0.0)	0	(0.0, 0.0)
Weight decreased	0	(0.0, 0.0)	0	(0.0, 0.0)

14.97. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
METABOLISM AND NUTRITION DISORDERS	12 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Decreased appetite	11 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Polydipsia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gout	0	(0.0, 0.0)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	474 (5.3)	(4.9, 5.8)	79 (0.9)	(0.7, 1.1)
Myalgia	359 (4.0)	(3.6, 4.4)	48 (0.5)	(0.4, 0.7)
Arthralgia	62 (0.7)	(0.5, 0.9)	15 (0.2)	(0.1, 0.3)
Pain in extremity	74 (0.8)	(0.7, 1.0)	10 (0.1)	(0.1, 0.2)
Back pain	5 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	8 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Neck pain	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Muscle spasms	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscular weakness	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal discomfort	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Joint stiffness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Limb discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle twitching	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flank pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Musculoskeletal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Osteoarthritis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pain in jaw	0	(0.0, 0.0)	0	(0.0, 0.0)
Tendonitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Arthritis reactive	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Axillary mass	0	(0.0, 0.0)	0	(0.0, 0.0)
Bone pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Bursitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Costochondritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Groin pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.97. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Joint swelling	0	(0.0, 0.0)	0	(0.0, 0.0)
Mobility decreased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle tightness	0	(0.0, 0.0)	0	(0.0, 0.0)
Periarthritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Psoriatic arthropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	431 (4.8)	(4.4, 5.3)	114 (1.3)	(1.1, 1.5)
Headache	390 (4.4)	(4.0, 4.8)	98 (1.1)	(0.9, 1.3)
Dizziness	21 (0.2)	(0.1, 0.4)	10 (0.1)	(0.1, 0.2)
Lethargy	17 (0.2)	(0.1, 0.3)	1 (0.0)	(0.0, 0.1)
Paraesthesia	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dysgeusia	2 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Somnolence	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tremor	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Presyncope	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disturbance in attention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tension headache	0	(0.0, 0.0)	0	(0.0, 0.0)
Hyperaesthesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dizziness postural	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial paralysis	0	(0.0, 0.0)	0	(0.0, 0.0)
Head discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Mental impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Migraine without aura	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinus headache	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Syncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Taste disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	0	(0.0, 0.0)
Aphasia	0	(0.0, 0.0)	0	(0.0, 0.0)
Burning sensation	0	(0.0, 0.0)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypersomnia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.97. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypogeusia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	0	(0.0, 0.0)
Migraine with aura	0	(0.0, 0.0)	0	(0.0, 0.0)
Nerve compression	0	(0.0, 0.0)	0	(0.0, 0.0)
Nystagmus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peripheral sensory neuropathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	14 (0.2)	(0.1, 0.3)	2 (0.0)	(0.0, 0.1)
Insomnia	7 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Anxiety	0	(0.0, 0.0)	0	(0.0, 0.0)
Abnormal dreams	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disorientation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Irritability	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Depression	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	0	(0.0, 0.0)
Nightmare	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paranoia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Bladder spasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pollakiuria	0	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Erectile dysfunction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Menorrhagia	0	(0.0, 0.0)	0	(0.0, 0.0)
Menstruation irregular	0	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	0	(0.0, 0.0)
Scrotal pain	0	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	24 (0.3)	(0.2, 0.4)	12 (0.1)	(0.1, 0.2)

14.97. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=8931) n[b] (%)	 (95% CI[c])	 Placebo (N[a]=8895) n[b] (%)	 (95% CI[c])
Oropharyngeal pain	5 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Nasal congestion	6 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Rhinorrhoea	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cough	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Throat irritation	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Paranasal sinus discomfort	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper-airway cough syndrome	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Sinus congestion	0	(0.0, 0.0)	0	(0.0, 0.0)
Sneezing	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Dyspnoea	0	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epistaxis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Oropharyngeal discomfort	0	(0.0, 0.0)	0	(0.0, 0.0)
Productive cough	0	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	0	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	0	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	42 (0.5)	(0.3, 0.6)	16 (0.2)	(0.1, 0.3)
Rash	6 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Hyperhidrosis	12 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Night sweats	8 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Pruritus	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Urticaria	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Erythema	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rash pruritic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin lesion	0	(0.0, 0.0)	0	(0.0, 0.0)
Alopecia	0	(0.0, 0.0)	0	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)

14.97. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Alopecia areata	0	(0.0, 0.0)	0	(0.0, 0.0)
Angioedema	0	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis allergic	0	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis contact	0	(0.0, 0.0)	0	(0.0, 0.0)
Drug eruption	0	(0.0, 0.0)	0	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eczema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Fixed eruption	0	(0.0, 0.0)	0	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pityriasis rosea	0	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	0	(0.0, 0.0)
Psoriasis	0	(0.0, 0.0)	0	(0.0, 0.0)
Rash papular	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	7 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Flushing	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hot flush	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypertension	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_1md2_rel_age_p3_saf

14.98. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	105 (0.5)	(0.4, 0.6)	81 (0.4)	(0.3, 0.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	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	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Palpitations	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Nausea	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Odynophagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	86 (0.4)	(0.3, 0.5)	59 (0.3)	(0.2, 0.3)
Injection site pain	75 (0.3)	(0.3, 0.4)	45 (0.2)	(0.1, 0.3)
Fatigue	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Injection site erythema	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Injection site swelling	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Injection site induration	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pyrexia	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chills	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site bruising	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site warmth	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.98. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 1, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pain in extremity	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	16 (0.1)	(0.0, 0.1)	16 (0.1)	(0.0, 0.1)
Headache	9 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dizziness	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Dysgeusia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Paraesthesia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Presyncope	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tension headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anxiety	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nephrolithiasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cough	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Throat irritation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Immediate AE refers to an AE reported in the 30-minute observation period after vaccination.
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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_d1_p3_saf

14.99. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	71 (0.3)	(0.3, 0.4)	54 (0.3)	(0.2, 0.3)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinnitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Nausea	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	59 (0.3)	(0.2, 0.4)	35 (0.2)	(0.1, 0.2)
Injection site pain	49 (0.2)	(0.2, 0.3)	28 (0.1)	(0.1, 0.2)
Chills	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyrexia	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fatigue	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site bruising	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Injection site pruritus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site erythema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malaise	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peripheral swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	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)
INVESTIGATIONS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood pressure diastolic increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Body temperature increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	8 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)

14.99. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21571)		Placebo (N[a]=21549)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Myalgia	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain in extremity	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	6 (0.0)	(0.0, 0.1)	14 (0.1)	(0.0, 0.1)
Headache	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Dizziness	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Paraesthesia	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Dysgeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Presyncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syncope	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)
Erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Night sweats	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Immediate AE refers to an AE reported in the 30-minute observation period after vaccination.
Note: Subjects who did not receive Dose 2 or who received a different vaccine at Dose 1 and Dose 2 were excluded from this table.
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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 29MAR2021 (04:19)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_d2_p3_saf

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	262 (1.2)	(1.1, 1.3)	150 (0.7)	(0.6, 0.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Lymphadenopathy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood loss anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Iron deficiency anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymph node pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	8 (0.0)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Tachycardia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute coronary syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute myocardial infarction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina pectoris	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)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	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)
Cardiac failure acute	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)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachyarrhythmia	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)
EAR AND LABYRINTH DISORDERS	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Vertigo	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo positional	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tinnitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Retinal detachment	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cataract	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	19 (0.1)	(0.1, 0.1)	16 (0.1)	(0.0, 0.1)
Diarrhoea	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Abdominal pain	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Nausea	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vomiting	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	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)	0	(0.0, 0.0)
Dyspepsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal pain	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, 0.0)
Haematochezia	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 obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varices oesophageal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	98 (0.4)	(0.4, 0.5)	6 (0.0)	(0.0, 0.1)
Pyrexia	38 (0.2)	(0.1, 0.2)	1 (0.0)	(0.0, 0.0)
Fatigue	24 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.0)
Injection site pain	19 (0.1)	(0.1, 0.1)	0	(0.0, 0.0)
Chills	18 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Pain	9 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site swelling	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malaise	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)
HEPATOBILIARY DISORDERS	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Cholelithiasis	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis acute	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)
Biliary colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug hypersensitivity	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	21 (0.1)	(0.1, 0.1)	23 (0.1)	(0.1, 0.2)
Appendicitis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Urinary tract infection	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Cellulitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Diverticulitis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinusitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess jaw	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Empyema	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)
Localised infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis externa	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paronychia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	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	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous 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)
Tooth infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	11 (0.1)	(0.0, 0.1)	22 (0.1)	(0.1, 0.2)
Fall	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	4 (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	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint dislocation	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ankle fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exposure during pregnancy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm 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)
Head injury	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)
Humerus fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ligament sprain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meniscus injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle strain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rib 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 column injury	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)
Subdural haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	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	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blood glucose abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Hypokalaemia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoglycaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dehydration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lactic acidosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obesity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	42 (0.2)	(0.1, 0.3)	20 (0.1)	(0.1, 0.1)
Myalgia	21 (0.1)	(0.1, 0.1)	3 (0.0)	(0.0, 0.0)
Arthralgia	4 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Back pain	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pain in extremity	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intervertebral disc protrusion	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Muscle spasms	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Osteoarthritis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Muscular weakness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Neck pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bursitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Costochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flank pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contracture	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)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	9 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Prostate cancer	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma gastric	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	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile squamous cell carcinoma	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)
Thyroid cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	42 (0.2)	(0.1, 0.3)	26 (0.1)	(0.1, 0.2)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Headache	25 (0.1)	(0.1, 0.2)	10 (0.0)	(0.0, 0.1)
Syncope	2 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Migraine	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervicogenic headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Generalised tonic-clonic seizure	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)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tension headache	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)
Transient ischaemic attack	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	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abortion spontaneous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Depression	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anxiety	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental status changes	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute kidney injury	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal colic	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	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	4 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Pulmonary embolism	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute respiratory failure	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinorrhoea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hidradenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Night sweats	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	9 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Deep vein thrombosis	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertension	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive crisis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Accelerated hypertension	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)

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

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 1md2 sev p3 saf

14.101. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	21 (0.1)	(0.1, 0.1)	26 (0.1)	(0.1, 0.2)
CARDIAC DISORDERS	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac arrest	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Junctional ectopic tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial ischaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Abdominal pain	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)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal mucosa hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal varices haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Volvulus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1 (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)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	4 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Appendicitis	2 (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)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.101. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulitis	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)
Pneumonia	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)
Subacute endocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Overdose	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Road traffic accident	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 haemothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	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)
Osteoarthritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Metastases to liver	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Syncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)

14.101. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Acute respiratory failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary embolism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Deep vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 1md2 life p3 saf

14.102. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	154 (1.2)	(1.0, 1.4)	74 (0.6)	(0.4, 0.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood loss anaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Iron deficiency anaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymph node pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute myocardial infarction	0	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure congestive	0	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.0)	0	(0.0, 0.0)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina pectoris	0	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	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	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)
Cardiac failure acute	0	(0.0, 0.0)	0	(0.0, 0.0)
Mitral valve incompetence	0	(0.0, 0.0)	0	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	0	(0.0, 0.0)
Supraventricular tachycardia	0	(0.0, 0.0)	0	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular arrhythmia	0	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.102. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Vertigo	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo positional	0	(0.0, 0.0)	0	(0.0, 0.0)
Deafness unilateral	0	(0.0, 0.0)	0	(0.0, 0.0)
Tinnitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal detachment	0	(0.0, 0.0)	0	(0.0, 0.0)
Cataract	0	(0.0, 0.0)	0	(0.0, 0.0)
Diplopia	0	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	11 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Diarrhoea	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abdominal pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nausea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vomiting	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abdominal pain upper	0	(0.0, 0.0)	0	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal adhesions	0	(0.0, 0.0)	0	(0.0, 0.0)
Colitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Constipation	0	(0.0, 0.0)	0	(0.0, 0.0)
Dyspepsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrooesophageal reflux disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haematochezia	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 obstruction	0	(0.0, 0.0)	0	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal ulcer	0	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	0	(0.0, 0.0)
Varices oesophageal	0	(0.0, 0.0)	0	(0.0, 0.0)

14.102. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	75 (0.6)	(0.5, 0.7)	4 (0.0)	(0.0, 0.1)
Pyrexia	34 (0.3)	(0.2, 0.4)	1 (0.0)	(0.0, 0.0)
Fatigue	16 (0.1)	(0.1, 0.2)	1 (0.0)	(0.0, 0.0)
Injection site pain	13 (0.1)	(0.1, 0.2)	0	(0.0, 0.0)
Chills	12 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Pain	7 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site swelling	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Non-cardiac chest pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Asthenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malaise	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)
HEPATOBILIARY DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholelithiasis	0	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary colic	0	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Cirrhosis alcoholic	0	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Drug hypersensitivity	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	10 (0.1)	(0.0, 0.1)	10 (0.1)	(0.0, 0.1)
Appendicitis	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Urinary tract infection	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cellulitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia	0	(0.0, 0.0)	0	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.0)	0	(0.0, 0.0)
Peritonsillar abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Sinusitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.102. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess jaw	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial sepsis	0	(0.0, 0.0)	0	(0.0, 0.0)
Bronchitis	0	(0.0, 0.0)	0	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Empyema	0	(0.0, 0.0)	0	(0.0, 0.0)
Infected bite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Localised infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Otitis externa	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paronychia	0	(0.0, 0.0)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngitis streptococcal	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	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sepsis	0	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	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)
Tooth infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	6 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.2)
Fall	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Foot fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Road traffic accident	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Facial bones fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint dislocation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ankle fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exposure during pregnancy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.102. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Femur fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm 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)
Head injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Ligament sprain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb injury	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	0	(0.0, 0.0)	0	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle strain	0	(0.0, 0.0)	0	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Skin laceration	0	(0.0, 0.0)	0	(0.0, 0.0)
Spinal column injury	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)
Subdural haematoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Traumatic intracranial haemorrhage	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	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	0	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypokalaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dehydration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.102. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Fluid retention	0	(0.0, 0.0)	0	(0.0, 0.0)
Lactic acidosis	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	30 (0.2)	(0.2, 0.3)	11 (0.1)	(0.0, 0.2)
Myalgia	18 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Arthralgia	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Back pain	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pain in extremity	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle spasms	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscular weakness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Neck pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bursitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Costochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flank pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle contracture	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)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostate cancer	0	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma pancreas	0	(0.0, 0.0)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	0	(0.0, 0.0)
Malignant melanoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Malignant melanoma of eyelid	0	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	0	(0.0, 0.0)	0	(0.0, 0.0)
Penile squamous cell carcinoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer metastatic	0	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cancer	0	(0.0, 0.0)	0	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	23 (0.2)	(0.1, 0.3)	15 (0.1)	(0.1, 0.2)

14.102. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Headache	15 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerebrovascular accident	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	0	(0.0, 0.0)
Cervicogenic headache	0	(0.0, 0.0)	0	(0.0, 0.0)
Generalised tonic-clonic seizure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tension headache	0	(0.0, 0.0)	0	(0.0, 0.0)
Transient global amnesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Transient ischaemic attack	0	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	0	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abortion spontaneous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Depression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anxiety	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disorientation	0	(0.0, 0.0)	0	(0.0, 0.0)
Mental status changes	0	(0.0, 0.0)	0	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.102. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nephrolithiasis	0	(0.0, 0.0)	0	(0.0, 0.0)
Acute kidney injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	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	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Prostatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pulmonary embolism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute respiratory failure	0	(0.0, 0.0)	0	(0.0, 0.0)
Rhinorrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	0	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary mass	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)
Hidradenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Night sweats	0	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus	0	(0.0, 0.0)	0	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia repair	0	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Deep vein thrombosis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertension	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive crisis	0	(0.0, 0.0)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	0	(0.0, 0.0)
Accelerated hypertension	0	(0.0, 0.0)	0	(0.0, 0.0)
Aortic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.102. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Haematoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 1md2 sev age p3 saf

14.103. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	108 (1.2)	(1.0, 1.5)	76 (0.9)	(0.7, 1.1)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Lymphadenopathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blood loss anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Iron deficiency anaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Lymph node pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytopenia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	5 (0.1)	(0.0, 0.1)	11 (0.1)	(0.1, 0.2)
Atrial fibrillation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Tachycardia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cardiac failure congestive	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Coronary artery disease	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute left ventricular failure	0	(0.0, 0.0)	0	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Angina unstable	0	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	0	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	0	(0.0, 0.0)
Bradycardia	0	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure acute	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)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Supraventricular tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	5 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Vertigo	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)

14.103. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Vertigo positional	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tinnitus	0	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Retinal detachment	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cataract	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	8 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.2)
Diarrhoea	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Abdominal pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Nausea	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)
Abdominal pain upper	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
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)
Constipation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspepsia	0	(0.0, 0.0)	0	(0.0, 0.0)
Flatulence	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrooesophageal reflux disease	0	(0.0, 0.0)	0	(0.0, 0.0)
Haematochezia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Incarcerated inguinal hernia	0	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Obstructive pancreatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal ulcer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pancreatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Varices oesophageal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.103. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	23 (0.3)	(0.2, 0.4)	2 (0.0)	(0.0, 0.1)
Pyrexia	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Fatigue	8 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.1)
Injection site pain	6 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Chills	6 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site swelling	0	(0.0, 0.0)	0	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Asthenia	0	(0.0, 0.0)	0	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site erythema	0	(0.0, 0.0)	0	(0.0, 0.0)
Malaise	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	0	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	6 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholelithiasis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Bile duct stone	0	(0.0, 0.0)	0	(0.0, 0.0)
Biliary colic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	0	(0.0, 0.0)
Drug hypersensitivity	0	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	11 (0.1)	(0.1, 0.2)	13 (0.1)	(0.1, 0.2)
Appendicitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary tract infection	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cellulitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Diverticulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Peritonsillar abscess	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Sinusitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abdominal abscess	0	(0.0, 0.0)	0	(0.0, 0.0)

14.103. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Abscess jaw	0	(0.0, 0.0)	0	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
COVID-19	0	(0.0, 0.0)	0	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Infected bite	0	(0.0, 0.0)	0	(0.0, 0.0)
Localised infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Meningitis bacterial	0	(0.0, 0.0)	0	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Otitis externa	0	(0.0, 0.0)	0	(0.0, 0.0)
Paronychia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Postoperative wound infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Suspected COVID-19	0	(0.0, 0.0)	0	(0.0, 0.0)
Tooth infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper respiratory tract infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (0.1)	(0.0, 0.1)	10 (0.1)	(0.1, 0.2)
Fall	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Foot fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Road traffic accident	0	(0.0, 0.0)	0	(0.0, 0.0)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint dislocation	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Ankle fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Exposure during pregnancy	0	(0.0, 0.0)	0	(0.0, 0.0)

14.103. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Flail chest	0	(0.0, 0.0)	0	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Hand fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Head injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hip fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Ligament sprain	0	(0.0, 0.0)	0	(0.0, 0.0)
Limb injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lower limb fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Meniscus injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Multiple injuries	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscle strain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Procedural haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Skin laceration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Spinal column injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spinal cord injury cervical	0	(0.0, 0.0)	0	(0.0, 0.0)
Subdural haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blood glucose abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Blood glucose increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Body temperature increased	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Weight decreased	0	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypokalaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoglycaemia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dehydration	0	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic ketoacidosis	0	(0.0, 0.0)	0	(0.0, 0.0)

14.103. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Fluid retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Lactic acidosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Obesity	0	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	12 (0.1)	(0.1, 0.2)	9 (0.1)	(0.0, 0.2)
Myalgia	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Arthralgia	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Back pain	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pain in extremity	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Muscle spasms	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Osteoarthritis	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Muscular weakness	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Neck pain	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bursitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Costochondritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Flank pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Muscle contracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Musculoskeletal chest pain	0	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	8 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Prostate cancer	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenocarcinoma gastric	0	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Penile squamous cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostate cancer metastatic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thyroid cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	19 (0.2)	(0.1, 0.3)	11 (0.1)	(0.1, 0.2)

14.103. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Headache	10 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Migraine	0	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cerebrovascular accident	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Amnesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cervicogenic headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Generalised tonic-clonic seizure	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Idiopathic intracranial hypertension	0	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	0	(0.0, 0.0)
Sciatica	0	(0.0, 0.0)	0	(0.0, 0.0)
Seizure	0	(0.0, 0.0)	0	(0.0, 0.0)
Tension headache	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)
Transient ischaemic attack	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	0	(0.0, 0.0)
Abortion spontaneous	0	(0.0, 0.0)	0	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Depression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anxiety	0	(0.0, 0.0)	0	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Depression suicidal	0	(0.0, 0.0)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mental status changes	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Panic attack	0	(0.0, 0.0)	0	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	0	(0.0, 0.0)	0	(0.0, 0.0)

14.103. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Suicide attempt	0	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute kidney injury	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Renal colic	0	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	0	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 0.0)	0	(0.0, 0.0)
Prostatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Uterine haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Pulmonary embolism	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute respiratory failure	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Rhinorrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspnoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hypoxia	0	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonia aspiration	0	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hidradenitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Night sweats	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pruritus	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urticaria	0	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
VASCULAR DISORDERS	5 (0.1)	(0.0, 0.1)	5 (0.1)	(0.0, 0.1)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Hypertension	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive crisis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Aortic stenosis	0	(0.0, 0.0)	0	(0.0, 0.0)

14.103. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Haematoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypotension	0	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 1md2 sev age p3 saf

14.104. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	8 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
CARDIAC DISORDERS	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac arrest	0	(0.0, 0.0)	0	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	0	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Junctional ectopic tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial ischaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	0	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abdominal pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diarrhoea	0	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal mucosa hyperaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal varices haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.0)	0	(0.0, 0.0)
Volvulus	0	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Appendicitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess intestinal	0	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	0	(0.0, 0.0)

14.104. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Complicated appendicitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Diverticulitis	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)
Pneumonia	0	(0.0, 0.0)	0	(0.0, 0.0)
Shigella sepsis	0	(0.0, 0.0)	0	(0.0, 0.0)
Subacute endocarditis	0	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Overdose	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Road traffic accident	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)
Traumatic haemothorax	0	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 0.0)	0	(0.0, 0.0)
Arthralgia	0	(0.0, 0.0)	0	(0.0, 0.0)
Osteoarthritis	0	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adrenal gland cancer	0	(0.0, 0.0)	0	(0.0, 0.0)
Biliary cancer metastatic	0	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Metastases to liver	0	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatic carcinoma	0	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.0)	0	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord compression	0	(0.0, 0.0)	0	(0.0, 0.0)
Subarachnoid haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Syncope	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	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)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.104. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Acute respiratory failure	0	(0.0, 0.0)	0	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary embolism	0	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	0	(0.0, 0.0)	0	(0.0, 0.0)
Arteriosclerosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Deep vein thrombosis	0	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 1md2 life age p3 saf

14.105. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	13 (0.1)	(0.1, 0.2)	15 (0.2)	(0.1, 0.3)
CARDIAC DISORDERS	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Acute myocardial infarction	0	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac arrest	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Aortic valve incompetence	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Arrhythmia supraventricular	0	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Junctional ectopic tachycardia	0	(0.0, 0.0)	0	(0.0, 0.0)
Myocardial ischaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal mucosa hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oesophageal varices haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Volvulus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 0.0)	0	(0.0, 0.0)
Death	0	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anaphylactic reaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Appendicitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.105. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diverticulitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Peritoneal abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonia	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)
Subacute endocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Overdose	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Toxicity to various agents	0	(0.0, 0.0)	0	(0.0, 0.0)
Traumatic haemothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	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)
Osteoarthritis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Adrenal gland cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Biliary cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Chronic myeloid leukaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to liver	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pancreatic carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hemiplegic migraine	0	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord compression	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)
Syncope	0	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	0	(0.0, 0.0)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	0	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	0	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.105. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Acute respiratory failure	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pulmonary embolism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Respiratory arrest	0	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	1 (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)
Deep vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 1md2 life age p3 saf

SUPPLEMENTAL TABLES

Phase 2/3

Adverse Events

14.106. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	4396	88.4	(85.8, 91.0)	2136	43.5	(41.7, 45.4)
Related[f]	3484	70.0	(67.7, 72.4)	884	18.0	(16.8, 19.2)
Severe	193	3.9	(3.4, 4.5)	124	2.5	(2.1, 3.0)
Life-threatening	13	0.3	(0.1, 0.4)	20	0.4	(0.2, 0.6)
Any serious adverse event	103	2.1	(1.7, 2.5)	117	2.4	(2.0, 2.9)
Related[f]	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Severe	56	1.1	(0.9, 1.5)	75	1.5	(1.2, 1.9)
Life-threatening	13	0.3	(0.1, 0.4)	20	0.4	(0.2, 0.6)
Any adverse event leading to withdrawal	22	0.4	(0.3, 0.7)	28	0.6	(0.4, 0.8)
Related[f]	9	0.2	(0.1, 0.3)	8	0.2	(0.1, 0.3)
Severe	5	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Life-threatening	3	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Death	3	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s092_unb_age_p3_saf

14.107. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	2551	75.7	(72.8, 78.7)	1432	43.3	(41.1, 45.6)
Related[f]	1762	52.3	(49.9, 54.8)	429	13.0	(11.8, 14.3)
Severe	163	4.8	(4.1, 5.6)	132	4.0	(3.3, 4.7)
Life-threatening	35	1.0	(0.7, 1.4)	34	1.0	(0.7, 1.4)
Any serious adverse event	165	4.9	(4.2, 5.7)	151	4.6	(3.9, 5.4)
Related[f]	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Severe	92	2.7	(2.2, 3.3)	81	2.4	(1.9, 3.0)
Life-threatening	35	1.0	(0.7, 1.4)	34	1.0	(0.7, 1.4)
Any adverse event leading to withdrawal	23	0.7	(0.4, 1.0)	23	0.7	(0.4, 1.0)
Related[f]	4	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Severe	5	0.1	(0.0, 0.3)	6	0.2	(0.1, 0.4)
Life-threatening	12	0.4	(0.2, 0.6)	11	0.3	(0.2, 0.6)
Death	12	0.4	(0.2, 0.6)	10	0.3	(0.1, 0.6)

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s092_unb_age_p3_saf

14.108. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=674, TE[b]=2.5)			Placebo (N[a]=705, TE[b]=2.6)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	179	70.7	(60.7, 81.9)	84	31.9	(25.5, 39.5)
Related[f]	131	51.8	(43.3, 61.4)	34	12.9	(8.9, 18.1)
Severe	13	5.1	(2.7, 8.8)	6	2.3	(0.8, 5.0)
Life-threatening	3	1.2	(0.2, 3.5)	1	0.4	(0.0, 2.1)
Any serious adverse event	10	4.0	(1.9, 7.3)	5	1.9	(0.6, 4.4)
Related[f]	0	0.0	(0.0, 1.5)	0	0.0	(0.0, 1.4)
Severe	8	3.2	(1.4, 6.2)	4	1.5	(0.4, 3.9)
Life-threatening	3	1.2	(0.2, 3.5)	1	0.4	(0.0, 2.1)
Any adverse event leading to withdrawal	3	1.2	(0.2, 3.5)	1	0.4	(0.0, 2.1)
Related[f]	0	0.0	(0.0, 1.5)	0	0.0	(0.0, 1.4)
Severe	0	0.0	(0.0, 1.5)	0	0.0	(0.0, 1.4)
Life-threatening	2	0.8	(0.1, 2.9)	0	0.0	(0.0, 1.4)
Death	2	0.8	(0.1, 2.9)	0	0.0	(0.0, 1.4)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s092 unb base p3 saf

14.109. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	6724	83.6	(81.7, 85.7)	3466	43.8	(42.4, 45.3)
Related[f]	5082	63.2	(61.5, 65.0)	1274	16.1	(15.2, 17.0)
Severe	340	4.2	(3.8, 4.7)	249	3.1	(2.8, 3.6)
Life-threatening	45	0.6	(0.4, 0.7)	53	0.7	(0.5, 0.9)
Any serious adverse event	256	3.2	(2.8, 3.6)	262	3.3	(2.9, 3.7)
Related[f]	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Severe	138	1.7	(1.4, 2.0)	152	1.9	(1.6, 2.3)
Life-threatening	45	0.6	(0.4, 0.7)	53	0.7	(0.5, 0.9)
Any adverse event leading to withdrawal	42	0.5	(0.4, 0.7)	50	0.6	(0.5, 0.8)
Related[f]	13	0.2	(0.1, 0.3)	12	0.2	(0.1, 0.3)
Severe	10	0.1	(0.1, 0.2)	12	0.2	(0.1, 0.3)
Life-threatening	13	0.2	(0.1, 0.3)	16	0.2	(0.1, 0.3)
Death	13	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.3)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s092_unb_base_p3_saf

14.110. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	1853	78.4	(74.9, 82.0)	1127	47.9	(45.1, 50.7)
Related[f]	1230	52.0	(49.2, 55.0)	341	14.5	(13.0, 16.1)
Severe	122	5.2	(4.3, 6.2)	80	3.4	(2.7, 4.2)
Life-threatening	6	0.3	(0.1, 0.6)	17	0.7	(0.4, 1.2)
Any serious adverse event	82	3.5	(2.8, 4.3)	85	3.6	(2.9, 4.5)
Related[f]	0	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Severe	53	2.2	(1.7, 2.9)	51	2.2	(1.6, 2.8)
Life-threatening	6	0.3	(0.1, 0.6)	17	0.7	(0.4, 1.2)
Any adverse event leading to withdrawal	11	0.5	(0.2, 0.8)	7	0.3	(0.1, 0.6)
Related[f]	3	0.1	(0.0, 0.4)	0	0.0	(0.0, 0.2)
Severe	3	0.1	(0.0, 0.4)	0	0.0	(0.0, 0.2)
Life-threatening	2	0.1	(0.0, 0.3)	6	0.3	(0.1, 0.6)
Death	2	0.1	(0.0, 0.3)	5	0.2	(0.1, 0.5)

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s092 unb eth p3 saf

14.111. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	5073	85.4	(83.1, 87.8)	2422	41.6	(40.0, 43.3)
Related[f]	4002	67.4	(65.3, 69.5)	964	16.6	(15.5, 17.7)
Severe	233	3.9	(3.4, 4.5)	175	3.0	(2.6, 3.5)
Life-threatening	42	0.7	(0.5, 1.0)	37	0.6	(0.4, 0.9)
Any serious adverse event	185	3.1	(2.7, 3.6)	182	3.1	(2.7, 3.6)
Related[f]	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Severe	94	1.6	(1.3, 1.9)	104	1.8	(1.5, 2.2)
Life-threatening	42	0.7	(0.5, 1.0)	37	0.6	(0.4, 0.9)
Any adverse event leading to withdrawal	34	0.6	(0.4, 0.8)	42	0.7	(0.5, 1.0)
Related[f]	10	0.2	(0.1, 0.3)	11	0.2	(0.1, 0.3)
Severe	7	0.1	(0.0, 0.2)	11	0.2	(0.1, 0.3)
Life-threatening	13	0.2	(0.1, 0.4)	10	0.2	(0.1, 0.3)
Death	13	0.2	(0.1, 0.4)	9	0.2	(0.1, 0.3)

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
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14.112. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Not Reported

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=111, TE[b]=0.4)			Placebo (N[a]=113, TE[b]=0.4)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	21	49.4	(30.6, 75.5)	19	43.3	(26.1, 67.6)
Related[f]	14	32.9	(18.0, 55.2)	8	18.2	(7.9, 35.9)
Severe	1	2.4	(0.1, 13.1)	1	2.3	(0.1, 12.7)
Life-threatening	0	0.0	(0.0, 8.7)	0	0.0	(0.0, 8.4)
Any serious adverse event	1	2.4	(0.1, 13.1)	1	2.3	(0.1, 12.7)
Related[f]	0	0.0	(0.0, 8.7)	0	0.0	(0.0, 8.4)
Severe	1	2.4	(0.1, 13.1)	1	2.3	(0.1, 12.7)
Life-threatening	0	0.0	(0.0, 8.7)	0	0.0	(0.0, 8.4)
Any adverse event leading to withdrawal	0	0.0	(0.0, 8.7)	2	4.6	(0.6, 16.5)
Related[f]	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
Severe	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
Life-threatening	0	0.0	(0.0, 8.7)	0	0.0	(0.0, 8.4)
Death	0	0.0	(0.0, 8.7)	0	0.0	(0.0, 8.4)

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
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14.113. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
Adverse Event	**n[c]**	**IR (/100 PY)[d]**	**(95% CI[e])**	**n[c]**	**IR (/100 PY)[d]**	**(95% CI[e])**
Any event	5728	83.1	(81.0, 85.3)	2985	43.9	(42.3, 45.5)
Related[f]	4268	61.9	(60.1, 63.8)	1012	14.9	(14.0, 15.8)
Severe	310	4.5	(4.0, 5.0)	224	3.3	(2.9, 3.8)
Life-threatening	42	0.6	(0.4, 0.8)	49	0.7	(0.5, 1.0)
Any serious adverse event	230	3.3	(2.9, 3.8)	239	3.5	(3.1, 4.0)
Related[f]	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Severe	129	1.9	(1.6, 2.2)	136	2.0	(1.7, 2.4)
Life-threatening	42	0.6	(0.4, 0.8)	49	0.7	(0.5, 1.0)
Any adverse event leading to withdrawal	40	0.6	(0.4, 0.8)	39	0.6	(0.4, 0.8)
Related[f]	13	0.2	(0.1, 0.3)	6	0.1	(0.0, 0.2)
Severe	10	0.1	(0.1, 0.3)	11	0.2	(0.1, 0.3)
Life-threatening	13	0.2	(0.1, 0.3)	16	0.2	(0.1, 0.4)
Death	13	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.3)

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.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s092 unb race p3 saf

14.114. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=2046, TE[b]=7.9)			Placebo (N[a]=2061, TE[b]=7.8)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	421	53.5	(48.5, 58.9)	275	35.3	(31.2, 39.7)
Related[f]	291	37.0	(32.9, 41.5)	120	15.4	(12.8, 18.4)
Severe	20	2.5	(1.6, 3.9)	22	2.8	(1.8, 4.3)
Life-threatening	3	0.4	(0.1, 1.1)	4	0.5	(0.1, 1.3)
Any serious adverse event	20	2.5	(1.6, 3.9)	20	2.6	(1.6, 4.0)
Related[f]	0	0.0	(0.0, 0.5)	0	0.0	(0.0, 0.5)
Severe	12	1.5	(0.8, 2.7)	15	1.9	(1.1, 3.2)
Life-threatening	3	0.4	(0.1, 1.1)	4	0.5	(0.1, 1.3)
Any adverse event leading to withdrawal	3	0.4	(0.1, 1.1)	8	1.0	(0.4, 2.0)
Related[f]	0	0.0	(0.0, 0.5)	5	0.6	(0.2, 1.5)
Severe	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Life-threatening	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Death	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)

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.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s092 unb race p3 saf

14.115. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1868, TE[b]=6.6)			Placebo (N[a]=1833, TE[b]=6.3)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	798	120.1	(111.9, 128.8)	308	48.6	(43.3, 54.3)
Related[f]	687	103.4	(95.8, 111.4)	181	28.5	(24.5, 33.0)
Severe	26	3.9	(2.6, 5.7)	10	1.6	(0.8, 2.9)
Life-threatening	3	0.5	(0.1, 1.3)	1	0.2	(0.0, 0.9)
Any serious adverse event	18	2.7	(1.6, 4.3)	9	1.4	(0.6, 2.7)
Related[f]	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Severe	7	1.1	(0.4, 2.2)	5	0.8	(0.3, 1.8)
Life-threatening	3	0.5	(0.1, 1.3)	1	0.2	(0.0, 0.9)
Any adverse event leading to withdrawal	2	0.3	(0.0, 1.1)	4	0.6	(0.2, 1.6)
Related[f]	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Severe	0	0.0	(0.0, 0.6)	0	0.0	(0.0, 0.6)
Life-threatening	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Death	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)

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.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s092_unb_race_p3_saf

14.116. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	3279	76.0	(73.4, 78.6)	1668	40.1	(38.2, 42.1)
Related[f]	2482	57.5	(55.3, 59.8)	619	14.9	(13.7, 16.1)
Severe	160	3.7	(3.2, 4.3)	129	3.1	(2.6, 3.7)
Life-threatening	34	0.8	(0.5, 1.1)	31	0.7	(0.5, 1.1)
Any serious adverse event	152	3.5	(3.0, 4.1)	140	3.4	(2.8, 4.0)
Related[f]	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Severe	83	1.9	(1.5, 2.4)	79	1.9	(1.5, 2.4)
Life-threatening	34	0.8	(0.5, 1.1)	31	0.7	(0.5, 1.1)
Any adverse event leading to withdrawal	16	0.4	(0.2, 0.6)	22	0.5	(0.3, 0.8)
Related[f]	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Severe	3	0.1	(0.0, 0.2)	6	0.1	(0.1, 0.3)
Life-threatening	10	0.2	(0.1, 0.4)	10	0.2	(0.1, 0.4)
Death	10	0.2	(0.1, 0.4)	8	0.2	(0.1, 0.4)

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s092_unb_sex_p3_saf

14.117. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	3668	91.0	(88.1, 94.0)	1900	46.8	(44.7, 49.0)
Related[f]	2764	68.6	(66.1, 71.2)	694	17.1	(15.8, 18.4)
Severe	196	4.9	(4.2, 5.6)	127	3.1	(2.6, 3.7)
Life-threatening	14	0.3	(0.2, 0.6)	23	0.6	(0.4, 0.9)
Any serious adverse event	116	2.9	(2.4, 3.5)	128	3.2	(2.6, 3.7)
Related[f]	4	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Severe	65	1.6	(1.2, 2.1)	77	1.9	(1.5, 2.4)
Life-threatening	14	0.3	(0.2, 0.6)	23	0.6	(0.4, 0.9)
Any adverse event leading to withdrawal	29	0.7	(0.5, 1.0)	29	0.7	(0.5, 1.0)
Related[f]	12	0.3	(0.2, 0.5)	8	0.2	(0.1, 0.4)
Severe	7	0.2	(0.1, 0.4)	6	0.1	(0.1, 0.3)
Life-threatening	5	0.1	(0.0, 0.3)	6	0.1	(0.1, 0.3)
Death	5	0.1	(0.0, 0.3)	6	0.1	(0.1, 0.3)

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s092_unb_sex_p3_saf

14.118. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=100, TE[b]=0.3)			Placebo (N[a]=100, TE[b]=0.3)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	29	95.8	(64.2, 137.6)	15	52.0	(29.1, 85.8)
Related[f]	19	62.8	(37.8, 98.0)	3	10.4	(2.1, 30.4)
Severe	2	6.6	(0.8, 23.9)	0	0.0	(0.0, 12.8)
Life-threatening	1	3.3	(0.1, 18.4)	1	3.5	(0.1, 19.3)
Any serious adverse event	2	6.6	(0.8, 23.9)	2	6.9	(0.8, 25.1)
Related[f]	0	0.0	(0.0, 12.2)	0	0.0	(0.0, 12.8)
Severe	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
Life-threatening	1	3.3	(0.1, 18.4)	1	3.5	(0.1, 19.3)
Any adverse event leading to withdrawal	2	6.6	(0.8, 23.9)	1	3.5	(0.1, 19.3)
Related[f]	0	0.0	(0.0, 12.2)	0	0.0	(0.0, 12.8)
Severe	0	0.0	(0.0, 12.2)	0	0.0	(0.0, 12.8)
Life-threatening	1	3.3	(0.1, 18.4)	1	3.5	(0.1, 19.3)
Death	1	3.3	(0.1, 18.4)	1	3.5	(0.1, 19.3)

Abbreviation: HIV = human immunodeficiency virus.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (14:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s092_hiv_unb_p3_saf

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	6947	83.2	(81.3, 85.2)	3568	43.4	(42.0, 44.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	118	1.4	(1.2, 1.7)	32	0.4	(0.3, 0.5)
Anaemia	8	0.1	(0.0, 0.2)	10	0.1	(0.1, 0.2)
Blood loss anaemia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coagulopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypochromic anaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Iron deficiency anaemia	9	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Leukocytosis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Leukopenia	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymph node pain	7	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Lymphadenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphadenopathy	87	1.0	(0.8, 1.3)	8	0.1	(0.0, 0.2)
Lymphadenopathy mediastinal	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymphocytosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphopenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Microcytic anaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Monoclonal B-cell lymphocytosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Neutropenia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Splenomegaly	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Thrombocytopenia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Thrombocytosis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
CARDIAC DISORDERS	87	1.0	(0.8, 1.3)	78	0.9	(0.8, 1.2)
Acute coronary syndrome	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Acute left ventricular failure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Acute myocardial infarction	6	0.1	(0.0, 0.2)	4	0.0	(0.0, 0.1)
Angina pectoris	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angina unstable	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Aortic valve incompetence	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Arrhythmia	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Arrhythmia supraventricular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Arteriosclerosis coronary artery	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Arteriospasm coronary	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrial fibrillation	13	0.2	(0.1, 0.3)	17	0.2	(0.1, 0.3)
Atrial flutter	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Atrioventricular block complete	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrioventricular block first degree	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bradycardia	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bundle branch block left	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bundle branch block right	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac arrest	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Cardiac disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac failure acute	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiomegaly	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiovascular disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Coronary artery disease	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Coronary artery dissection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Coronary artery occlusion	0	0.0	(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, 0.0)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Left atrial enlargement	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Left ventricular dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Left ventricular hypertrophy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mitral valve incompetence	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Mitral valve prolapse	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myocardial infarction	4	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Myocardial ischaemia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Myocarditis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Palpitations	7	0.1	(0.0, 0.2)	16	0.2	(0.1, 0.3)
Pericardial effusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pericarditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Postural orthostatic tachycardia syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Sinus bradycardia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Sinus tachycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Supraventricular tachycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tachyarrhythmia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tachycardia	15	0.2	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Tricuspid valve incompetence	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ventricular arrhythmia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ventricular extrasystoles	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ventricular tachycardia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	4	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Arnold-Chiari malformation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Congenital bladder neck obstruction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Congenital cystic kidney disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Congenital ureteropelvic junction obstruction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Developmental hip dysplasia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastrointestinal arteriovenous malformation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Heart disease congenital	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Protein S deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Type V hyperlipidaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	76	0.9	(0.7, 1.1)	61	0.7	(0.6, 1.0)
Allergic otitis media	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerumen impaction	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deafness	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Deafness neurosensory	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Deafness unilateral	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear discomfort	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear disorder	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Ear pain	13	0.2	(0.1, 0.3)	11	0.1	(0.1, 0.2)
Ear pruritus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eustachian tube dysfunction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyperacusis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypoacusis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Meniere's disease	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Otorrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sudden hearing loss	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tinnitus	9	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Tympanic membrane perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vertigo	31	0.4	(0.3, 0.5)	26	0.3	(0.2, 0.5)
Vertigo positional	8	0.1	(0.0, 0.2)	4	0.0	(0.0, 0.1)
ENDOCRINE DISORDERS	17	0.2	(0.1, 0.3)	11	0.1	(0.1, 0.2)
Autoimmune thyroiditis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Goitre	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperprolactinaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperthyroidism	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypogonadism	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypothyroidism	8	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Oestrogen deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Thyroid cyst	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Thyroid mass	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EYE DISORDERS	70	0.8	(0.7, 1.1)	65	0.8	(0.6, 1.0)
Amaurosis fugax	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Angle closure glaucoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Asthenopia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Astigmatism	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blepharitis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blepharospasm	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cataract	7	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Chalazion	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Choroidal neovascularisation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Conjunctival haemorrhage	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Conjunctival hyperaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Conjunctival oedema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Conjunctivitis allergic	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Corneal irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dacryostenosis acquired	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diabetic retinopathy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diplopia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dry age-related macular degeneration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dry eye	1	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Episcleritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eye allergy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eye haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eye inflammation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eye irritation	6	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Eye pain	7	0.1	(0.0, 0.2)	4	0.0	(0.0, 0.1)
Eye pruritus	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye swelling	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eyelid haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eyelid oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eyelid pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eyelids pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Glaucoma	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypermetropia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Iritis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Keratitis	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Lacrimation increased	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Macular oedema	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ocular discomfort	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ocular hyperaemia	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Photophobia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal artery occlusion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal detachment	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Retinal tear	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Scleral discolouration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Swelling of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ulcerative keratitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uveitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vision blurred	7	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Visual acuity reduced	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Visual impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vitreous detachment	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vitreous floaters	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	748	9.0	(8.3, 9.6)	511	6.2	(5.7, 6.8)
Abdominal adhesions	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abdominal discomfort	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Abdominal distension	7	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Abdominal hernia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abdominal pain	23	0.3	(0.2, 0.4)	22	0.3	(0.2, 0.4)
Abdominal pain lower	3	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Abdominal pain upper	27	0.3	(0.2, 0.5)	15	0.2	(0.1, 0.3)
Abdominal rigidity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abnormal faeces	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Acute abdomen	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Anal pruritus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Angular cheilitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Aphthous ulcer	9	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Appendix disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cheilitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Chronic gastritis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Coeliac artery aneurysm	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Coeliac disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Colitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colitis ischaemic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Colitis microscopic	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Colitis ulcerative	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Constipation	10	0.1	(0.1, 0.2)	13	0.2	(0.1, 0.3)
Crohn's disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dental caries	10	0.1	(0.1, 0.2)	8	0.1	(0.0, 0.2)
Diarrhoea	255	3.1	(2.7, 3.5)	189	2.3	(2.0, 2.7)
Diverticular perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diverticulum	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulum intestinal	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Diverticulum intestinal haemorrhagic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dry mouth	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Duodenal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Duodenal ulcer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dyspepsia	15	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.3)
Dysphagia	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Enterocolitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Epiploic appendagitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eructation	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Faeces soft	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Femoral hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Flatulence	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Food poisoning	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Frequent bowel movements	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastric antral vascular ectasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastric polyps	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastric ulcer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastric ulcer haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastritis	5	0.1	(0.0, 0.1)	14	0.2	(0.1, 0.3)
Gastritis erosive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastrointestinal disorder	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal haemorrhage	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal mucosa hyperaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastrointestinal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastrooesophageal reflux disease	15	0.2	(0.1, 0.3)	23	0.3	(0.2, 0.4)
Gingival bleeding	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Gingival discomfort	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gingival pain	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gingival swelling	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Glossitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Glossodynia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haematemesis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haematochezia	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haemorrhoids	5	0.1	(0.0, 0.1)	11	0.1	(0.1, 0.2)
Hiatus hernia	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hypoaesthesia oral	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypoaesthesia teeth	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ileus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Impaired gastric emptying	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Incarcerated inguinal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Inguinal hernia	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Internal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intestinal obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal perforation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intestinal polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intestinal strangulation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intra-abdominal fluid collection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Irritable bowel syndrome	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Large intestine perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Large intestine polyp	4	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Lip oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lip swelling	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Loose tooth	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mouth ulceration	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Nausea	277	3.3	(2.9, 3.7)	88	1.1	(0.9, 1.3)
Noninfective gingivitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Obstructive pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Odynophagia	13	0.2	(0.1, 0.3)	8	0.1	(0.0, 0.2)
Oesophageal food impaction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oesophageal spasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oesophageal ulcer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oesophageal varices haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oesophagitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Oral discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Oral lichenoid reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oral mucosa haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oral pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Palatal disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pancreatic cyst	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pancreatic failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pancreatitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pancreatitis acute	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Paraesthesia oral	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Parotid duct obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peptic ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Precancerous lesion of digestive tract	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Proctalgia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectal haemorrhage	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectal polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Retching	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retroperitoneal haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Salivary gland calculus	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Salivary gland mucocoele	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Small intestinal obstruction	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Stomatitis	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Swollen tongue	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Teething	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tongue discolouration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tongue discomfort	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tongue oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tongue pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tongue ulceration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tooth disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tooth impacted	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Toothache	26	0.3	(0.2, 0.5)	28	0.3	(0.2, 0.5)
Umbilical hernia	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Varices oesophageal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Volvulus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vomiting	68	0.8	(0.6, 1.0)	35	0.4	(0.3, 0.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4748	56.9	(55.3, 58.5)	1010	12.3	(11.5, 13.1)
Adverse drug reaction	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Application site erythema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Application site pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Application site pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Application site rash	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Application site reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Asthenia	77	0.9	(0.7, 1.2)	25	0.3	(0.2, 0.4)
Axillary pain	14	0.2	(0.1, 0.3)	3	0.0	(0.0, 0.1)
Capsular contracture associated with breast implant	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Chest discomfort	5	0.1	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Chest pain	17	0.2	(0.1, 0.3)	16	0.2	(0.1, 0.3)
Chills	1368	16.4	(15.5, 17.3)	121	1.5	(1.2, 1.8)
Chronic fatigue syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cyst	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Drug withdrawal syndrome	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Effusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Exercise tolerance decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Face oedema	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Facial pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fatigue	1466	17.6	(16.7, 18.5)	379	4.6	(4.2, 5.1)
Feeling abnormal	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Feeling cold	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Feeling hot	8	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Gait disturbance	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Illness	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Induration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Inflammation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Influenza like illness	24	0.3	(0.2, 0.4)	4	0.0	(0.0, 0.1)
Injection site bruising	13	0.2	(0.1, 0.3)	18	0.2	(0.1, 0.3)
Injection site dermatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site discolouration	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site discomfort	6	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Injection site erythema	185	2.2	(1.9, 2.6)	29	0.4	(0.2, 0.5)
Injection site haematoma	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Injection site haemorrhage	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Injection site hyperaesthesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site induration	10	0.1	(0.1, 0.2)	4	0.0	(0.0, 0.1)
Injection site injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site macule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site mass	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site nodule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site oedema	12	0.1	(0.1, 0.3)	0	0.0	(0.0, 0.0)
Injection site pain	2917	35.0	(33.7, 36.2)	399	4.9	(4.4, 5.4)
Injection site papule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site paraesthesia	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Injection site plaque	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Injection site pruritus	38	0.5	(0.3, 0.6)	6	0.1	(0.0, 0.2)
Injection site rash	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site reaction	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site swelling	140	1.7	(1.4, 2.0)	23	0.3	(0.2, 0.4)
Injection site urticaria	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site warmth	14	0.2	(0.1, 0.3)	5	0.1	(0.0, 0.1)
Injury associated with device	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Malaise	130	1.6	(1.3, 1.8)	22	0.3	(0.2, 0.4)
Mass	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Medical device pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Medical device site granuloma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mucosal disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nodule	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Non-cardiac chest pain	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Oedema peripheral	8	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Pain	628	7.5	(6.9, 8.1)	62	0.8	(0.6, 1.0)
Peripheral swelling	8	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Pyrexia	1520	18.2	(17.3, 19.2)	78	0.9	(0.8, 1.2)
Sensation of foreign body	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sluggishness	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sudden cardiac death	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Swelling	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Swelling face	2	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Temperature intolerance	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Therapeutic response unexpected	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Thirst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Vaccination site induration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vaccination site pain	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Vaccination site swelling	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vascular stent occlusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vessel puncture site bruise	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vessel puncture site haematoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vessel puncture site induration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	24	0.3	(0.2, 0.4)	16	0.2	(0.1, 0.3)
Bile duct stone	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary colic	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary dyskinesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholecystitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Cholecystitis acute	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Cholecystitis chronic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cholelithiasis	11	0.1	(0.1, 0.2)	5	0.1	(0.0, 0.1)
Cirrhosis alcoholic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gallbladder disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hepatic cirrhosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hepatic cyst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatic steatosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hepatocellular injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nonalcoholic fatty liver disease	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	23	0.3	(0.2, 0.4)	34	0.4	(0.3, 0.6)
Allergy to animal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Allergy to arthropod bite	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Allergy to arthropod sting	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anaphylactic shock	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Drug hypersensitivity	7	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Food allergy	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hypersensitivity	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Jarisch-Herxheimer reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Milk allergy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Seasonal allergy	8	0.1	(0.0, 0.2)	16	0.2	(0.1, 0.3)
INFECTIONS AND INFESTATIONS	417	5.0	(4.5, 5.5)	499	6.1	(5.6, 6.6)
Abdominal abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abscess	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abscess intestinal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Abscess jaw	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abscess limb	0	0.0	(0.0, 0.0)	4	0.0	(0.0, 0.1)
Abscess neck	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abscess oral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Acarodermatitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Acute sinusitis	1	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Anal abscess	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anal fistula infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Appendicitis	14	0.2	(0.1, 0.3)	9	0.1	(0.1, 0.2)
Appendicitis perforated	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arthritis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bacterial blepharitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bacterial infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bacterial rhinitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bacterial sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bacterial vaginosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bacterial vulvovaginitis	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Balanitis candida	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bartholin's abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bartholinitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blister infected	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bone abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Brain abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bronchitis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.0)	13	0.2	(0.1, 0.3)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Campylobacter infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Carbuncle	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Catheter site infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cellulitis	15	0.2	(0.1, 0.3)	20	0.2	(0.1, 0.4)
Cellulitis orbital	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chlamydial infection	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Chronic sinusitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clostridium difficile infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Complicated appendicitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Conjunctivitis	12	0.1	(0.1, 0.3)	11	0.1	(0.1, 0.2)
Conjunctivitis bacterial	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Coxsackie viral infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cystitis	8	0.1	(0.0, 0.2)	12	0.1	(0.1, 0.3)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dental fistula	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dermatitis infected	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Device related infection	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diabetic foot infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diverticulitis	10	0.1	(0.1, 0.2)	11	0.1	(0.1, 0.2)
Ear infection	11	0.1	(0.1, 0.2)	17	0.2	(0.1, 0.3)
Emphysematous cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Empyema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Erysipelas	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Escherichia sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Escherichia urinary tract infection	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Extradural abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eye infection	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Eye infection bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Folliculitis	7	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.0)
Fungal infection	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Fungal skin infection	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Furuncle	3	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Gangrene	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastroenteritis	6	0.1	(0.0, 0.2)	12	0.1	(0.1, 0.3)
Gastroenteritis viral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Genital herpes	0	0.0	(0.0, 0.0)	5	0.1	(0.0, 0.1)
Genital herpes simplex	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Genitourinary chlamydia infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gingival abscess	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Gingivitis	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Gonorrhoea	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Groin abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Helicobacter gastritis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Helicobacter infection	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Hepatitis A	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hepatitis C	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Herpes ophthalmic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Herpes simplex	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Herpes virus infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Herpes zoster	18	0.2	(0.1, 0.3)	16	0.2	(0.1, 0.3)
Herpes zoster cutaneous disseminated	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Herpes zoster oticus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hordeolum	8	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Impetigo	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Infected bite	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Infected dermal cyst	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Infectious mononucleosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Influenza	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Kidney infection	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Labyrinthitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Laryngitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Localised infection	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Lyme disease	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Mastitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mastoiditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Meningitis bacterial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nail infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nasopharyngitis	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Onychomycosis	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Ophthalmic herpes zoster	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral candidiasis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral fungal infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oral herpes	7	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Oral infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Orchitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Osteomyelitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Otitis externa	6	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Otitis media	9	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Otitis media acute	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Otitis media bacterial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Papilloma viral infection	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Parasitic gastroenteritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Paronychia	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Parotitis	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Pelvic inflammatory disease	0	0.0	(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, 0.0)
Periodontitis	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peritonitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritonsillar abscess	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pharyngitis	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Pharyngitis bacterial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pharyngitis streptococcal	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pharyngotonsillitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pilonidal cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pneumonia	4	0.0	(0.0, 0.1)	9	0.1	(0.1, 0.2)
Post procedural infection	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Postoperative wound infection	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Primary syphilis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pulmonary tuberculosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Puncture site infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pustule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pyelonephritis	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Pyelonephritis acute	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Rash pustular	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Renal abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Respiratory tract infection viral	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Rhinitis	6	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Sepsis	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Septic shock	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Shigella sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sialoadenitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinusitis	20	0.2	(0.1, 0.4)	31	0.4	(0.3, 0.5)
Sinusitis bacterial	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin bacterial infection	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Skin infection	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Soft tissue infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Staphylococcal infection	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Staphylococcal sepsis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subacute endocarditis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subcutaneous abscess	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Syphilis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tinea cruris	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tinea infection	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Tinea versicolour	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Tonsillitis	0	0.0	(0.0, 0.0)	6	0.1	(0.0, 0.2)
Tonsillitis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tooth abscess	12	0.1	(0.1, 0.3)	6	0.1	(0.0, 0.2)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Tooth infection	26	0.3	(0.2, 0.5)	33	0.4	(0.3, 0.6)
Trichomoniasis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper respiratory tract infection	10	0.1	(0.1, 0.2)	9	0.1	(0.1, 0.2)
Ureaplasma infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Urinary tract infection	74	0.9	(0.7, 1.1)	82	1.0	(0.8, 1.2)
Urosepsis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vaginal infection	0	0.0	(0.0, 0.0)	7	0.1	(0.0, 0.2)
Varicella	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Viral infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Viral upper respiratory tract infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vulval abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vulvovaginal candidiasis	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Vulvovaginal mycotic infection	6	0.1	(0.0, 0.2)	10	0.1	(0.1, 0.2)
Vulvovaginitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Wound infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	294	3.5	(3.1, 3.9)	378	4.6	(4.1, 5.1)
Administration related reaction	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Alcohol poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anaemia postoperative	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Animal bite	3	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Ankle fracture	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Arthropod bite	12	0.1	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Arthropod sting	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Back injury	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Bone contusion	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bone fissure	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Brain contusion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Burn oral cavity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Burns first degree	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Burns second degree	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cartilage injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cervical vertebral fracture	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chest injury	5	0.1	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Chillblains	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Clavicle fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colon injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Concussion	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Contusion	14	0.2	(0.1, 0.3)	22	0.3	(0.2, 0.4)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Corneal abrasion	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Craniocerebral injury	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Delayed recovery from anaesthesia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dental restoration failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ear canal abrasion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ear injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Epicondylitis	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Exposure during pregnancy	30	0.4	(0.2, 0.5)	42	0.5	(0.4, 0.7)
Exposure to communicable disease	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eye contusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eyelid injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Facial bones fracture	5	0.1	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Fall	62	0.7	(0.6, 1.0)	76	0.9	(0.7, 1.2)
Femur fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Fibula fracture	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Flail chest	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Foot fracture	7	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Forearm fracture	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Foreign body	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Foreign body aspiration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Foreign body in eye	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fractured sacrum	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hand fracture	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Head injury	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Heat stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hip fracture	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Humerus fracture	0	0.0	(0.0, 0.0)	5	0.1	(0.0, 0.1)
Injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Jaw fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Joint dislocation	8	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Joint injury	6	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Ligament injury	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Ligament rupture	2	0.0	(0.0, 0.1)	10	0.1	(0.1, 0.2)
Ligament sprain	21	0.3	(0.2, 0.4)	27	0.3	(0.2, 0.5)
Limb fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Limb injury	8	0.1	(0.0, 0.2)	16	0.2	(0.1, 0.3)
Limb traumatic amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lip injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lower limb fracture	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Lumbar vertebral fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Maternal exposure before pregnancy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Maternal exposure during breast feeding	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Maternal exposure during pregnancy	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Meniscus injury	6	0.1	(0.0, 0.2)	10	0.1	(0.1, 0.2)
Mouth injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Multiple injuries	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Muscle contusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Muscle injury	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Muscle rupture	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Muscle strain	18	0.2	(0.1, 0.3)	17	0.2	(0.1, 0.3)
Overdose	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Patella fracture	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pelvic fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Penis injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pharyngeal perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Post concussion syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post procedural discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post procedural haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Post procedural haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Post procedural swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post-traumatic pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Postoperative ileus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Procedural dizziness	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Procedural haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Procedural hypotension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Procedural pain	9	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Radius fracture	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Respiratory fume inhalation disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rib fracture	3	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Road traffic accident	16	0.2	(0.1, 0.3)	20	0.2	(0.1, 0.4)
Scapula fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Scar	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin abrasion	8	0.1	(0.0, 0.2)	15	0.2	(0.1, 0.3)
Skin injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin laceration	18	0.2	(0.1, 0.3)	24	0.3	(0.2, 0.4)
Skull fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Soft tissue injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spinal column injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Spinal compression fracture	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Spinal cord injury cervical	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Spinal fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Stab wound	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Stoma site rash	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Stress fracture	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Subdural haematoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sunburn	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tendon injury	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Tendon rupture	0	0.0	(0.0, 0.0)	6	0.1	(0.0, 0.2)
Thermal burn	3	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Tibia fracture	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tooth fracture	10	0.1	(0.1, 0.2)	10	0.1	(0.1, 0.2)
Tooth injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Toxicity to various agents	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Traumatic haemothorax	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ulna fracture	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Upper limb fracture	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vaccination complication	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Venom poisoning	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vulvovaginal injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Wound	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Wrist fracture	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
INVESTIGATIONS	183	2.2	(1.9, 2.5)	51	0.6	(0.5, 0.8)
Alanine aminotransferase increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Aspartate aminotransferase increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Autoantibody positive	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Biopsy breast normal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood chloride decreased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood cholesterol increased	5	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blood creatinine decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood creatinine increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood glucose abnormal	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood glucose fluctuation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood glucose increased	8	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Blood immunoglobulin E increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood iron decreased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Blood potassium decreased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood pressure abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood pressure diastolic increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood pressure increased	6	0.1	(0.0, 0.2)	10	0.1	(0.1, 0.2)
Blood pressure systolic increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood sodium decreased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood testosterone decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood testosterone increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood thyroid stimulating hormone increased	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood triglycerides increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood urea increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Body temperature	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Body temperature decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Body temperature increased	121	1.5	(1.2, 1.7)	13	0.2	(0.1, 0.3)
C-reactive protein	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac stress test abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Electrocardiogram QT prolonged	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Glomerular filtration rate decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haemoglobin decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Heart rate increased	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Heart rate irregular	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hepatic enzyme increased	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Hepatitis C antibody positive	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Herpes simplex test positive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
High density lipoprotein increased	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Intraocular pressure increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Liver function test increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Low density lipoprotein increased	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymphocyte count decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Mammogram abnormal	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Mean cell haemoglobin decreased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mean cell volume decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Mean cell volume increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Monocyte count increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Platelet count decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Platelet count increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Prostatic specific antigen increased	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Red blood cell morphology abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Respiratory rate increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
SARS-CoV-2 antibody test positive	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Serum ferritin decreased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Thyroid function test abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Troponin increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urine ketone body present	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Weight decreased	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Weight increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
White blood cell count increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
White blood cells urine positive	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	129	1.5	(1.3, 1.8)	117	1.4	(1.2, 1.7)
Decreased appetite	39	0.5	(0.3, 0.6)	9	0.1	(0.1, 0.2)
Dehydration	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Diabetes mellitus	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Diabetic ketoacidosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dyslipidaemia	7	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Fluid retention	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Folate deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Food intolerance	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Glucose tolerance impaired	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Gout	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hypercholesterolaemia	7	0.1	(0.0, 0.2)	21	0.3	(0.2, 0.4)
Hyperglycaemia	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Hyperkalaemia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperlipidaemia	9	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Hypernatraemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypertriglyceridaemia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperuricaemia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypocalcaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypocholesterolaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoglycaemia	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hypokalaemia	8	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Hypomagnesaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyponatraemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypovolaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Impaired fasting glucose	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Increased appetite	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Insulin resistance	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Iron deficiency	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lactic acidosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Obesity	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Polydipsia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Type 2 diabetes mellitus	14	0.2	(0.1, 0.3)	13	0.2	(0.1, 0.3)
Vitamin B12 deficiency	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Vitamin D deficiency	12	0.1	(0.1, 0.3)	10	0.1	(0.1, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1859	22.3	(21.3, 23.3)	622	7.6	(7.0, 8.2)
Arthralgia	281	3.4	(3.0, 3.8)	122	1.5	(1.2, 1.8)
Arthritis	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Arthritis reactive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Arthropathy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Axillary mass	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Back pain	104	1.2	(1.0, 1.5)	99	1.2	(1.0, 1.5)
Bone disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bone pain	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bone swelling	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bursitis	11	0.1	(0.1, 0.2)	5	0.1	(0.0, 0.1)
Coccydynia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Costochondritis	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dupuytren's contracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Exostosis	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Fibromyalgia	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Flank pain	3	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Groin pain	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc compression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intervertebral disc degeneration	4	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Intervertebral disc disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	10	0.1	(0.1, 0.2)	11	0.1	(0.1, 0.2)
Joint effusion	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Joint instability	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Joint range of motion decreased	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Joint stiffness	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Joint swelling	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Limb discomfort	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Metatarsalgia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Mobility decreased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Muscle contracture	4	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Muscle discomfort	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Muscle fatigue	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle spasms	29	0.3	(0.2, 0.5)	16	0.2	(0.1, 0.3)
Muscle tightness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Muscle twitching	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscular weakness	13	0.2	(0.1, 0.3)	3	0.0	(0.0, 0.1)
Musculoskeletal chest pain	11	0.1	(0.1, 0.2)	7	0.1	(0.0, 0.2)
Musculoskeletal discomfort	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Musculoskeletal pain	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Musculoskeletal stiffness	12	0.1	(0.1, 0.3)	6	0.1	(0.0, 0.2)
Myalgia	1245	14.9	(14.1, 15.8)	170	2.1	(1.8, 2.4)
Myalgia intercostal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Neck pain	34	0.4	(0.3, 0.6)	36	0.4	(0.3, 0.6)
Osteitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteoarthritis	15	0.2	(0.1, 0.3)	23	0.3	(0.2, 0.4)
Osteochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Osteochondrosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Osteopenia	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Osteoporosis	0	0.0	(0.0, 0.0)	6	0.1	(0.0, 0.2)
Pain in extremity	189	2.3	(2.0, 2.6)	52	0.6	(0.5, 0.8)
Pain in jaw	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Patellofemoral pain syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Periarthritis	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Plantar fasciitis	4	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Polyarthritis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Psoriatic arthropathy	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Rhabdomyolysis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rheumatoid arthritis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Rotator cuff syndrome	5	0.1	(0.0, 0.1)	13	0.2	(0.1, 0.3)
Scoliosis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Sinus tarsi syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spinal disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spinal osteoarthritis	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Spinal stenosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spondylitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spondylolisthesis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Synovial cyst	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Synovitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Systemic lupus erythematosus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Temporomandibular joint syndrome	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Tendon disorder	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tendon pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tendonitis	12	0.1	(0.1, 0.3)	10	0.1	(0.1, 0.2)
Tenosynovitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tenosynovitis stenosans	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Torticollis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Trigger finger	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	67	0.8	(0.6, 1.0)	69	0.8	(0.7, 1.1)
Acrochordon	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Acute myeloid leukaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma of colon	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma pancreas	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenoma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adrenal gland cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
B-cell lymphoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Basal cell carcinoma	3	0.0	(0.0, 0.1)	11	0.1	(0.1, 0.2)
Benign breast neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Benign hydatidiform mole	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Benign pancreatic neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Benign uterine neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary cancer metastatic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bladder cancer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Borderline serous tumour of ovary	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Breast cancer	2	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Breast cancer in situ	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Breast cancer stage I	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Carcinoid tumour of the stomach	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chondroma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Colon adenoma	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Fibroadenoma of breast	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Gallbladder cancer stage II	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastric cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Glomus tumour	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Haemangioma of skin	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Infected naevus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Invasive ductal breast carcinoma	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Leydig cell tumour of the testis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lipoma	5	0.1	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Lobular breast carcinoma in situ	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lung adenocarcinoma	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphoproliferative disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Malignant melanoma	3	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Malignant melanoma of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Meningioma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Meningioma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to liver	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Non-Hodgkin's lymphoma recurrent	0	0.0	(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, 0.0)
Oropharyngeal cancer recurrent	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oropharyngeal squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ovarian germ cell teratoma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pancreatic carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Papillary serous endometrial carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Papillary thyroid cancer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Penile neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Penile squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Plasma cell myeloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Polycythaemia vera	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Prostate cancer	5	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Prostate cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Seborrhoeic keratosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin papilloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Squamous cell carcinoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Squamous cell carcinoma of head and neck	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Squamous cell carcinoma of skin	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Teratoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Thyroid cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tonsil cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Transitional cell carcinoma	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Uterine cancer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Uterine leiomyoma	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	1602	19.2	(18.3, 20.2)	635	7.7	(7.1, 8.4)
Ageusia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Amnesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Amyotrophic lateral sclerosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Aphasia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Balance disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Burning sensation	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Carpal tunnel syndrome	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Cerebellar infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebral atrophy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebral capillary telangiectasia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebral infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebrovascular accident	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cervical radiculopathy	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Cervicogenic headache	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dementia Alzheimer's type	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Depressed level of consciousness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diabetic neuropathy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Disturbance in attention	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dizziness	81	1.0	(0.8, 1.2)	64	0.8	(0.6, 1.0)
Dizziness postural	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug withdrawal headache	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dysgeusia	12	0.1	(0.1, 0.3)	8	0.1	(0.0, 0.2)
Dyskinesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dystonia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Facial paralysis	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial paresis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Generalised tonic-clonic seizure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Guillain-Barre syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haemorrhagic stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Head discomfort	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Headache	1348	16.2	(15.3, 17.0)	429	5.2	(4.7, 5.7)
Hemiparaesthesia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hemiplegic migraine	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hyperaesthesia	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypersomnia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoaesthesia	5	0.1	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Hypogeusia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hyposmia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Idiopathic intracranial hypertension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intraventricular haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ischaemic stroke	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lethargy	25	0.3	(0.2, 0.4)	6	0.1	(0.0, 0.2)
Mental impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Migraine	26	0.3	(0.2, 0.5)	13	0.2	(0.1, 0.3)
Migraine with aura	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Migraine without aura	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Morton's neuralgia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Motor dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Muscle spasticity	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Myoclonus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nerve compression	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Neuralgia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neuritis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Neuropathy peripheral	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Nystagmus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Paraesthesia	23	0.3	(0.2, 0.4)	24	0.3	(0.2, 0.4)
Paraparesis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Parkinsonism	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Parosmia	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Periodic limb movement disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peripheral nerve lesion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peripheral sensory neuropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Piriformis syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post herpetic neuralgia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Presyncope	8	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Radiculopathy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Restless legs syndrome	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sciatic nerve neuropathy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Sciatica	13	0.2	(0.1, 0.3)	11	0.1	(0.1, 0.2)
Seizure	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Sinus headache	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Somnolence	9	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Spinal cord compression	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subarachnoid haemorrhage	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Syncope	14	0.2	(0.1, 0.3)	13	0.2	(0.1, 0.3)
Taste disorder	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tension headache	11	0.1	(0.1, 0.2)	9	0.1	(0.1, 0.2)
Thoracic radiculopathy	0	0.0	(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, 0.0)
Transient global amnesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Transient ischaemic attack	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Tremor	9	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Trigeminal neuralgia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
VIth nerve paralysis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Abortion incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abortion spontaneous	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Retained products of conception	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
PRODUCT ISSUES	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Device breakage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Device connection issue	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	112	1.3	(1.1, 1.6)	108	1.3	(1.1, 1.6)
Abnormal dreams	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adjustment disorder with depressed mood	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Alcohol abuse	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Alcohol withdrawal syndrome	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Anxiety	27	0.3	(0.2, 0.5)	31	0.4	(0.3, 0.5)
Anxiety disorder	4	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Attention deficit hyperactivity disorder	5	0.1	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Bipolar disorder	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Bruxism	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Confusional state	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cyclothymic disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Depressed mood	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Depression	23	0.3	(0.2, 0.4)	26	0.3	(0.2, 0.5)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Depression suicidal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Disorientation	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dysphemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastrointestinal somatic symptom disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Generalised anxiety disorder	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Insomnia	25	0.3	(0.2, 0.4)	13	0.2	(0.1, 0.3)
Irritability	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Libido decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Libido increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Listless	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Major depression	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mental disorder	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Mental fatigue	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mental status changes	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Mood swings	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nightmare	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Panic attack	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Panic disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Panic reaction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Paranoia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post-traumatic stress disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Restlessness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Schizophrenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sleep disorder	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Stress	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Substance abuse	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Suicidal ideation	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Suicide attempt	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	52	0.6	(0.5, 0.8)	48	0.6	(0.4, 0.8)
Acute kidney injury	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Bladder spasm	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chronic kidney disease	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Costovertebral angle tenderness	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dysuria	8	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Haematuria	5	0.1	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Hydronephrosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypertonic bladder	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Micturition urgency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Nephrolithiasis	14	0.2	(0.1, 0.3)	15	0.2	(0.1, 0.3)
Nocturia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Obstructive nephropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oedematous kidney	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Perinephric oedema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pollakiuria	5	0.1	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Polyuria	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Renal atrophy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Renal colic	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Renal cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Renal cyst haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Renal failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subcapsular renal haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ureterolithiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urethral discharge	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Urethral stenosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urinary bladder polyp	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Urinary retention	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Urinary tract obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urine odour abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vesical fistula	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	50	0.6	(0.4, 0.8)	58	0.7	(0.5, 0.9)
Adenomyosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Adnexal torsion	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Amenorrhoea	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Benign prostatic hyperplasia	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Breast calcifications	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Breast cyst	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Breast hyperplasia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Breast mass	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Breast pain	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cervical dysplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cervical polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dysfunctional uterine bleeding	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dysmenorrhoea	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Ejaculation disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Endometriosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Erectile dysfunction	1	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Genital erythema	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haematospermia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haemorrhagic ovarian cyst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mammary duct ectasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Menometrorrhagia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Menorrhagia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Menstruation delayed	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Menstruation irregular	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metrorrhagia	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Nipple pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ovarian cyst	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ovarian mass	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pelvic pain	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Penile vein thrombosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Polycystic ovaries	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Postmenopausal haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Premenstrual syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Prostatitis	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Prostatomegaly	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pruritus genital	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectocele	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Scrotal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Testicular pain	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Testicular torsion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Uterine haemorrhage	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Uterine inflammation	0	0.0	(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, 0.0)
Vaginal discharge	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vaginal haemorrhage	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Vaginal prolapse	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vulvovaginal pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	224	2.7	(2.3, 3.1)	195	2.4	(2.1, 2.7)
Acute respiratory failure	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Allergic respiratory disease	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Allergic sinusitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Asthma	15	0.2	(0.1, 0.3)	9	0.1	(0.1, 0.2)
Asthma exercise induced	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Asthmatic crisis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atelectasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bronchospasm	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	6	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cough	23	0.3	(0.2, 0.4)	15	0.2	(0.1, 0.3)
Dry throat	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dysphonia	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Dyspnoea	6	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Dyspnoea exertional	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Emphysema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Epistaxis	6	0.1	(0.0, 0.2)	9	0.1	(0.1, 0.2)
Haemoptysis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hiccups	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypoxia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Interstitial lung disease	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lung infiltration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nasal congestion	30	0.4	(0.2, 0.5)	33	0.4	(0.3, 0.6)
Nasal discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Nasal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Nasal polyps	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal septum deviation	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal turbinate hypertrophy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nasal valve collapse	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nasopharyngeal polyp	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oropharyngeal discomfort	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Oropharyngeal pain	36	0.4	(0.3, 0.6)	31	0.4	(0.3, 0.5)
Paranasal sinus discomfort	4	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Paranasal sinus hypersecretion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pharyngeal lesion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pharyngeal swelling	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Pleurisy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pleuritic pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pneumonia aspiration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pneumothorax	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Productive cough	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pulmonary embolism	8	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Pulmonary hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pulmonary mass	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pulmonary oedema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pulmonary pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Reflux laryngitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Respiratory failure	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory tract congestion	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Rhinalgia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rhinitis allergic	13	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.3)
Rhinitis perennial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rhinorrhoea	21	0.3	(0.2, 0.4)	13	0.2	(0.1, 0.3)
Sinus congestion	6	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Sinus disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Sleep apnoea syndrome	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Sneezing	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Snoring	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sputum discoloured	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Throat irritation	7	0.1	(0.0, 0.2)	9	0.1	(0.1, 0.2)
Tonsillar hypertrophy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Upper respiratory tract congestion	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper-airway cough syndrome	8	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Wheezing	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	254	3.0	(2.7, 3.4)	194	2.4	(2.0, 2.7)
Acne	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Acne cystic	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Actinic keratosis	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Alopecia	5	0.1	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Alopecia areata	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angioedema	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blister	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Cold sweat	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dermal cyst	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis	5	0.1	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Dermatitis acneiform	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dermatitis allergic	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Dermatitis atopic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dermatitis bullous	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dermatitis contact	14	0.2	(0.1, 0.3)	21	0.3	(0.2, 0.4)
Dermatitis exfoliative	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Diabetic foot	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug eruption	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Dry skin	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dyshidrotic eczema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ecchymosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Eczema	7	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Erythema	9	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Erythema nodosum	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fixed eruption	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hand dermatitis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hangnail	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hidradenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperhidrosis	31	0.4	(0.3, 0.5)	9	0.1	(0.1, 0.2)
Ingrowing nail	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Intertrigo	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lipodystrophy acquired	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Livedo reticularis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Macule	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mechanical urticaria	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Night sweats	17	0.2	(0.1, 0.3)	3	0.0	(0.0, 0.1)
Onycholysis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Onychomadesis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pain of skin	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peau d'orange	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Perioral dermatitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pityriasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pityriasis rosea	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Pruritus	24	0.3	(0.2, 0.4)	20	0.2	(0.1, 0.4)
Pruritus allergic	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Pseudofolliculitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Psoriasis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Purpura	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Rash	62	0.7	(0.6, 1.0)	52	0.6	(0.5, 0.8)
Rash erythematous	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Rash maculo-papular	7	0.1	(0.0, 0.2)	4	0.0	(0.0, 0.1)
Rash papular	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rash pruritic	8	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Rosacea	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Seborrhoeic dermatitis	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Skin discolouration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin induration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Skin irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin lesion	3	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Skin mass	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Stasis dermatitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Transient acantholytic dermatosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urticaria	18	0.2	(0.1, 0.3)	15	0.2	(0.1, 0.3)
Urticaria contact	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Urticaria papular	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
High risk sexual behaviour	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Menopause	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Miscarriage of partner	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	33	0.4	(0.3, 0.6)	26	0.3	(0.2, 0.5)
Abortion induced	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Apicectomy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Botulinum toxin injection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac pacemaker replacement	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardioversion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Carpal tunnel decompression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cataract operation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Chondroplasty	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dental care	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Dental implantation	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Drug titration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Endodontic procedure	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facet joint block	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Finger amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gingival operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Inguinal hernia repair	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lacrimal duct procedure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lens extraction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mammoplasty	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Medical device implantation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nasal polypectomy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Open reduction of fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Postoperative care	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Retinal operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Rhinoplasty	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rotator cuff repair	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sclerotherapy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin neoplasm excision	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Toe amputation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Toe operation	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Tonsillectomy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tooth extraction	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Vasectomy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Wisdom teeth removal	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Wound drainage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
VASCULAR DISORDERS	112	1.3	(1.1, 1.6)	118	1.4	(1.2, 1.7)
Accelerated hypertension	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Aortic aneurysm	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Aortic dilatation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Aortic rupture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Aortic stenosis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Arteriosclerosis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blood pressure inadequately controlled	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Deep vein thrombosis	7	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Diastolic hypertension	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Essential hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Flushing	11	0.1	(0.1, 0.2)	2	0.0	(0.0, 0.1)
Haematoma	4	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Hot flush	7	0.1	(0.0, 0.2)	9	0.1	(0.1, 0.2)
Hypertension	61	0.7	(0.6, 0.9)	68	0.8	(0.6, 1.0)
Hypertensive crisis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertensive emergency	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypertensive urgency	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypotension	6	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Intermittent claudication	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphoedema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lymphorrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Orthostatic hypotension	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Pallor	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.119. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Peripheral arterial occlusive disease	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Peripheral artery stenosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Phlebitis superficial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Phlebolith	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Raynaud's phenomenon	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subgaleal haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Systolic hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Thrombophlebitis superficial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Varicose vein	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Venous thrombosis limb	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_all_exp_p3_saf

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	4396	88.4	(85.8, 91.0)	2136	43.5	(41.7, 45.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	84	1.7	(1.3, 2.1)	15	0.3	(0.2, 0.5)
Anaemia	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Blood loss anaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Iron deficiency anaemia	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Leukocytosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Leukopenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymph node pain	6	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Lymphadenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphadenopathy	69	1.4	(1.1, 1.8)	5	0.1	(0.0, 0.2)
Lymphadenopathy mediastinal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Microcytic anaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neutropenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Thrombocytosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
CARDIAC DISORDERS	30	0.6	(0.4, 0.9)	31	0.6	(0.4, 0.9)
Acute coronary syndrome	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Acute left ventricular failure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Acute myocardial infarction	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angina pectoris	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Angina unstable	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arrhythmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arrhythmia supraventricular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arteriospasm coronary	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrial fibrillation	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Atrial flutter	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrioventricular block first degree	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bradycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bundle branch block right	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiac disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiac failure congestive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coronary artery disease	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Junctional ectopic tachycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Left atrial enlargement	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Left ventricular hypertrophy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mitral valve incompetence	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Mitral valve prolapse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myocardial infarction	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Myocardial ischaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Myocarditis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Palpitations	3	0.1	(0.0, 0.2)	13	0.3	(0.1, 0.5)
Postural orthostatic tachycardia syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinus tachycardia	1	0.0	(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, 0.1)
Tachycardia	10	0.2	(0.1, 0.4)	4	0.1	(0.0, 0.2)
Tricuspid valve incompetence	0	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	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Arnold-Chiari malformation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Congenital cystic kidney disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Congenital ureteropelvic junction obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Developmental hip dysplasia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Protein S deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	41	0.8	(0.6, 1.1)	29	0.6	(0.4, 0.8)
Allergic otitis media	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerumen impaction	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Deafness unilateral	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear discomfort	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ear disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear pain	9	0.2	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Eustachian tube dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperacusis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypoacusis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meniere's disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Otorrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sudden hearing loss	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Tinnitus	4	0.1	(0.0, 0.2)	8	0.2	(0.1, 0.3)
Tympanic membrane perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vertigo	14	0.3	(0.2, 0.5)	15	0.3	(0.2, 0.5)
Vertigo positional	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
ENDOCRINE DISORDERS	8	0.2	(0.1, 0.3)	6	0.1	(0.0, 0.3)
Autoimmune thyroiditis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyperprolactinaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypogonadism	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypothyroidism	5	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Thyroid cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thyroid mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EYE DISORDERS	39	0.8	(0.6, 1.1)	28	0.6	(0.4, 0.8)
Amaurosis fugax	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angle closure glaucoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthenopia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Astigmatism	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blepharitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blepharospasm	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chalazion	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Choroidal neovascularisation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Conjunctival haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Conjunctival oedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Conjunctivitis allergic	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Corneal irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diplopia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dry eye	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Episcleritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eye allergy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye irritation	5	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Eye pain	5	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Eye pruritus	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eyelid oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eyelid pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Eyelids pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glaucoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypermetropia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Keratitis	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Lacrimation increased	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ocular hyperaemia	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Photophobia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal tear	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Scleral discolouration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Swelling of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ulcerative keratitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uveitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vision blurred	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Visual impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vitreous detachment	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vitreous floaters	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	471	9.5	(8.6, 10.4)	307	6.3	(5.6, 7.0)
Abdominal discomfort	5	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Abdominal distension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abdominal hernia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abdominal pain	13	0.3	(0.1, 0.4)	16	0.3	(0.2, 0.5)
Abdominal pain lower	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abdominal pain upper	19	0.4	(0.2, 0.6)	8	0.2	(0.1, 0.3)
Acute abdomen	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angular cheilitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Aphthous ulcer	6	0.1	(0.0, 0.3)	2	0.0	(0.0, 0.1)
Appendix disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cheilitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coeliac disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colitis ulcerative	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Constipation	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Crohn's disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dental caries	7	0.1	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Diarrhoea	163	3.3	(2.8, 3.8)	117	2.4	(2.0, 2.9)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Diverticular perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulum	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulum intestinal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulum intestinal haemorrhagic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dry mouth	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Dyspepsia	9	0.2	(0.1, 0.3)	10	0.2	(0.1, 0.4)
Dysphagia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Eructation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Faeces soft	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Flatulence	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Food poisoning	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastric ulcer haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastritis	3	0.1	(0.0, 0.2)	10	0.2	(0.1, 0.4)
Gastritis erosive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastrointestinal disorder	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastrointestinal sounds abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrooesophageal reflux disease	8	0.2	(0.1, 0.3)	15	0.3	(0.2, 0.5)
Gingival bleeding	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gingival discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gingival pain	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gingival swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haematemesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haematochezia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haemorrhoids	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Hiatus hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypoaesthesia oral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoaesthesia teeth	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ileus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Impaired gastric emptying	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Incarcerated inguinal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Inguinal hernia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Internal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intestinal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intestinal perforation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intra-abdominal fluid collection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Irritable bowel syndrome	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Large intestine polyp	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lip oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lip swelling	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Loose tooth	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mouth ulceration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nausea	186	3.7	(3.2, 4.3)	61	1.2	(1.0, 1.6)
Noninfective gingivitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Obstructive pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Odynophagia	9	0.2	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Oesophageal food impaction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oesophageal varices haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oesophagitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral lichenoid reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oral mucosa haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Palatal disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatic failure	0	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, 0.1)
Pancreatitis acute	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Paraesthesia oral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peptic ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Proctalgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectal haemorrhage	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectal polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Retching	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Salivary gland calculus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Salivary gland mucocoele	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Small intestinal obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Stomatitis	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Swollen tongue	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Teething	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tongue discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tooth impacted	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Toothache	16	0.3	(0.2, 0.5)	17	0.3	(0.2, 0.6)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Umbilical hernia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vomiting	56	1.1	(0.9, 1.5)	23	0.5	(0.3, 0.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3167	63.7	(61.5, 65.9)	693	14.1	(13.1, 15.2)
Adverse drug reaction	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Application site erythema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Application site pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Application site rash	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Application site reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthenia	46	0.9	(0.7, 1.2)	18	0.4	(0.2, 0.6)
Axillary pain	9	0.2	(0.1, 0.3)	2	0.0	(0.0, 0.1)
Capsular contracture associated with breast implant	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chest discomfort	4	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Chest pain	10	0.2	(0.1, 0.4)	15	0.3	(0.2, 0.5)
Chills	968	19.5	(18.3, 20.7)	77	1.6	(1.2, 2.0)
Chronic fatigue syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Effusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Exercise tolerance decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fatigue	1013	20.4	(19.1, 21.7)	270	5.5	(4.9, 6.2)
Feeling abnormal	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Feeling cold	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Feeling hot	6	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.1)
Illness	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Inflammation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Influenza like illness	16	0.3	(0.2, 0.5)	3	0.1	(0.0, 0.2)
Injection site bruising	8	0.2	(0.1, 0.3)	11	0.2	(0.1, 0.4)
Injection site dermatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site discolouration	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site discomfort	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site erythema	119	2.4	(2.0, 2.9)	19	0.4	(0.2, 0.6)
Injection site haematoma	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Injection site haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site hyperaesthesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site induration	5	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Injection site injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site macule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site mass	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site nodule	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site oedema	10	0.2	(0.1, 0.4)	0	0.0	(0.0, 0.1)
Injection site pain	1930	38.8	(37.1, 40.6)	286	5.8	(5.2, 6.5)
Injection site papule	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site paraesthesia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site pruritus	23	0.5	(0.3, 0.7)	5	0.1	(0.0, 0.2)
Injection site rash	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site reaction	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Injection site swelling	86	1.7	(1.4, 2.1)	12	0.2	(0.1, 0.4)
Injection site warmth	8	0.2	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Injury associated with device	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Malaise	86	1.7	(1.4, 2.1)	11	0.2	(0.1, 0.4)
Medical device pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Medical device site granuloma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mucosal disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nodule	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Non-cardiac chest pain	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Oedema peripheral	3	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Pain	430	8.6	(7.8, 9.5)	41	0.8	(0.6, 1.1)
Peripheral swelling	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Pyrexia	1118	22.5	(21.2, 23.8)	55	1.1	(0.8, 1.5)
Sensation of foreign body	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Shoulder injury related to vaccine administration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Swelling face	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Thirst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaccination site induration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vaccination site pain	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Vascular stent occlusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vessel puncture site bruise	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vessel puncture site haematoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vessel puncture site induration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	9	0.2	(0.1, 0.3)	9	0.2	(0.1, 0.3)
Bile duct stone	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary colic	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cholecystitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Cholecystitis acute	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cholecystitis chronic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholelithiasis	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Hepatic steatosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatocellular injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	20	0.4	(0.2, 0.6)	20	0.4	(0.2, 0.6)
Allergy to arthropod bite	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Allergy to arthropod sting	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Drug hypersensitivity	7	0.1	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Food allergy	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Hypersensitivity	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Jarisch-Herxheimer reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Milk allergy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Seasonal allergy	7	0.1	(0.1, 0.3)	8	0.2	(0.1, 0.3)
INFECTIONS AND INFESTATIONS	230	4.6	(4.0, 5.3)	290	5.9	(5.2, 6.6)
Abdominal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess jaw	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess limb	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abscess neck	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abscess oral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Acarodermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Acute sinusitis	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Anal abscess	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anal fistula infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Appendicitis	12	0.2	(0.1, 0.4)	7	0.1	(0.1, 0.3)
Arthritis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bacterial blepharitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bacterial rhinitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bacterial vaginosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bacterial vulvovaginitis	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Bartholin's abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bartholinitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blister infected	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Carbuncle	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cellulitis	10	0.2	(0.1, 0.4)	9	0.2	(0.1, 0.3)
Chlamydial infection	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Chronic sinusitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Clostridium difficile infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Conjunctivitis	6	0.1	(0.0, 0.3)	6	0.1	(0.0, 0.3)
Conjunctivitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coxsackie viral infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cystitis	3	0.1	(0.0, 0.2)	9	0.2	(0.1, 0.3)
Dermatitis infected	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diabetic foot infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulitis	3	0.1	(0.0, 0.2)	8	0.2	(0.1, 0.3)
Ear infection	7	0.1	(0.1, 0.3)	13	0.3	(0.1, 0.5)
Escherichia urinary tract infection	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Folliculitis	6	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Fungal infection	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Fungal skin infection	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Furuncle	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Gangrene	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastroenteritis	3	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Gastroenteritis viral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Genital herpes	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Genital herpes simplex	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Genitourinary chlamydia infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Gingival abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gingivitis	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Gonorrhoea	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Groin abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Helicobacter gastritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Helicobacter infection	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Hepatitis A	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Herpes simplex	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Herpes zoster	9	0.2	(0.1, 0.3)	7	0.1	(0.1, 0.3)
Herpes zoster cutaneous disseminated	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Herpes zoster oticus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hordeolum	3	0.1	(0.0, 0.2)	7	0.1	(0.1, 0.3)
Impetigo	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Infected bite	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Infected dermal cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Infectious mononucleosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Influenza	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Kidney infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Labyrinthitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Localised infection	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Lyme disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mastitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meningitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nail infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasopharyngitis	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Onychomycosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ophthalmic herpes zoster	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral candidiasis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral fungal infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral herpes	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Oral infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Orchitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Otitis externa	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Otitis media	7	0.1	(0.1, 0.3)	6	0.1	(0.0, 0.3)
Otitis media acute	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Papilloma viral infection	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Parasitic gastroenteritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paronychia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pelvic inflammatory disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Periodontitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peritonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pharyngitis	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Pharyngitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pharyngitis streptococcal	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Pharyngotonsillitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pilonidal cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Postoperative wound infection	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pulmonary tuberculosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Puncture site infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pustule	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pyelonephritis	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Rash pustular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Renal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rhinitis	6	0.1	(0.0, 0.3)	8	0.2	(0.1, 0.3)
Sepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sialoadenitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinusitis	10	0.2	(0.1, 0.4)	17	0.3	(0.2, 0.6)
Sinusitis bacterial	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin infection	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Soft tissue infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Staphylococcal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Subcutaneous abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Syphilis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tinea cruris	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tinea infection	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Tinea versicolour	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Tonsillitis	0	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.3)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Tonsillitis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tooth abscess	6	0.1	(0.0, 0.3)	2	0.0	(0.0, 0.1)
Tooth infection	9	0.2	(0.1, 0.3)	21	0.4	(0.3, 0.7)
Trichomoniasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Upper respiratory tract infection	7	0.1	(0.1, 0.3)	7	0.1	(0.1, 0.3)
Ureaplasma infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urinary tract infection	36	0.7	(0.5, 1.0)	39	0.8	(0.6, 1.1)
Urosepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaginal infection	0	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.3)
Varicella	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Viral infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Viral upper respiratory tract infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vulval abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vulvovaginal candidiasis	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Vulvovaginal mycotic infection	5	0.1	(0.0, 0.2)	8	0.2	(0.1, 0.3)
Wound infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	163	3.3	(2.8, 3.8)	202	4.1	(3.6, 4.7)
Administration related reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Animal bite	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Ankle fracture	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Arthropod bite	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Arthropod sting	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Back injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bone contusion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bone fissure	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Burns second degree	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cervical vertebral fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chest injury	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Chillblains	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clavicle fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colon injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Concussion	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Contusion	10	0.2	(0.1, 0.4)	12	0.2	(0.1, 0.4)
Corneal abrasion	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Craniocerebral injury	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Ear injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Epicondylitis	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Exposure during pregnancy	30	0.6	(0.4, 0.9)	42	0.9	(0.6, 1.2)
Exposure to communicable disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye contusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eyelid injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Facial bones fracture	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Fall	23	0.5	(0.3, 0.7)	20	0.4	(0.2, 0.6)
Fibula fracture	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Flail chest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foot fracture	4	0.1	(0.0, 0.2)	7	0.1	(0.1, 0.3)
Forearm fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foreign body	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Foreign body in eye	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hand fracture	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Head injury	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Heat stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hip fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Humerus fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Joint dislocation	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Joint injury	3	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Ligament injury	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Ligament rupture	1	0.0	(0.0, 0.1)	8	0.2	(0.1, 0.3)
Ligament sprain	10	0.2	(0.1, 0.4)	18	0.4	(0.2, 0.6)
Limb injury	5	0.1	(0.0, 0.2)	9	0.2	(0.1, 0.3)
Limb traumatic amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lip injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lower limb fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lumbar vertebral fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Maternal exposure before pregnancy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Maternal exposure during breast feeding	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Maternal exposure during pregnancy	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Meniscus injury	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Multiple injuries	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle rupture	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscle strain	8	0.2	(0.1, 0.3)	8	0.2	(0.1, 0.3)
Overdose	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Penis injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post procedural discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post procedural haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Post procedural swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Postoperative ileus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Procedural dizziness	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Procedural haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Procedural pain	6	0.1	(0.0, 0.3)	2	0.0	(0.0, 0.1)
Radius fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rib fracture	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Road traffic accident	11	0.2	(0.1, 0.4)	13	0.3	(0.1, 0.5)
Scar	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin abrasion	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Skin injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin laceration	11	0.2	(0.1, 0.4)	9	0.2	(0.1, 0.3)
Skull fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Soft tissue injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal compression fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Spinal cord injury cervical	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Stab wound	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Stress fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tendon injury	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Tendon rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thermal burn	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Tibia fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tooth fracture	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Toxicity to various agents	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ulna fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper limb fracture	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Vaccination complication	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Vulvovaginal injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Wound	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Wrist fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
INVESTIGATIONS	110	2.2	(1.8, 2.7)	27	0.5	(0.4, 0.8)
Alanine aminotransferase increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Aspartate aminotransferase increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biopsy breast normal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood cholesterol increased	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Blood creatinine decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood creatinine increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood glucose abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood glucose increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood immunoglobulin E increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood iron decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood potassium decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood pressure diastolic increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood pressure increased	3	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Blood testosterone decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood thyroid stimulating hormone increased	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Body temperature	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Body temperature increased	81	1.6	(1.3, 2.0)	10	0.2	(0.1, 0.4)
C-reactive protein	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Electrocardiogram QT prolonged	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Heart rate increased	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Heart rate irregular	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Herpes simplex test positive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Low density lipoprotein increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mammogram abnormal	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Red blood cell morphology abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SARS-CoV-2 antibody test positive	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Serum ferritin decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Weight decreased	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Weight increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	73	1.5	(1.2, 1.8)	63	1.3	(1.0, 1.6)
Decreased appetite	26	0.5	(0.3, 0.8)	6	0.1	(0.0, 0.3)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dehydration	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Diabetes mellitus	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diabetic ketoacidosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dyslipidaemia	5	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Folate deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Food intolerance	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glucose tolerance impaired	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Gout	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypercholesterolaemia	5	0.1	(0.0, 0.2)	12	0.2	(0.1, 0.4)
Hyperglycaemia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hyperlipidaemia	4	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Hypertriglyceridaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperuricaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypocalcaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypocholesterolaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoglycaemia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypokalaemia	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Impaired fasting glucose	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Insulin resistance	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Iron deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Obesity	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Polydipsia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Type 2 diabetes mellitus	8	0.2	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Vitamin B12 deficiency	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vitamin D deficiency	5	0.1	(0.0, 0.2)	9	0.2	(0.1, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1226	24.6	(23.3, 26.1)	346	7.0	(6.3, 7.8)
Arthralgia	182	3.7	(3.1, 4.2)	62	1.3	(1.0, 1.6)
Arthritis	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Arthropathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Axillary mass	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Back pain	61	1.2	(0.9, 1.6)	65	1.3	(1.0, 1.7)
Bone pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bone swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Bursitis	5	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Coccydynia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Costochondritis	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Exostosis	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Fibromyalgia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Flank pain	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Groin pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc degeneration	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Intervertebral disc disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	5	0.1	(0.0, 0.2)	8	0.2	(0.1, 0.3)
Joint effusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Joint range of motion decreased	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Joint stiffness	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Joint swelling	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Limb discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Metatarsalgia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscle contracture	4	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Muscle discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle fatigue	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Muscle spasms	14	0.3	(0.2, 0.5)	6	0.1	(0.0, 0.3)
Muscle tightness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Muscle twitching	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscular weakness	6	0.1	(0.0, 0.3)	2	0.0	(0.0, 0.1)
Musculoskeletal chest pain	9	0.2	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Musculoskeletal discomfort	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Musculoskeletal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Musculoskeletal stiffness	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Myalgia	873	17.5	(16.4, 18.8)	104	2.1	(1.7, 2.6)
Myalgia intercostal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neck pain	23	0.5	(0.3, 0.7)	24	0.5	(0.3, 0.7)
Osteitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteoarthritis	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Osteochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Osteochondrosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteoporosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pain in extremity	101	2.0	(1.7, 2.5)	27	0.5	(0.4, 0.8)
Pain in jaw	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Patellofemoral pain syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Periarthritis	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Plantar fasciitis	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.3)
Psoriatic arthropathy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rhabdomyolysis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rheumatoid arthritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rotator cuff syndrome	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Scoliosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Spinal disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal osteoarthritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal stenosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Spondylitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spondylolisthesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Synovial cyst	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Synovitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Systemic lupus erythematosus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Temporomandibular joint syndrome	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Tendon disorder	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Tendon pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tendonitis	7	0.1	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Tenosynovitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tenosynovitis stenosans	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Torticollis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Trigger finger	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	22	0.4	(0.3, 0.7)	23	0.5	(0.3, 0.7)
Acrochordon	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
B-cell lymphoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Benign breast neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Benign hydatidiform mole	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Benign pancreatic neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Benign uterine neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Breast cancer	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Chondroma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colon adenoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Fibroadenoma of breast	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Haemangioma of skin	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Invasive ductal breast carcinoma	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Leydig cell tumour of the testis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lipoma	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Malignant melanoma	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meningioma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ovarian germ cell teratoma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Papillary thyroid cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Plasma cell myeloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Teratoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Transitional cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Uterine leiomyoma	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	1085	21.8	(20.5, 23.1)	407	8.3	(7.5, 9.1)
Ageusia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Amnesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aphasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Burning sensation	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Carpal tunnel syndrome	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebral capillary telangiectasia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebrovascular accident	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cervical radiculopathy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depressed level of consciousness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Disturbance in attention	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dizziness	46	0.9	(0.7, 1.2)	34	0.7	(0.5, 1.0)
Dysgeusia	9	0.2	(0.1, 0.3)	3	0.1	(0.0, 0.2)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dystonia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial paralysis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Generalised tonic-clonic seizure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Guillain-Barre syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Head discomfort	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Headache	934	18.8	(17.6, 20.0)	293	6.0	(5.3, 6.7)
Hemiparaesthesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hemiplegic migraine	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyperaesthesia	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypersomnia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoaesthesia	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Hypogeusia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyposmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Idiopathic intracranial hypertension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ischaemic stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lethargy	7	0.1	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Mental impairment	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Migraine	23	0.5	(0.3, 0.7)	11	0.2	(0.1, 0.4)
Migraine with aura	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Migraine without aura	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Motor dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nerve compression	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Neuritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neuropathy peripheral	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paraesthesia	18	0.4	(0.2, 0.6)	15	0.3	(0.2, 0.5)
Paraparesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Parosmia	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Peripheral nerve lesion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peripheral sensory neuropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Presyncope	6	0.1	(0.0, 0.3)	5	0.1	(0.0, 0.2)
Radiculopathy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Restless legs syndrome	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Sciatic nerve neuropathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sciatica	9	0.2	(0.1, 0.3)	9	0.2	(0.1, 0.3)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Seizure	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinus headache	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Somnolence	5	0.1	(0.0, 0.2)	11	0.2	(0.1, 0.4)
Subarachnoid haemorrhage	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Syncope	10	0.2	(0.1, 0.4)	5	0.1	(0.0, 0.2)
Taste disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tension headache	10	0.2	(0.1, 0.4)	7	0.1	(0.1, 0.3)
Transient ischaemic attack	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tremor	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Trigeminal neuralgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.3)
Abortion incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abortion spontaneous	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retained products of conception	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	75	1.5	(1.2, 1.9)	81	1.6	(1.3, 2.1)
Abnormal dreams	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adjustment disorder with depressed mood	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Alcohol abuse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Alcohol withdrawal syndrome	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Anxiety	21	0.4	(0.3, 0.6)	26	0.5	(0.3, 0.8)
Anxiety disorder	3	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Attention deficit hyperactivity disorder	5	0.1	(0.0, 0.2)	8	0.2	(0.1, 0.3)
Bipolar disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bruxism	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Confusional state	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cyclothymic disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depressed mood	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Depression	17	0.3	(0.2, 0.5)	17	0.3	(0.2, 0.6)
Depression suicidal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Disorientation	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastrointestinal somatic symptom disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Generalised anxiety disorder	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Insomnia	17	0.3	(0.2, 0.5)	8	0.2	(0.1, 0.3)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Irritability	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Major depression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mental disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mental fatigue	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Panic attack	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Panic disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Panic reaction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Post-traumatic stress disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Schizophrenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sleep disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Stress	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Substance abuse	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Suicidal ideation	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Suicide attempt	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	20	0.4	(0.2, 0.6)	22	0.4	(0.3, 0.7)
Acute kidney injury	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Chronic kidney disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Costovertebral angle tenderness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dysuria	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Haematuria	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Hydronephrosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nephrolithiasis	9	0.2	(0.1, 0.3)	7	0.1	(0.1, 0.3)
Pollakiuria	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Renal atrophy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Renal colic	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Subcapsular renal haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ureterolithiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urethral discharge	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urinary bladder polyp	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urinary retention	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	35	0.7	(0.5, 1.0)	43	0.9	(0.6, 1.2)
Adenomyosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Adnexal torsion	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Amenorrhoea	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Benign prostatic hyperplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cyst	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Breast hyperplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast mass	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Breast pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cervical dysplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dysfunctional uterine bleeding	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dysmenorrhoea	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Endometriosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Erectile dysfunction	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Genital erythema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haematospermia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haemorrhagic ovarian cyst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mammary duct ectasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Menometrorrhagia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Menorrhagia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Menstruation delayed	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Menstruation irregular	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metrorrhagia	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Nipple pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ovarian cyst	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Pelvic pain	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Penile vein thrombosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Polycystic ovaries	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Postmenopausal haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Premenstrual syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Prostatitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Prostatomegaly	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pruritus genital	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectocele	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Scrotal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Testicular pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Testicular torsion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Uterine haemorrhage	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Uterine inflammation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaginal discharge	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaginal haemorrhage	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vaginal prolapse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	127	2.6	(2.1, 3.0)	133	2.7	(2.3, 3.2)
Allergic respiratory disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Allergic sinusitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthma	8	0.2	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Asthma exercise induced	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Asthmatic crisis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bronchospasm	2	0.0	(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	(0.0, 0.1)
Cough	13	0.3	(0.1, 0.4)	11	0.2	(0.1, 0.4)
Dry throat	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dysphonia	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Dyspnoea	3	0.1	(0.0, 0.2)	7	0.1	(0.1, 0.3)
Dyspnoea exertional	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Epistaxis	1	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.3)
Haemoptysis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoxia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Interstitial lung disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lung infiltration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal congestion	18	0.4	(0.2, 0.6)	29	0.6	(0.4, 0.8)
Nasal discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nasal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nasal polyps	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nasal septum deviation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oropharyngeal discomfort	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Oropharyngeal pain	24	0.5	(0.3, 0.7)	23	0.5	(0.3, 0.7)
Paranasal sinus discomfort	3	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Pharyngeal swelling	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pleuritic pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonia aspiration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Productive cough	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pulmonary embolism	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Pulmonary mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pulmonary pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Reflux laryngitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory tract congestion	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Rhinitis allergic	12	0.2	(0.1, 0.4)	12	0.2	(0.1, 0.4)
Rhinorrhoea	12	0.2	(0.1, 0.4)	8	0.2	(0.1, 0.3)
Sinus congestion	4	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Sleep apnoea syndrome	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Sneezing	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Snoring	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sputum discoloured	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Throat irritation	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Tonsillar hypertrophy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Upper respiratory tract congestion	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper-airway cough syndrome	5	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Wheezing	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	140	2.8	(2.4, 3.3)	107	2.2	(1.8, 2.6)
Acne	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Acne cystic	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Alopecia	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Alopecia areata	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Angioedema	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blister	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cold sweat	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dermal cyst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis acneiform	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dermatitis allergic	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Dermatitis atopic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis bullous	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis contact	7	0.1	(0.1, 0.3)	12	0.2	(0.1, 0.4)
Diabetic foot	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Drug eruption	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ecchymosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eczema	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Erythema	5	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Erythema nodosum	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fixed eruption	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hand dermatitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hangnail	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hidradenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperhidrosis	18	0.4	(0.2, 0.6)	5	0.1	(0.0, 0.2)
Ingrowing nail	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Intertrigo	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Livedo reticularis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Macule	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mechanical urticaria	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Night sweats	9	0.2	(0.1, 0.3)	1	0.0	(0.0, 0.1)
Onycholysis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pain of skin	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peau d'orange	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pityriasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pityriasis rosea	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Pruritus	9	0.2	(0.1, 0.3)	13	0.3	(0.1, 0.5)
Pruritus allergic	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Psoriasis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rash	37	0.7	(0.5, 1.0)	25	0.5	(0.3, 0.8)
Rash erythematous	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Rash maculo-papular	5	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Rash papular	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rash pruritic	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Seborrhoeic dermatitis	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Skin irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin lesion	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Skin ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transient acantholytic dermatosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Urticaria	12	0.2	(0.1, 0.4)	8	0.2	(0.1, 0.3)
Urticaria contact	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
High risk sexual behaviour	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Menopause	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Miscarriage of partner	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	13	0.3	(0.1, 0.4)	18	0.4	(0.2, 0.6)
Abortion induced	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cataract operation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chondroplasty	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dental care	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Dental implantation	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Drug titration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Endodontic procedure	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gingival operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mammoplasty	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Medical device implantation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal polypectomy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rhinoplasty	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sclerotherapy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Toe operation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tonsillectomy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tooth extraction	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vasectomy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Wisdom teeth removal	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
VASCULAR DISORDERS	56	1.1	(0.9, 1.5)	50	1.0	(0.8, 1.3)
Accelerated hypertension	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arteriosclerosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deep vein thrombosis	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Diastolic hypertension	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Essential hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Flushing	6	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)

14.120. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Haematoma	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hot flush	5	0.1	(0.0, 0.2)	8	0.2	(0.1, 0.3)
Hypertension	27	0.5	(0.4, 0.8)	27	0.5	(0.4, 0.8)
Hypertensive urgency	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypotension	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Intermittent claudication	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphoedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peripheral arterial occlusive disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Phlebitis superficial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subgaleal haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Systolic hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Thrombophlebitis superficial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Varicose vein	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Venous thrombosis limb	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_exp_age_p3_saf

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	2551	75.7	(72.8, 78.7)	1432	43.3	(41.1, 45.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	34	1.0	(0.7, 1.4)	17	0.5	(0.3, 0.8)
Anaemia	4	0.1	(0.0, 0.3)	6	0.2	(0.1, 0.4)
Blood loss anaemia	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Coagulopathy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypochromic anaemia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Iron deficiency anaemia	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Leukopenia	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lymph node pain	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Lymphadenopathy	18	0.5	(0.3, 0.8)	3	0.1	(0.0, 0.3)
Lymphadenopathy mediastinal	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lymphocytosis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lymphopenia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Monoclonal B-cell lymphocytosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Neutropenia	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Splenomegaly	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Thrombocytopenia	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Thrombocytosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
CARDIAC DISORDERS	57	1.7	(1.3, 2.2)	47	1.4	(1.0, 1.9)
Acute coronary syndrome	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Acute myocardial infarction	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Angina pectoris	4	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Angina unstable	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Aortic valve incompetence	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Arrhythmia	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Arteriosclerosis coronary artery	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Atrial fibrillation	11	0.3	(0.2, 0.6)	14	0.4	(0.2, 0.7)
Atrial flutter	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Atrioventricular block complete	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Bradycardia	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Bundle branch block left	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cardiac arrest	6	0.2	(0.1, 0.4)	2	0.1	(0.0, 0.2)
Cardiac failure acute	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Cardiac failure congestive	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Cardiomegaly	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cardiovascular disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Coronary artery disease	5	0.1	(0.0, 0.3)	5	0.2	(0.0, 0.4)
Coronary artery dissection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Coronary artery occlusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Hypertensive heart disease	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Left ventricular dysfunction	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Left ventricular hypertrophy	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Mitral valve incompetence	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Mitral valve prolapse	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Myocardial infarction	4	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Myocardial ischaemia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Palpitations	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Pericardial effusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pericarditis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Sinus bradycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Supraventricular tachycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Tachyarrhythmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Tachycardia	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Tricuspid valve incompetence	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ventricular arrhythmia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ventricular extrasystoles	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ventricular tachycardia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Congenital bladder neck obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Gastrointestinal arteriovenous malformation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Heart disease congenital	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Type V hyperlipidaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
EAR AND LABYRINTH DISORDERS	35	1.0	(0.7, 1.4)	32	1.0	(0.7, 1.4)
Cerumen impaction	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Deafness	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Deafness neurosensory	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Deafness unilateral	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Ear discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Ear disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Ear pain	4	0.1	(0.0, 0.3)	7	0.2	(0.1, 0.4)
Ear pruritus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Eustachian tube dysfunction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Hypoacusis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Meniere's disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Tinnitus	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Vertigo	17	0.5	(0.3, 0.8)	11	0.3	(0.2, 0.6)
Vertigo positional	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
ENDOCRINE DISORDERS	9	0.3	(0.1, 0.5)	5	0.2	(0.0, 0.4)
Goitre	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hyperthyroidism	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypogonadism	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypothyroidism	3	0.1	(0.0, 0.3)	5	0.2	(0.0, 0.4)
Oestrogen deficiency	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Thyroid mass	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
EYE DISORDERS	31	0.9	(0.6, 1.3)	37	1.1	(0.8, 1.5)
Blepharitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Blepharospasm	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cataract	7	0.2	(0.1, 0.4)	8	0.2	(0.1, 0.5)
Chalazion	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Conjunctival haemorrhage	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.3)
Conjunctival hyperaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Conjunctivitis allergic	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dacryostenosis acquired	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Diabetic retinopathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Diplopia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dry age-related macular degeneration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Dry eye	0	0.0	(0.0, 0.1)	5	0.2	(0.0, 0.4)
Eye haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Eye inflammation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Eye irritation	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Eye pain	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Eye swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Eyelid haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Glaucoma	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Iritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Keratitis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Lacrimation increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Macular oedema	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ocular discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Ocular hyperaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Retinal artery occlusion	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Retinal detachment	2	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Vision blurred	4	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Visual acuity reduced	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Vitreous detachment	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Vitreous floaters	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	277	8.2	(7.3, 9.2)	204	6.2	(5.4, 7.1)
Abdominal adhesions	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Abdominal discomfort	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Abdominal distension	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Abdominal hernia	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Abdominal pain	10	0.3	(0.1, 0.5)	6	0.2	(0.1, 0.4)
Abdominal pain lower	3	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Abdominal pain upper	8	0.2	(0.1, 0.5)	7	0.2	(0.1, 0.4)
Abdominal rigidity	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Abnormal faeces	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Anal pruritus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Aphthous ulcer	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Cheilitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Chronic gastritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Coeliac artery aneurysm	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Colitis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Colitis ischaemic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Colitis microscopic	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Colitis ulcerative	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Constipation	5	0.1	(0.0, 0.3)	9	0.3	(0.1, 0.5)
Dental caries	3	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Diarrhoea	92	2.7	(2.2, 3.3)	72	2.2	(1.7, 2.7)
Diverticulum	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Diverticulum intestinal	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Dry mouth	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Duodenal obstruction	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Duodenal ulcer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Dyspepsia	6	0.2	(0.1, 0.4)	4	0.1	(0.0, 0.3)
Dysphagia	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Enterocolitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Epiploic appendagitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Eructation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Faeces soft	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Femoral hernia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Flatulence	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Food poisoning	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Frequent bowel movements	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Gastric antral vascular ectasia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastric polyps	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Gastric ulcer	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Gastritis	2	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Gastrointestinal disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Gastrointestinal haemorrhage	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Gastrointestinal mucosa hyperaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Gastrointestinal pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastrooesophageal reflux disease	7	0.2	(0.1, 0.4)	8	0.2	(0.1, 0.5)
Gingival discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Glossitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Glossodynia	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Haematochezia	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Haemorrhoidal haemorrhage	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Haemorrhoids	3	0.1	(0.0, 0.3)	8	0.2	(0.1, 0.5)
Hiatus hernia	3	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Hypoaesthesia oral	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Impaired gastric emptying	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Inguinal hernia	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Intestinal obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Intestinal polyp	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Intestinal strangulation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Irritable bowel syndrome	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Large intestine perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Large intestine polyp	3	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Lip swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Mouth ulceration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Nausea	91	2.7	(2.2, 3.3)	27	0.8	(0.5, 1.2)
Odynophagia	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Oesophageal spasm	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Oesophageal ulcer	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Oesophagitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Oral discomfort	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Oral pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pancreatic cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pancreatitis	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Pancreatitis acute	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Paraesthesia oral	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Parotid duct obstruction	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Precancerous lesion of digestive tract	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Proctalgia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Retching	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Retroperitoneal haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Salivary gland calculus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Small intestinal obstruction	4	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Stomatitis	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Swollen tongue	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Tongue discolouration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Tongue oedema	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Tongue pruritus	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Tongue ulceration	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Tooth disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Toothache	10	0.3	(0.1, 0.5)	11	0.3	(0.2, 0.6)
Umbilical hernia	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Varices oesophageal	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Volvulus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Vomiting	12	0.4	(0.2, 0.6)	12	0.4	(0.2, 0.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1581	46.9	(44.6, 49.3)	317	9.6	(8.6, 10.7)
Application site pruritus	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Asthenia	31	0.9	(0.6, 1.3)	7	0.2	(0.1, 0.4)
Axillary pain	5	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Chest discomfort	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Chest pain	7	0.2	(0.1, 0.4)	1	0.0	(0.0, 0.2)
Chills	400	11.9	(10.7, 13.1)	44	1.3	(1.0, 1.8)
Cyst	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Discomfort	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Drug withdrawal syndrome	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Face oedema	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Facial pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Fatigue	453	13.4	(12.2, 14.7)	109	3.3	(2.7, 4.0)
Feeling hot	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gait disturbance	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Induration	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Influenza like illness	8	0.2	(0.1, 0.5)	1	0.0	(0.0, 0.2)
Injection site bruising	5	0.1	(0.0, 0.3)	7	0.2	(0.1, 0.4)
Injection site discolouration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Injection site discomfort	4	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Injection site erythema	66	2.0	(1.5, 2.5)	10	0.3	(0.1, 0.6)
Injection site haematoma	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Injection site haemorrhage	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Injection site induration	5	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Injection site irritation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site mass	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Injection site nodule	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site oedema	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site pain	987	29.3	(27.5, 31.2)	113	3.4	(2.8, 4.1)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site paraesthesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Injection site plaque	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Injection site pruritus	15	0.4	(0.2, 0.7)	1	0.0	(0.0, 0.2)
Injection site rash	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Injection site reaction	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site swelling	54	1.6	(1.2, 2.1)	11	0.3	(0.2, 0.6)
Injection site urticaria	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site warmth	6	0.2	(0.1, 0.4)	1	0.0	(0.0, 0.2)
Malaise	44	1.3	(0.9, 1.8)	11	0.3	(0.2, 0.6)
Mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Nodule	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Non-cardiac chest pain	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Oedema peripheral	5	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Pain	198	5.9	(5.1, 6.8)	21	0.6	(0.4, 1.0)
Peripheral swelling	3	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Pyrexia	402	11.9	(10.8, 13.2)	23	0.7	(0.4, 1.0)
Sensation of foreign body	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Sluggishness	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Sudden cardiac death	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Swelling	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Swelling face	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Temperature intolerance	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Therapeutic response unexpected	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Vaccination site swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Vessel puncture site bruise	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	15	0.4	(0.2, 0.7)	7	0.2	(0.1, 0.4)
Biliary colic	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Biliary dyskinesia	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Cholecystitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cholecystitis acute	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Cholelithiasis	9	0.3	(0.1, 0.5)	1	0.0	(0.0, 0.2)
Cirrhosis alcoholic	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gallbladder disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hepatic cirrhosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hepatic cyst	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hepatic steatosis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Nonalcoholic fatty liver disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	3	0.1	(0.0, 0.3)	14	0.4	(0.2, 0.7)
Allergy to animal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Allergy to arthropod bite	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Anaphylactic shock	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Drug hypersensitivity	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Food allergy	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypersensitivity	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Seasonal allergy	1	0.0	(0.0, 0.2)	8	0.2	(0.1, 0.5)
INFECTIONS AND INFESTATIONS	187	5.5	(4.8, 6.4)	209	6.3	(5.5, 7.2)
Abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Abscess intestinal	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Abscess limb	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Acarodermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Acute sinusitis	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Appendicitis	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Appendicitis perforated	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Bacterial infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Bacterial sepsis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Balanitis candida	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Bone abscess	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Brain abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Bronchitis	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
COVID-19	0	0.0	(0.0, 0.1)	8	0.2	(0.1, 0.5)
COVID-19 pneumonia	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Campylobacter infection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Catheter site infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cellulitis	5	0.1	(0.0, 0.3)	11	0.3	(0.2, 0.6)
Cellulitis orbital	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Chronic sinusitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Complicated appendicitis	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Conjunctivitis	6	0.2	(0.1, 0.4)	5	0.2	(0.0, 0.4)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Conjunctivitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cystitis	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Dental fistula	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Device related infection	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Diverticulitis	7	0.2	(0.1, 0.4)	3	0.1	(0.0, 0.3)
Ear infection	4	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Emphysematous cholecystitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Empyema	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Erysipelas	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Escherichia sepsis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Extradural abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Eye infection	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Eye infection bacterial	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Folliculitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Fungal infection	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Fungal skin infection	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.3)
Furuncle	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Gastroenteritis	3	0.1	(0.0, 0.3)	6	0.2	(0.1, 0.4)
Genital herpes	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Gingival abscess	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Gingivitis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Helicobacter gastritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Helicobacter infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Hepatitis C	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Herpes ophthalmic	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Herpes simplex	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Herpes virus infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Herpes zoster	9	0.3	(0.1, 0.5)	9	0.3	(0.1, 0.5)
Hordeolum	5	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Impetigo	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Infected bite	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Infected dermal cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Influenza	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site abscess	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Kidney infection	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Labyrinthitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Laryngitis	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Localised infection	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Lyme disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Mastoiditis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Onychomycosis	2	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Ophthalmic herpes zoster	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Oral herpes	3	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Orchitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Osteomyelitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Otitis externa	2	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Otitis media	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Otitis media acute	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Otitis media bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Paronychia	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Parotitis	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Penile infection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Periodontitis	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Peritonitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Peritonsillar abscess	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pharyngitis streptococcal	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pneumonia	3	0.1	(0.0, 0.3)	8	0.2	(0.1, 0.5)
Post procedural infection	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Postoperative wound infection	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Primary syphilis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pustule	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pyelonephritis	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Pyelonephritis acute	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Rash pustular	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Respiratory tract infection viral	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Rhinitis	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.3)
Sepsis	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Septic shock	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Shigella sepsis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Sialoadenitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Sinusitis	10	0.3	(0.1, 0.5)	14	0.4	(0.2, 0.7)
Skin bacterial infection	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Skin infection	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Staphylococcal infection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Staphylococcal sepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Subacute endocarditis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Subcutaneous abscess	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Tooth abscess	6	0.2	(0.1, 0.4)	4	0.1	(0.0, 0.3)
Tooth infection	17	0.5	(0.3, 0.8)	12	0.4	(0.2, 0.6)
Trichomoniasis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Upper respiratory tract infection	3	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Urinary tract infection	38	1.1	(0.8, 1.5)	43	1.3	(0.9, 1.8)
Vaginal infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Vulvovaginal candidiasis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Vulvovaginal mycotic infection	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Vulvovaginitis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	131	3.9	(3.2, 4.6)	176	5.3	(4.6, 6.2)
Administration related reaction	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Alcohol poisoning	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Anaemia postoperative	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Animal bite	0	0.0	(0.0, 0.1)	6	0.2	(0.1, 0.4)
Ankle fracture	3	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Arthropod bite	9	0.3	(0.1, 0.5)	5	0.2	(0.0, 0.4)
Arthropod sting	3	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Back injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Bone contusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Brain contusion	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Burn oral cavity	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Burns first degree	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Burns second degree	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cartilage injury	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cervical vertebral fracture	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Chest injury	4	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Clavicle fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Concussion	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Contusion	4	0.1	(0.0, 0.3)	10	0.3	(0.1, 0.6)
Corneal abrasion	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Craniocerebral injury	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Delayed recovery from anaesthesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Dental restoration failure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Ear canal abrasion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Ear injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Epicondylitis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Facial bones fracture	3	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Fall	39	1.2	(0.8, 1.6)	56	1.7	(1.3, 2.2)
Femur fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Fibula fracture	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Foot fracture	3	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Forearm fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Foreign body aspiration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Fractured sacrum	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hand fracture	3	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Head injury	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Hip fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Humerus fracture	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Jaw fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Joint dislocation	5	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Joint injury	3	0.1	(0.0, 0.3)	5	0.2	(0.0, 0.4)
Ligament rupture	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Ligament sprain	11	0.3	(0.2, 0.6)	9	0.3	(0.1, 0.5)
Limb fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Limb injury	3	0.1	(0.0, 0.3)	7	0.2	(0.1, 0.4)
Lower limb fracture	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Lumbar vertebral fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Meniscus injury	3	0.1	(0.0, 0.3)	7	0.2	(0.1, 0.4)
Mouth injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Muscle contusion	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Muscle injury	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Muscle rupture	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.3)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Muscle strain	10	0.3	(0.1, 0.5)	9	0.3	(0.1, 0.5)
Overdose	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Patella fracture	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Pelvic fracture	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pharyngeal perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Post concussion syndrome	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Post procedural haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Post-traumatic pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Procedural hypotension	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Procedural pain	3	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Radius fracture	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Respiratory fume inhalation disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Rib fracture	3	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Road traffic accident	5	0.1	(0.0, 0.3)	7	0.2	(0.1, 0.4)
Scapula fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Skin abrasion	5	0.1	(0.0, 0.3)	13	0.4	(0.2, 0.7)
Skin injury	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Skin laceration	7	0.2	(0.1, 0.4)	15	0.5	(0.3, 0.7)
Spinal column injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Spinal compression fracture	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Spinal fracture	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Stoma site rash	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Stress fracture	1	0.0	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Subdural haematoma	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Sunburn	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Tendon rupture	0	0.0	(0.0, 0.1)	5	0.2	(0.0, 0.4)
Thermal burn	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Tibia fracture	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Tooth fracture	5	0.1	(0.0, 0.3)	6	0.2	(0.1, 0.4)
Tooth injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Traumatic haemothorax	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ulna fracture	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Upper limb fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Vaccination complication	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Venom poisoning	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Wound	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Wrist fracture	2	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.3)
INVESTIGATIONS	73	2.2	(1.7, 2.7)	24	0.7	(0.5, 1.1)
Autoantibody positive	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Blood chloride decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Blood cholesterol increased	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Blood glucose abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Blood glucose fluctuation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Blood glucose increased	8	0.2	(0.1, 0.5)	0	0.0	(0.0, 0.1)
Blood potassium decreased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Blood pressure abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Blood pressure increased	3	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Blood pressure systolic increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Blood sodium decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Blood testosterone increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Blood thyroid stimulating hormone increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Blood triglycerides increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Blood urea increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Body temperature decreased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Body temperature increased	40	1.2	(0.8, 1.6)	3	0.1	(0.0, 0.3)
Cardiac stress test abnormal	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Fractional exhaled nitric oxide increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Glomerular filtration rate decreased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Haemoglobin decreased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Heart rate increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hepatic enzyme increased	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Hepatitis C antibody positive	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
High density lipoprotein increased	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Intraocular pressure increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Liver function test increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Low density lipoprotein increased	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Lymphocyte count decreased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Mean cell haemoglobin decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Mean cell volume decreased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Mean cell volume increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Monocyte count increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Platelet count decreased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Platelet count increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Prostatic specific antigen increased	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Respiratory rate increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
SARS-CoV-2 antibody test positive	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Thyroid function test abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Troponin increased	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Urine ketone body present	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
White blood cell count increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
White blood cells urine positive	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	56	1.7	(1.3, 2.2)	54	1.6	(1.2, 2.1)
Decreased appetite	13	0.4	(0.2, 0.7)	3	0.1	(0.0, 0.3)
Dehydration	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Diabetes mellitus inadequate control	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.3)
Dyslipidaemia	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Fluid retention	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Glucose tolerance impaired	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Gout	3	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Hypercholesterolaemia	2	0.1	(0.0, 0.2)	9	0.3	(0.1, 0.5)
Hyperglycaemia	2	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Hyperkalaemia	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hyperlipidaemia	5	0.1	(0.0, 0.3)	5	0.2	(0.0, 0.4)
Hypernatraemia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypertriglyceridaemia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hyperuricaemia	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypoglycaemia	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hypokalaemia	5	0.1	(0.0, 0.3)	5	0.2	(0.0, 0.4)
Hypomagnesaemia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hyponatraemia	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hypovolaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Increased appetite	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Insulin resistance	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Iron deficiency	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Lactic acidosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Polydipsia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Type 2 diabetes mellitus	6	0.2	(0.1, 0.4)	8	0.2	(0.1, 0.5)
Vitamin B12 deficiency	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Vitamin D deficiency	7	0.2	(0.1, 0.4)	1	0.0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	633	18.8	(17.3, 20.3)	276	8.3	(7.4, 9.4)
Arthralgia	99	2.9	(2.4, 3.6)	60	1.8	(1.4, 2.3)
Arthritis	3	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Arthritis reactive	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Arthropathy	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Axillary mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Back pain	43	1.3	(0.9, 1.7)	34	1.0	(0.7, 1.4)
Bone disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Bone pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Bursitis	6	0.2	(0.1, 0.4)	3	0.1	(0.0, 0.3)
Costochondritis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dupuytren's contracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Exostosis	2	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Fibromyalgia	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Flank pain	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Groin pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Intervertebral disc compression	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Intervertebral disc degeneration	3	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Intervertebral disc protrusion	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Joint effusion	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Joint instability	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Joint range of motion decreased	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Joint stiffness	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Joint swelling	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.3)
Limb discomfort	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Mobility decreased	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Muscle contracture	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Muscle fatigue	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Muscle spasms	15	0.4	(0.2, 0.7)	10	0.3	(0.1, 0.6)
Muscle twitching	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Muscular weakness	7	0.2	(0.1, 0.4)	1	0.0	(0.0, 0.2)
Musculoskeletal chest pain	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Musculoskeletal discomfort	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Musculoskeletal pain	1	0.0	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Musculoskeletal stiffness	9	0.3	(0.1, 0.5)	4	0.1	(0.0, 0.3)
Myalgia	372	11.0	(9.9, 12.2)	66	2.0	(1.5, 2.5)
Neck pain	11	0.3	(0.2, 0.6)	12	0.4	(0.2, 0.6)
Osteitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Osteoarthritis	12	0.4	(0.2, 0.6)	20	0.6	(0.4, 0.9)
Osteopenia	1	0.0	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Osteoporosis	0	0.0	(0.0, 0.1)	5	0.2	(0.0, 0.4)
Pain in extremity	88	2.6	(2.1, 3.2)	25	0.8	(0.5, 1.1)
Pain in jaw	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Periarthritis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Plantar fasciitis	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Polyarthritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Psoriatic arthropathy	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Rhabdomyolysis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Rheumatoid arthritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Rotator cuff syndrome	2	0.1	(0.0, 0.2)	10	0.3	(0.1, 0.6)
Sinus tarsi syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Spinal osteoarthritis	2	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Spinal stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Spondylitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Spondylolisthesis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Synovial cyst	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Temporomandibular joint syndrome	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Tendonitis	5	0.1	(0.0, 0.3)	5	0.2	(0.0, 0.4)
Tenosynovitis stenosans	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Trigger finger	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	45	1.3	(1.0, 1.8)	46	1.4	(1.0, 1.9)
Acrochordon	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Acute myeloid leukaemia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Adenocarcinoma of colon	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Adenocarcinoma pancreas	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Adenoma benign	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Adrenal gland cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Basal cell carcinoma	3	0.1	(0.0, 0.3)	11	0.3	(0.2, 0.6)
Biliary cancer metastatic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Bladder cancer	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Borderline serous tumour of ovary	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Breast cancer	2	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Breast cancer in situ	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Breast cancer stage I	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Carcinoid tumour of the stomach	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Colon adenoma	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Gallbladder cancer stage II	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastric cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Glomus tumour	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Infected naevus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Invasive ductal breast carcinoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lipoma	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Lobular breast carcinoma in situ	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Lung adenocarcinoma	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Lymphoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lymphoproliferative disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Malignant melanoma	1	0.0	(0.0, 0.2)	5	0.2	(0.0, 0.4)
Malignant melanoma of eyelid	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Meningioma benign	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Metastases to liver	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Metastases to lymph nodes	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Non-Hodgkin's lymphoma recurrent	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Non-small cell lung cancer stage IV	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Oropharyngeal cancer recurrent	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Oropharyngeal squamous cell carcinoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pancreatic carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Papillary serous endometrial carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Penile neoplasm	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Penile squamous cell carcinoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Polycythaemia vera	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Prostate cancer	5	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Prostate cancer metastatic	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Seborrhoeic keratosis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Skin cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Skin papilloma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Squamous cell carcinoma	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Squamous cell carcinoma of head and neck	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Squamous cell carcinoma of skin	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Thyroid cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Tonsil cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Transitional cell carcinoma	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Uterine cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Uterine leiomyoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	517	15.3	(14.0, 16.7)	228	6.9	(6.0, 7.8)
Amnesia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Amyotrophic lateral sclerosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Aphasia	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Balance disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Burning sensation	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Carpal tunnel syndrome	1	0.0	(0.0, 0.2)	5	0.2	(0.0, 0.4)
Cerebellar infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cerebral atrophy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cerebral infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cerebrovascular accident	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Cervical radiculopathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cervicogenic headache	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Dementia Alzheimer's type	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Diabetic neuropathy	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Disturbance in attention	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dizziness	35	1.0	(0.7, 1.4)	30	0.9	(0.6, 1.3)
Dizziness postural	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Drug withdrawal headache	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dysgeusia	3	0.1	(0.0, 0.3)	5	0.2	(0.0, 0.4)
Dyskinesia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Facial paralysis	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Facial paresis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Haemorrhagic stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Head discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Headache	414	12.3	(11.1, 13.5)	136	4.1	(3.5, 4.9)
Hyperaesthesia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypersomnia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypoaesthesia	3	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Intraventricular haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Ischaemic stroke	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Lethargy	18	0.5	(0.3, 0.8)	1	0.0	(0.0, 0.2)
Mental impairment	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Migraine	3	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Migraine with aura	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Migraine without aura	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Morton's neuralgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Muscle spasticity	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Myoclonus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Nerve compression	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Neuralgia	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Neuropathy peripheral	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Nystagmus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Paraesthesia	5	0.1	(0.0, 0.3)	9	0.3	(0.1, 0.5)
Parkinsonism	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Parosmia	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Periodic limb movement disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Piriformis syndrome	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Post herpetic neuralgia	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Presyncope	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Sciatica	4	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Sinus headache	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Somnolence	4	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Spinal cord compression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Subarachnoid haemorrhage	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Syncope	4	0.1	(0.0, 0.3)	8	0.2	(0.1, 0.5)
Taste disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Tension headache	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Thoracic radiculopathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Toxic encephalopathy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Transient global amnesia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Transient ischaemic attack	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Tremor	5	0.1	(0.0, 0.3)	6	0.2	(0.1, 0.4)
Trigeminal neuralgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Uraemic encephalopathy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
VIth nerve paralysis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
PRODUCT ISSUES	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Device breakage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Device connection issue	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	37	1.1	(0.8, 1.5)	27	0.8	(0.5, 1.2)
Abnormal dreams	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Anxiety	6	0.2	(0.1, 0.4)	5	0.2	(0.0, 0.4)
Anxiety disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Bipolar disorder	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Depression	6	0.2	(0.1, 0.4)	9	0.3	(0.1, 0.5)
Disorientation	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Dysphemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Insomnia	8	0.2	(0.1, 0.5)	5	0.2	(0.0, 0.4)
Irritability	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Libido decreased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Libido increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Listless	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Mental disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Mental status changes	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Mood swings	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Nightmare	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Panic attack	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Paranoia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Restlessness	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Sleep disorder	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Suicidal ideation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Suicide attempt	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	32	0.9	(0.6, 1.3)	26	0.8	(0.5, 1.2)
Acute kidney injury	6	0.2	(0.1, 0.4)	3	0.1	(0.0, 0.3)
Bladder spasm	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Chronic kidney disease	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Dysuria	4	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Haematuria	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Hydronephrosis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hypertonic bladder	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Micturition urgency	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Nephrolithiasis	5	0.1	(0.0, 0.3)	8	0.2	(0.1, 0.5)
Nocturia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Obstructive nephropathy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Oedematous kidney	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Perinephric oedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pollakiuria	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Polyuria	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Renal cyst	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Renal cyst haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Renal failure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Urethral stenosis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Urinary retention	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Urinary tract obstruction	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Urine odour abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Vesical fistula	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	15	0.4	(0.2, 0.7)	15	0.5	(0.3, 0.7)
Benign prostatic hyperplasia	2	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Breast calcifications	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Breast cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Breast hyperplasia	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Breast mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Breast pain	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cervical polyp	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ejaculation disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Erectile dysfunction	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Genital erythema	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ovarian cyst	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ovarian mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pelvic pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Prostatitis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Prostatomegaly	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pruritus genital	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Testicular pain	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Uterine prolapse	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Vaginal haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Vulvovaginal pruritus	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	97	2.9	(2.3, 3.5)	62	1.9	(1.4, 2.4)
Acute respiratory failure	2	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Asthma	7	0.2	(0.1, 0.4)	4	0.1	(0.0, 0.3)
Atelectasis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Bronchospasm	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Chronic obstructive pulmonary disease	5	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Cough	10	0.3	(0.1, 0.5)	4	0.1	(0.0, 0.3)
Dry throat	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dysphonia	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Dyspnoea	3	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Dyspnoea exertional	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Emphysema	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Epistaxis	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Haemoptysis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hiccups	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Interstitial lung disease	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Nasal congestion	12	0.4	(0.2, 0.6)	4	0.1	(0.0, 0.3)
Nasal polyps	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Nasal septum deviation	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Nasal turbinate hypertrophy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Nasal valve collapse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Nasopharyngeal polyp	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Oropharyngeal discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Oropharyngeal pain	12	0.4	(0.2, 0.6)	8	0.2	(0.1, 0.5)
Paranasal sinus discomfort	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Paranasal sinus hypersecretion	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pharyngeal lesion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pharyngeal swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pleurisy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pneumonia aspiration	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pneumonitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pneumothorax	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Productive cough	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pulmonary embolism	4	0.1	(0.0, 0.3)	6	0.2	(0.1, 0.4)
Pulmonary hypertension	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pulmonary mass	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Pulmonary oedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Respiratory failure	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Respiratory tract congestion	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Rhinalgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Rhinitis allergic	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Rhinitis perennial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Rhinorrhoea	9	0.3	(0.1, 0.5)	5	0.2	(0.0, 0.4)
Sinus congestion	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Sinus disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Sleep apnoea syndrome	4	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Sneezing	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Throat irritation	5	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Upper respiratory tract congestion	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Upper-airway cough syndrome	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Wheezing	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	114	3.4	(2.8, 4.1)	87	2.6	(2.1, 3.2)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Acne	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Actinic keratosis	3	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Alopecia	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Alopecia areata	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Angioedema	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Blister	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Cold sweat	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dermal cyst	4	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Dermatitis	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Dermatitis allergic	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Dermatitis contact	7	0.2	(0.1, 0.4)	9	0.3	(0.1, 0.5)
Dermatitis exfoliative	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Diabetic foot	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Drug eruption	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Dry skin	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dyshidrotic eczema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Ecchymosis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Eczema	3	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Erythema	4	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Hand dermatitis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hyperhidrosis	13	0.4	(0.2, 0.7)	4	0.1	(0.0, 0.3)
Lipodystrophy acquired	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Macule	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Night sweats	8	0.2	(0.1, 0.5)	2	0.1	(0.0, 0.2)
Onychomadesis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pain of skin	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Papule	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Perioral dermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pruritus	15	0.4	(0.2, 0.7)	7	0.2	(0.1, 0.4)
Pseudofolliculitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Psoriasis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Purpura	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Rash	25	0.7	(0.5, 1.1)	27	0.8	(0.5, 1.2)
Rash erythematous	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Rash maculo-papular	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Rash pruritic	4	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Rosacea	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Skin discolouration	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Skin induration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Skin lesion	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Skin mass	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Stasis dermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Urticaria	6	0.2	(0.1, 0.4)	7	0.2	(0.1, 0.4)
Urticaria papular	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
SOCIAL CIRCUMSTANCES	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Menopause	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	20	0.6	(0.4, 0.9)	8	0.2	(0.1, 0.5)
Apicectomy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Botulinum toxin injection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cardiac pacemaker replacement	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cardioversion	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Carpal tunnel decompression	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dental implantation	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Facet joint block	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Finger amputation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Inguinal hernia repair	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lacrimal duct procedure	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lens extraction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Open reduction of fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Postoperative care	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Rotator cuff repair	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Skin neoplasm excision	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Toe amputation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Toe operation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Tooth extraction	4	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Wound drainage	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
VASCULAR DISORDERS	56	1.7	(1.3, 2.2)	68	2.1	(1.6, 2.6)
Accelerated hypertension	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Aortic aneurysm	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)

14.121. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Aortic dilatation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Aortic rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Aortic stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Arteriosclerosis	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Blood pressure inadequately controlled	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Deep vein thrombosis	3	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Flushing	5	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Haematoma	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Hot flush	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hypertension	34	1.0	(0.7, 1.4)	41	1.2	(0.9, 1.7)
Hypertensive crisis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hypertensive emergency	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Hypertensive urgency	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypotension	2	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Lymphorrhoea	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Orthostatic hypotension	1	0.0	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Pallor	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Peripheral artery stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Phlebolith	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Raynaud's phenomenon	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_exp_age_p3_saf

14.122. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=674, TE[b]=2.5)			Placebo (N[a]=705, TE[b]=2.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	179	70.7	(60.7, 81.9)	84	31.9	(25.5, 39.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	2	0.8	(0.1, 2.9)	1	0.4	(0.0, 2.1)
Anaemia	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Lymphadenopathy	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Microcytic anaemia	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
CARDIAC DISORDERS	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Acute left ventricular failure	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Cardiac failure congestive	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
EAR AND LABYRINTH DISORDERS	1	0.4	(0.0, 2.2)	1	0.4	(0.0, 2.1)
Vertigo	1	0.4	(0.0, 2.2)	1	0.4	(0.0, 2.1)
EYE DISORDERS	3	1.2	(0.2, 3.5)	0	0.0	(0.0, 1.4)
Dry eye	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Lacrimation increased	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Photophobia	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
GASTROINTESTINAL DISORDERS	15	5.9	(3.3, 9.8)	16	6.1	(3.5, 9.9)
Abdominal pain	0	0.0	(0.0, 1.5)	2	0.8	(0.1, 2.7)
Colitis microscopic	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Diarrhoea	9	3.6	(1.6, 6.7)	4	1.5	(0.4, 3.9)
Food poisoning	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Gastritis	0	0.0	(0.0, 1.5)	3	1.1	(0.2, 3.3)
Gingival pain	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Hiatus hernia	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Intestinal perforation	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Nausea	3	1.2	(0.2, 3.5)	3	1.1	(0.2, 3.3)
Oesophageal varices haemorrhage	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Paraesthesia oral	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Parotid duct obstruction	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Retching	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Toothache	1	0.4	(0.0, 2.2)	1	0.4	(0.0, 2.1)
Vomiting	0	0.0	(0.0, 1.5)	2	0.8	(0.1, 2.7)

14.122. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=674, TE[b]=2.5)			Placebo (N[a]=705, TE[b]=2.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	113	44.6	(36.8, 53.7)	26	9.9	(6.5, 14.5)
Asthenia	2	0.8	(0.1, 2.9)	0	0.0	(0.0, 1.4)
Chest pain	1	0.4	(0.0, 2.2)	1	0.4	(0.0, 2.1)
Chills	24	9.5	(6.1, 14.1)	4	1.5	(0.4, 3.9)
Fatigue	34	13.4	(9.3, 18.8)	5	1.9	(0.6, 4.4)
Injection site bruising	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Injection site discomfort	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Injection site erythema	2	0.8	(0.1, 2.9)	0	0.0	(0.0, 1.4)
Injection site haematoma	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Injection site induration	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Injection site pain	72	28.4	(22.3, 35.8)	14	5.3	(2.9, 8.9)
Injection site pruritus	2	0.8	(0.1, 2.9)	1	0.4	(0.0, 2.1)
Injection site swelling	5	2.0	(0.6, 4.6)	0	0.0	(0.0, 1.4)
Malaise	2	0.8	(0.1, 2.9)	1	0.4	(0.0, 2.1)
Pain	8	3.2	(1.4, 6.2)	0	0.0	(0.0, 1.4)
Peripheral swelling	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Pyrexia	33	13.0	(9.0, 18.3)	3	1.1	(0.2, 3.3)
HEPATOBILIARY DISORDERS	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Cholecystitis acute	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
IMMUNE SYSTEM DISORDERS	1	0.4	(0.0, 2.2)	1	0.4	(0.0, 2.1)
Drug hypersensitivity	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Hypersensitivity	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
INFECTIONS AND INFESTATIONS	12	4.7	(2.4, 8.3)	11	4.2	(2.1, 7.5)
Appendicitis	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Balanitis candida	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Cellulitis	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Ear infection	2	0.8	(0.1, 2.9)	0	0.0	(0.0, 1.4)
Escherichia urinary tract infection	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Folliculitis	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Gingivitis	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Groin abscess	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Hepatitis C	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)

14.122. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=674, TE[b]=2.5)			Placebo (N[a]=705, TE[b]=2.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Herpes zoster	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Hordeolum	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Impetigo	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Oral herpes	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Parotitis	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Pneumonia	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Pulmonary tuberculosis	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Pyelonephritis	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Upper respiratory tract infection	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Urinary tract infection	2	0.8	(0.1, 2.9)	0	0.0	(0.0, 1.4)
Vulvovaginal mycotic infection	0	0.0	(0.0, 1.5)	2	0.8	(0.1, 2.7)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	12	4.7	(2.4, 8.3)	7	2.7	(1.1, 5.5)
Animal bite	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Bone fissure	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Chest injury	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Contusion	3	1.2	(0.2, 3.5)	0	0.0	(0.0, 1.4)
Exposure during pregnancy	1	0.4	(0.0, 2.2)	1	0.4	(0.0, 2.1)
Fall	2	0.8	(0.1, 2.9)	1	0.4	(0.0, 2.1)
Joint dislocation	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Joint injury	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Ligament rupture	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Limb injury	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Maternal exposure during pregnancy	2	0.8	(0.1, 2.9)	1	0.4	(0.0, 2.1)
Muscle injury	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Muscle strain	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Overdose	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Rib fracture	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Road traffic accident	1	0.4	(0.0, 2.2)	1	0.4	(0.0, 2.1)
Thermal burn	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
INVESTIGATIONS	2	0.8	(0.1, 2.9)	1	0.4	(0.0, 2.1)
Body temperature increased	2	0.8	(0.1, 2.9)	0	0.0	(0.0, 1.4)
Red blood cell morphology abnormal	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)

14.122. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=674, TE[b]=2.5)			Placebo (N[a]=705, TE[b]=2.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
METABOLISM AND NUTRITION DISORDERS	4	1.6	(0.4, 4.0)	3	1.1	(0.2, 3.3)
Decreased appetite	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Glucose tolerance impaired	0	0.0	(0.0, 1.5)	2	0.8	(0.1, 2.7)
Hyperlipidaemia	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Hypokalaemia	2	0.8	(0.1, 2.9)	1	0.4	(0.0, 2.1)
Hypomagnesaemia	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	49	19.4	(14.3, 25.6)	12	4.6	(2.4, 8.0)
Arthralgia	7	2.8	(1.1, 5.7)	2	0.8	(0.1, 2.7)
Back pain	5	2.0	(0.6, 4.6)	2	0.8	(0.1, 2.7)
Bursitis	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Joint effusion	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Muscle contracture	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Muscle spasms	3	1.2	(0.2, 3.5)	0	0.0	(0.0, 1.4)
Musculoskeletal chest pain	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Musculoskeletal discomfort	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Musculoskeletal stiffness	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Myalgia	27	10.7	(7.0, 15.5)	6	2.3	(0.8, 5.0)
Pain in extremity	4	1.6	(0.4, 4.0)	2	0.8	(0.1, 2.7)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2	0.8	(0.1, 2.9)	2	0.8	(0.1, 2.7)
Acrochordon	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Adenocarcinoma of colon	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Colon adenoma	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Lipoma	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
NERVOUS SYSTEM DISORDERS	38	15.0	(10.6, 20.6)	13	4.9	(2.6, 8.4)
Carpal tunnel syndrome	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Dizziness	5	2.0	(0.6, 4.6)	0	0.0	(0.0, 1.4)
Headache	30	11.9	(8.0, 16.9)	11	4.2	(2.1, 7.5)
Hemiparaesthesia	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Migraine	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Presyncope	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Somnolence	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Tension headache	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)

14.122. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=674, TE[b]=2.5)			Placebo (N[a]=705, TE[b]=2.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	0.0	(0.0, 1.5)	2	0.8	(0.1, 2.7)
Abortion spontaneous incomplete	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Retained products of conception	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
PSYCHIATRIC DISORDERS	3	1.2	(0.2, 3.5)	1	0.4	(0.0, 2.1)
Anxiety	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Depression	1	0.4	(0.0, 2.2)	1	0.4	(0.0, 2.1)
Insomnia	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1	0.4	(0.0, 2.2)	3	1.1	(0.2, 3.3)
Endometriosis	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Ovarian cyst	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Vaginal haemorrhage	0	0.0	(0.0, 1.5)	2	0.8	(0.1, 2.7)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	5	2.0	(0.6, 4.6)	5	1.9	(0.6, 4.4)
Cough	3	1.2	(0.2, 3.5)	0	0.0	(0.0, 1.4)
Haemoptysis	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Nasal congestion	1	0.4	(0.0, 2.2)	1	0.4	(0.0, 2.1)
Oropharyngeal pain	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Pulmonary embolism	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Rhinitis allergic	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Rhinorrhoea	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2	0.8	(0.1, 2.9)	4	1.5	(0.4, 3.9)
Dermatitis allergic	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Dry skin	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Eczema	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Pruritus	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Psoriasis	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Rash	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
VASCULAR DISORDERS	5	2.0	(0.6, 4.6)	2	0.8	(0.1, 2.7)
Arteriosclerosis	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Deep vein thrombosis	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)

14.122. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=674, TE[b]=2.5)			Placebo (N[a]=705, TE[b]=2.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hypertension	3	1.2	(0.2, 3.5)	2	0.8	(0.1, 2.7)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_unb_base_p3_saf

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	6724	83.6	(81.7, 85.7)	3466	43.8	(42.4, 45.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	113	1.4	(1.2, 1.7)	31	0.4	(0.3, 0.6)
Anaemia	7	0.1	(0.0, 0.2)	10	0.1	(0.1, 0.2)
Blood loss anaemia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coagulopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypochromic anaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Iron deficiency anaemia	9	0.1	(0.1, 0.2)	5	0.1	(0.0, 0.1)
Leukocytosis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Leukopenia	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymph node pain	7	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Lymphadenopathy	84	1.0	(0.8, 1.3)	8	0.1	(0.0, 0.2)
Lymphadenopathy mediastinal	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymphocytosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphopenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Monoclonal B-cell lymphocytosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Neutropenia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Splenomegaly	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Thrombocytopenia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Thrombocytosis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
CARDIAC DISORDERS	86	1.1	(0.9, 1.3)	78	1.0	(0.8, 1.2)
Acute coronary syndrome	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Acute myocardial infarction	6	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.1)
Angina pectoris	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angina unstable	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Aortic valve incompetence	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Arrhythmia	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Arrhythmia supraventricular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Arteriosclerosis coronary artery	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Arteriospasm coronary	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrial fibrillation	13	0.2	(0.1, 0.3)	17	0.2	(0.1, 0.3)
Atrial flutter	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Atrioventricular block complete	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Atrioventricular block first degree	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bradycardia	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bundle branch block left	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bundle branch block right	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac arrest	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Cardiac disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac failure acute	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiomegaly	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiovascular disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Coronary artery disease	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Coronary artery dissection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Coronary artery occlusion	0	0.0	(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, 0.0)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Left atrial enlargement	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Left ventricular dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Left ventricular hypertrophy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mitral valve incompetence	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Mitral valve prolapse	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myocardial infarction	4	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Myocardial ischaemia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Myocarditis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Palpitations	7	0.1	(0.0, 0.2)	16	0.2	(0.1, 0.3)
Pericardial effusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pericarditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Postural orthostatic tachycardia syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Sinus bradycardia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Sinus tachycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Supraventricular tachycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tachyarrhythmia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tachycardia	15	0.2	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Tricuspid valve incompetence	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Ventricular arrhythmia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ventricular extrasystoles	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ventricular tachycardia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	4	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Arnold-Chiari malformation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Congenital bladder neck obstruction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Congenital cystic kidney disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Congenital ureteropelvic junction obstruction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Developmental hip dysplasia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastrointestinal arteriovenous malformation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Heart disease congenital	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Protein S deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Type V hyperlipidaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	74	0.9	(0.7, 1.2)	60	0.8	(0.6, 1.0)
Allergic otitis media	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerumen impaction	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deafness	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Deafness neurosensory	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Deafness unilateral	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear discomfort	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear disorder	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Ear pain	13	0.2	(0.1, 0.3)	11	0.1	(0.1, 0.2)
Ear pruritus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eustachian tube dysfunction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyperacusis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypoacusis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Meniere's disease	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Otorrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sudden hearing loss	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tinnitus	9	0.1	(0.1, 0.2)	11	0.1	(0.1, 0.2)
Tympanic membrane perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vertigo	30	0.4	(0.3, 0.5)	25	0.3	(0.2, 0.5)
Vertigo positional	7	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
ENDOCRINE DISORDERS	16	0.2	(0.1, 0.3)	10	0.1	(0.1, 0.2)
Goitre	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperprolactinaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperthyroidism	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypogonadism	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypothyroidism	8	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Oestrogen deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Thyroid cyst	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Thyroid mass	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EYE DISORDERS	66	0.8	(0.6, 1.0)	63	0.8	(0.6, 1.0)
Amaurosis fugax	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Angle closure glaucoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Asthenopia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Astigmatism	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blepharitis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blepharospasm	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cataract	7	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Chalazion	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Choroidal neovascularisation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Conjunctival haemorrhage	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Conjunctival hyperaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Conjunctival oedema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Conjunctivitis allergic	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Corneal irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dacryostenosis acquired	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diabetic retinopathy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diplopia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dry age-related macular degeneration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dry eye	0	0.0	(0.0, 0.0)	6	0.1	(0.0, 0.2)
Episcleritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eye allergy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eye haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Eye inflammation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eye irritation	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Eye pain	7	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.1)
Eye pruritus	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye swelling	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eyelid haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eyelid oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eyelid pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eyelids pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Glaucoma	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypermetropia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Iritis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Keratitis	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Lacrimation increased	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Macular oedema	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ocular discomfort	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ocular hyperaemia	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Photophobia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal artery occlusion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal detachment	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Retinal tear	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Scleral discolouration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Swelling of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ulcerative keratitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uveitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vision blurred	7	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Visual acuity reduced	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Visual impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vitreous detachment	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vitreous floaters	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	727	9.0	(8.4, 9.7)	493	6.2	(5.7, 6.8)
Abdominal adhesions	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abdominal discomfort	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Abdominal distension	7	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Abdominal hernia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abdominal pain	21	0.3	(0.2, 0.4)	20	0.3	(0.2, 0.4)
Abdominal pain lower	3	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Abdominal pain upper	27	0.3	(0.2, 0.5)	15	0.2	(0.1, 0.3)
Abdominal rigidity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abnormal faeces	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Acute abdomen	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Anal pruritus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Angular cheilitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Aphthous ulcer	9	0.1	(0.1, 0.2)	3	0.0	(0.0, 0.1)
Appendix disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cheilitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Chronic gastritis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Coeliac artery aneurysm	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Coeliac disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Colitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colitis ischaemic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Colitis microscopic	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Colitis ulcerative	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Constipation	10	0.1	(0.1, 0.2)	13	0.2	(0.1, 0.3)
Crohn's disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dental caries	10	0.1	(0.1, 0.2)	8	0.1	(0.0, 0.2)
Diarrhoea	245	3.0	(2.7, 3.5)	184	2.3	(2.0, 2.7)
Diverticular perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diverticulum	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulum intestinal	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Diverticulum intestinal haemorrhagic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dry mouth	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Duodenal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Duodenal ulcer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dyspepsia	15	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.3)
Dysphagia	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Enterocolitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Epiploic appendagitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eructation	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Faeces soft	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Femoral hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Flatulence	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Food poisoning	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Frequent bowel movements	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastric antral vascular ectasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastric polyps	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastric ulcer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastric ulcer haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastritis	5	0.1	(0.0, 0.1)	11	0.1	(0.1, 0.2)
Gastritis erosive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastrointestinal disorder	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal haemorrhage	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal mucosa hyperaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastrointestinal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastrooesophageal reflux disease	15	0.2	(0.1, 0.3)	23	0.3	(0.2, 0.4)
Gingival bleeding	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gingival discomfort	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gingival pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gingival swelling	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Glossitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Glossodynia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haematemesis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haematochezia	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haemorrhoids	5	0.1	(0.0, 0.1)	11	0.1	(0.1, 0.2)
Hiatus hernia	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hypoaesthesia oral	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypoaesthesia teeth	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ileus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Impaired gastric emptying	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Incarcerated inguinal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Inguinal hernia	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Internal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intestinal obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intestinal strangulation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intra-abdominal fluid collection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Irritable bowel syndrome	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Large intestine perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Large intestine polyp	4	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Lip oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lip swelling	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Loose tooth	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mouth ulceration	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Nausea	271	3.4	(3.0, 3.8)	84	1.1	(0.8, 1.3)
Noninfective gingivitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Obstructive pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Odynophagia	13	0.2	(0.1, 0.3)	8	0.1	(0.0, 0.2)
Oesophageal food impaction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oesophageal spasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oesophageal ulcer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oesophagitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Oral discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oral lichenoid reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oral mucosa haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oral pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Palatal disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pancreatic cyst	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pancreatic failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pancreatitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pancreatitis acute	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Paraesthesia oral	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Parotid duct obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peptic ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Precancerous lesion of digestive tract	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Proctalgia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectal haemorrhage	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectal polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Retching	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Retroperitoneal haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Salivary gland calculus	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Salivary gland mucocoele	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Small intestinal obstruction	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Stomatitis	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Swollen tongue	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Teething	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tongue discolouration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tongue discomfort	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tongue oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tongue pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tongue ulceration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tooth disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tooth impacted	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Toothache	25	0.3	(0.2, 0.5)	27	0.3	(0.2, 0.5)
Umbilical hernia	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Varices oesophageal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Volvulus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vomiting	68	0.8	(0.7, 1.1)	33	0.4	(0.3, 0.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4604	57.3	(55.6, 59.0)	980	12.4	(11.6, 13.2)
Adverse drug reaction	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Application site erythema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Application site pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Application site pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Application site rash	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Application site reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Asthenia	73	0.9	(0.7, 1.1)	25	0.3	(0.2, 0.5)
Axillary pain	14	0.2	(0.1, 0.3)	3	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Capsular contracture associated with breast implant	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Chest discomfort	5	0.1	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Chest pain	16	0.2	(0.1, 0.3)	15	0.2	(0.1, 0.3)
Chills	1338	16.6	(15.8, 17.6)	117	1.5	(1.2, 1.8)
Chronic fatigue syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cyst	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Drug withdrawal syndrome	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Effusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Exercise tolerance decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Face oedema	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Facial pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fatigue	1422	17.7	(16.8, 18.6)	373	4.7	(4.3, 5.2)
Feeling abnormal	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Feeling cold	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Feeling hot	8	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Gait disturbance	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Illness	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Induration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Inflammation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Influenza like illness	24	0.3	(0.2, 0.4)	4	0.1	(0.0, 0.1)
Injection site bruising	12	0.1	(0.1, 0.3)	18	0.2	(0.1, 0.4)
Injection site dermatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site discolouration	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site discomfort	5	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Injection site erythema	181	2.3	(1.9, 2.6)	29	0.4	(0.2, 0.5)
Injection site haematoma	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Injection site haemorrhage	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Injection site hyperaesthesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site induration	8	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.1)
Injection site injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Injection site irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site macule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site mass	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site nodule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site oedema	12	0.1	(0.1, 0.3)	0	0.0	(0.0, 0.0)
Injection site pain	2826	35.2	(33.9, 36.5)	385	4.9	(4.4, 5.4)
Injection site papule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site paraesthesia	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Injection site plaque	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Injection site pruritus	35	0.4	(0.3, 0.6)	5	0.1	(0.0, 0.1)
Injection site rash	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site reaction	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site swelling	133	1.7	(1.4, 2.0)	22	0.3	(0.2, 0.4)
Injection site urticaria	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site warmth	13	0.2	(0.1, 0.3)	5	0.1	(0.0, 0.1)
Injury associated with device	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Malaise	128	1.6	(1.3, 1.9)	20	0.3	(0.2, 0.4)
Mass	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Medical device pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Medical device site granuloma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mucosal disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nodule	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Non-cardiac chest pain	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Oedema peripheral	8	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Pain	617	7.7	(7.1, 8.3)	61	0.8	(0.6, 1.0)
Peripheral swelling	7	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Pyrexia	1476	18.4	(17.4, 19.3)	75	0.9	(0.7, 1.2)
Sensation of foreign body	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sluggishness	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sudden cardiac death	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Swelling	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Swelling face	2	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Temperature intolerance	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Therapeutic response unexpected	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Thirst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaccination site induration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vaccination site pain	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Vaccination site swelling	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vascular stent occlusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vessel puncture site bruise	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vessel puncture site haematoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vessel puncture site induration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	21	0.3	(0.2, 0.4)	15	0.2	(0.1, 0.3)
Bile duct stone	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary colic	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary dyskinesia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cholecystitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Cholecystitis acute	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Cholelithiasis	11	0.1	(0.1, 0.2)	5	0.1	(0.0, 0.1)
Cirrhosis alcoholic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hepatic cirrhosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hepatic cyst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatic steatosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hepatocellular injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nonalcoholic fatty liver disease	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	22	0.3	(0.2, 0.4)	33	0.4	(0.3, 0.6)
Allergy to animal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Allergy to arthropod bite	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Allergy to arthropod sting	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anaphylactic shock	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Drug hypersensitivity	6	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Food allergy	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hypersensitivity	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Jarisch-Herxheimer reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Milk allergy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Seasonal allergy	8	0.1	(0.0, 0.2)	16	0.2	(0.1, 0.3)
INFECTIONS AND INFESTATIONS	401	5.0	(4.5, 5.5)	484	6.1	(5.6, 6.7)
Abdominal abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abscess	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abscess intestinal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abscess jaw	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abscess limb	0	0.0	(0.0, 0.0)	4	0.1	(0.0, 0.1)
Abscess neck	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abscess oral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Acarodermatitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Acute sinusitis	1	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Anal abscess	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anal fistula infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Appendicitis	13	0.2	(0.1, 0.3)	9	0.1	(0.1, 0.2)
Appendicitis perforated	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arthritis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bacterial blepharitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bacterial infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bacterial rhinitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bacterial sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bacterial vaginosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bacterial vulvovaginitis	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bartholin's abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bartholinitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blister infected	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bone abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Brain abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bronchitis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.0)	13	0.2	(0.1, 0.3)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Campylobacter infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Carbuncle	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Catheter site infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cellulitis	15	0.2	(0.1, 0.3)	19	0.2	(0.1, 0.4)
Cellulitis orbital	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chlamydial infection	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Chronic sinusitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clostridium difficile infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Complicated appendicitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Conjunctivitis	12	0.1	(0.1, 0.3)	11	0.1	(0.1, 0.2)
Conjunctivitis bacterial	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Coxsackie viral infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cystitis	8	0.1	(0.0, 0.2)	12	0.2	(0.1, 0.3)
Dental fistula	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dermatitis infected	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Device related infection	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diabetic foot infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diverticulitis	10	0.1	(0.1, 0.2)	11	0.1	(0.1, 0.2)
Ear infection	9	0.1	(0.1, 0.2)	17	0.2	(0.1, 0.3)
Emphysematous cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Empyema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Erysipelas	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Escherichia sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Escherichia urinary tract infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Extradural abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eye infection	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Eye infection bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Folliculitis	6	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.0)
Fungal infection	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Fungal skin infection	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Furuncle	3	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Gangrene	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastroenteritis	6	0.1	(0.0, 0.2)	12	0.2	(0.1, 0.3)
Gastroenteritis viral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Genital herpes	0	0.0	(0.0, 0.0)	5	0.1	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Genital herpes simplex	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Genitourinary chlamydia infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gingival abscess	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Gingivitis	5	0.1	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Gonorrhoea	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Helicobacter gastritis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Helicobacter infection	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Hepatitis A	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Herpes ophthalmic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Herpes simplex	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Herpes virus infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Herpes zoster	16	0.2	(0.1, 0.3)	15	0.2	(0.1, 0.3)
Herpes zoster cutaneous disseminated	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Herpes zoster oticus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hordeolum	8	0.1	(0.0, 0.2)	10	0.1	(0.1, 0.2)
Impetigo	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Infected bite	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Infected dermal cyst	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Infectious mononucleosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Influenza	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Kidney infection	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Labyrinthitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Laryngitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Localised infection	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Lyme disease	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Mastitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mastoiditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Meningitis bacterial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nail infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nasopharyngitis	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Onychomycosis	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Ophthalmic herpes zoster	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral candidiasis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Oral fungal infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oral herpes	6	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Oral infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Orchitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Osteomyelitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Otitis externa	6	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Otitis media	9	0.1	(0.1, 0.2)	8	0.1	(0.0, 0.2)
Otitis media acute	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Otitis media bacterial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Papilloma viral infection	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Parasitic gastroenteritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Paronychia	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Parotitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pelvic inflammatory disease	0	0.0	(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, 0.0)
Periodontitis	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peritonitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritonsillar abscess	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pharyngitis	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Pharyngitis bacterial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pharyngitis streptococcal	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pharyngotonsillitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pilonidal cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pneumonia	3	0.0	(0.0, 0.1)	9	0.1	(0.1, 0.2)
Post procedural infection	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Postoperative wound infection	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Primary syphilis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Puncture site infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pustule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pyelonephritis	5	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pyelonephritis acute	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Rash pustular	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Renal abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Respiratory tract infection viral	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Rhinitis	6	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Sepsis	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Septic shock	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Shigella sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sialoadenitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinusitis	20	0.2	(0.2, 0.4)	31	0.4	(0.3, 0.6)
Sinusitis bacterial	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin bacterial infection	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Skin infection	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Soft tissue infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Staphylococcal infection	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Staphylococcal sepsis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subacute endocarditis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subcutaneous abscess	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Syphilis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tinea cruris	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tinea infection	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Tinea versicolour	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Tonsillitis	0	0.0	(0.0, 0.0)	6	0.1	(0.0, 0.2)
Tonsillitis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tooth abscess	12	0.1	(0.1, 0.3)	6	0.1	(0.0, 0.2)
Tooth infection	25	0.3	(0.2, 0.5)	33	0.4	(0.3, 0.6)
Trichomoniasis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper respiratory tract infection	10	0.1	(0.1, 0.2)	8	0.1	(0.0, 0.2)
Ureaplasma infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Urinary tract infection	71	0.9	(0.7, 1.1)	81	1.0	(0.8, 1.3)
Urosepsis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vaginal infection	0	0.0	(0.0, 0.0)	6	0.1	(0.0, 0.2)
Varicella	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Viral infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Viral upper respiratory tract infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vulval abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Vulvovaginal candidiasis	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Vulvovaginal mycotic infection	6	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Vulvovaginitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Wound infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	282	3.5	(3.1, 3.9)	369	4.7	(4.2, 5.2)
Administration related reaction	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Alcohol poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anaemia postoperative	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Animal bite	2	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Ankle fracture	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Arthropod bite	12	0.1	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Arthropod sting	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Back injury	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Bone contusion	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bone fissure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Brain contusion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Burn oral cavity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Burns first degree	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Burns second degree	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cartilage injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cervical vertebral fracture	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chest injury	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Chillblains	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Clavicle fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colon injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Concussion	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Contusion	11	0.1	(0.1, 0.2)	22	0.3	(0.2, 0.4)
Corneal abrasion	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Craniocerebral injury	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Delayed recovery from anaesthesia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dental restoration failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ear canal abrasion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ear injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Epicondylitis	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Exposure during pregnancy	29	0.4	(0.2, 0.5)	41	0.5	(0.4, 0.7)
Exposure to communicable disease	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eye contusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eyelid injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Facial bones fracture	5	0.1	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Fall	60	0.7	(0.6, 1.0)	75	0.9	(0.7, 1.2)
Femur fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Fibula fracture	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Flail chest	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Foot fracture	7	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Forearm fracture	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Foreign body	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Foreign body aspiration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Foreign body in eye	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fractured sacrum	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hand fracture	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Head injury	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Heat stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hip fracture	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Humerus fracture	0	0.0	(0.0, 0.0)	5	0.1	(0.0, 0.1)
Injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Jaw fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Joint dislocation	7	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Joint injury	5	0.1	(0.0, 0.1)	11	0.1	(0.1, 0.2)
Ligament injury	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Ligament rupture	2	0.0	(0.0, 0.1)	9	0.1	(0.1, 0.2)
Ligament sprain	21	0.3	(0.2, 0.4)	27	0.3	(0.2, 0.5)
Limb fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Limb injury	8	0.1	(0.0, 0.2)	15	0.2	(0.1, 0.3)
Limb traumatic amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lip injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lower limb fracture	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Lumbar vertebral fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Maternal exposure before pregnancy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Maternal exposure during breast feeding	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Maternal exposure during pregnancy	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Meniscus injury	6	0.1	(0.0, 0.2)	10	0.1	(0.1, 0.2)
Mouth injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Multiple injuries	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Muscle contusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Muscle injury	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Muscle rupture	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Muscle strain	17	0.2	(0.1, 0.3)	16	0.2	(0.1, 0.3)
Overdose	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Patella fracture	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pelvic fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Penis injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pharyngeal perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Post concussion syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post procedural discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post procedural haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Post procedural haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Post procedural swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post-traumatic pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Postoperative ileus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Procedural dizziness	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Procedural haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Procedural hypotension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Procedural pain	9	0.1	(0.1, 0.2)	4	0.1	(0.0, 0.1)
Radius fracture	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Respiratory fume inhalation disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rib fracture	3	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Road traffic accident	15	0.2	(0.1, 0.3)	19	0.2	(0.1, 0.4)
Scapula fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Scar	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin abrasion	8	0.1	(0.0, 0.2)	15	0.2	(0.1, 0.3)
Skin injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Skin laceration	18	0.2	(0.1, 0.4)	24	0.3	(0.2, 0.5)
Skull fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Soft tissue injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spinal column injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spinal compression fracture	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Spinal cord injury cervical	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Spinal fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Stab wound	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Stoma site rash	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Stress fracture	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Subdural haematoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sunburn	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tendon injury	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Tendon rupture	0	0.0	(0.0, 0.0)	6	0.1	(0.0, 0.2)
Thermal burn	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Tibia fracture	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tooth fracture	10	0.1	(0.1, 0.2)	10	0.1	(0.1, 0.2)
Tooth injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Toxicity to various agents	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Traumatic haemothorax	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ulna fracture	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Upper limb fracture	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vaccination complication	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Venom poisoning	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vulvovaginal injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Wound	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Wrist fracture	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
INVESTIGATIONS	180	2.2	(1.9, 2.6)	50	0.6	(0.5, 0.8)
Alanine aminotransferase increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Aspartate aminotransferase increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Autoantibody positive	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Biopsy breast normal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood chloride decreased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Blood cholesterol increased	5	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blood creatinine decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood creatinine increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood glucose abnormal	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood glucose fluctuation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood glucose increased	8	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Blood immunoglobulin E increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood iron decreased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood potassium decreased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood pressure abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood pressure diastolic increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood pressure increased	6	0.1	(0.0, 0.2)	10	0.1	(0.1, 0.2)
Blood pressure systolic increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood sodium decreased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood testosterone decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood testosterone increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood thyroid stimulating hormone increased	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood triglycerides increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood urea increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Body temperature	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Body temperature decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Body temperature increased	119	1.5	(1.2, 1.8)	13	0.2	(0.1, 0.3)
C-reactive protein	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac stress test abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Electrocardiogram QT prolonged	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Glomerular filtration rate decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haemoglobin decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Heart rate increased	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Heart rate irregular	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hepatic enzyme increased	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Hepatitis C antibody positive	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Herpes simplex test positive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
High density lipoprotein increased	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Intraocular pressure increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Liver function test increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Low density lipoprotein increased	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymphocyte count decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Mammogram abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Mean cell haemoglobin decreased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mean cell volume decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Mean cell volume increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Monocyte count increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Platelet count decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Platelet count increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Prostatic specific antigen increased	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Respiratory rate increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
SARS-CoV-2 antibody test positive	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Serum ferritin decreased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Thyroid function test abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Troponin increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urine ketone body present	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Weight decreased	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Weight increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
White blood cell count increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
White blood cells urine positive	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	125	1.6	(1.3, 1.9)	113	1.4	(1.2, 1.7)
Decreased appetite	38	0.5	(0.3, 0.6)	9	0.1	(0.1, 0.2)
Dehydration	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Diabetes mellitus	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Diabetic ketoacidosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dyslipidaemia	7	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Fluid retention	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Folate deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Food intolerance	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Glucose tolerance impaired	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Gout	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hypercholesterolaemia	7	0.1	(0.0, 0.2)	20	0.3	(0.2, 0.4)
Hyperglycaemia	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Hyperkalaemia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperlipidaemia	8	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Hypernatraemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypertriglyceridaemia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperuricaemia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypocalcaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypocholesterolaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoglycaemia	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hypokalaemia	6	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Hyponatraemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypovolaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Impaired fasting glucose	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Increased appetite	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Insulin resistance	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Iron deficiency	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lactic acidosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Obesity	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Polydipsia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Type 2 diabetes mellitus	14	0.2	(0.1, 0.3)	13	0.2	(0.1, 0.3)
Vitamin B12 deficiency	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Vitamin D deficiency	12	0.1	(0.1, 0.3)	10	0.1	(0.1, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1801	22.4	(21.4, 23.5)	607	7.7	(7.1, 8.3)
Arthralgia	272	3.4	(3.0, 3.8)	120	1.5	(1.3, 1.8)
Arthritis	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Arthritis reactive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Arthropathy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Axillary mass	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Back pain	98	1.2	(1.0, 1.5)	97	1.2	(1.0, 1.5)
Bone disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bone pain	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Bone swelling	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bursitis	10	0.1	(0.1, 0.2)	5	0.1	(0.0, 0.1)
Coccydynia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Costochondritis	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dupuytren's contracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Exostosis	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Fibromyalgia	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Flank pain	3	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Groin pain	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc compression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intervertebral disc degeneration	4	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Intervertebral disc disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	9	0.1	(0.1, 0.2)	11	0.1	(0.1, 0.2)
Joint effusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Joint instability	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Joint range of motion decreased	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Joint stiffness	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Joint swelling	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Limb discomfort	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Metatarsalgia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Mobility decreased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Muscle contracture	3	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Muscle discomfort	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Muscle fatigue	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle spasms	26	0.3	(0.2, 0.5)	14	0.2	(0.1, 0.3)
Muscle tightness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Muscle twitching	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscular weakness	13	0.2	(0.1, 0.3)	3	0.0	(0.0, 0.1)
Musculoskeletal chest pain	10	0.1	(0.1, 0.2)	7	0.1	(0.0, 0.2)
Musculoskeletal discomfort	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Musculoskeletal pain	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Musculoskeletal stiffness	11	0.1	(0.1, 0.2)	6	0.1	(0.0, 0.2)
Myalgia	1213	15.1	(14.3, 16.0)	163	2.1	(1.8, 2.4)
Myalgia intercostal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Neck pain	34	0.4	(0.3, 0.6)	36	0.5	(0.3, 0.6)
Osteitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteoarthritis	15	0.2	(0.1, 0.3)	23	0.3	(0.2, 0.4)
Osteochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Osteochondrosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Osteopenia	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Osteoporosis	0	0.0	(0.0, 0.0)	6	0.1	(0.0, 0.2)
Pain in extremity	184	2.3	(2.0, 2.6)	50	0.6	(0.5, 0.8)
Pain in jaw	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Patellofemoral pain syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Periarthritis	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Plantar fasciitis	4	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Polyarthritis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Psoriatic arthropathy	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Rhabdomyolysis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rheumatoid arthritis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Rotator cuff syndrome	5	0.1	(0.0, 0.1)	13	0.2	(0.1, 0.3)
Scoliosis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Sinus tarsi syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spinal disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spinal osteoarthritis	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Spinal stenosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spondylitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spondylolisthesis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Synovial cyst	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Synovitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Systemic lupus erythematosus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Temporomandibular joint syndrome	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Tendon disorder	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tendon pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tendonitis	12	0.1	(0.1, 0.3)	10	0.1	(0.1, 0.2)
Tenosynovitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tenosynovitis stenosans	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Torticollis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Trigger finger	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	65	0.8	(0.6, 1.0)	66	0.8	(0.6, 1.1)
Acrochordon	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Acute myeloid leukaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma pancreas	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenoma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adrenal gland cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
B-cell lymphoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Basal cell carcinoma	3	0.0	(0.0, 0.1)	10	0.1	(0.1, 0.2)
Benign breast neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Benign hydatidiform mole	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Benign pancreatic neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Benign uterine neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary cancer metastatic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bladder cancer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Borderline serous tumour of ovary	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Breast cancer	2	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Breast cancer in situ	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Breast cancer stage I	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Carcinoid tumour of the stomach	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chondroma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Colon adenoma	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Fibroadenoma of breast	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Gallbladder cancer stage II	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastric cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Glomus tumour	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haemangioma of skin	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Infected naevus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Invasive ductal breast carcinoma	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Leydig cell tumour of the testis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lipoma	4	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Lobular breast carcinoma in situ	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lung adenocarcinoma	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphoproliferative disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Malignant melanoma	3	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Malignant melanoma of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Meningioma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Meningioma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to liver	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Non-Hodgkin's lymphoma recurrent	0	0.0	(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, 0.0)
Oropharyngeal cancer recurrent	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oropharyngeal squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ovarian germ cell teratoma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pancreatic carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Papillary serous endometrial carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Papillary thyroid cancer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Penile neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Penile squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Plasma cell myeloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Polycythaemia vera	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Prostate cancer	5	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Prostate cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Seborrhoeic keratosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin papilloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Squamous cell carcinoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Squamous cell carcinoma of head and neck	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Squamous cell carcinoma of skin	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Teratoma	0	0.0	(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, 0.0)
Tonsil cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Transitional cell carcinoma	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Uterine cancer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Uterine leiomyoma	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	1554	19.3	(18.4, 20.3)	618	7.8	(7.2, 8.5)
Ageusia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Amnesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Amyotrophic lateral sclerosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Aphasia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Balance disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Burning sensation	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Carpal tunnel syndrome	1	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Cerebellar infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebral atrophy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebral capillary telangiectasia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebral infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebrovascular accident	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cervical radiculopathy	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Cervicogenic headache	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dementia Alzheimer's type	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Depressed level of consciousness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diabetic neuropathy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Disturbance in attention	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dizziness	76	0.9	(0.7, 1.2)	63	0.8	(0.6, 1.0)
Dizziness postural	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug withdrawal headache	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dysgeusia	12	0.1	(0.1, 0.3)	8	0.1	(0.0, 0.2)
Dyskinesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dystonia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Facial paralysis	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial paresis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Generalised tonic-clonic seizure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Guillain-Barre syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haemorrhagic stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Head discomfort	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Headache	1310	16.3	(15.4, 17.2)	414	5.2	(4.7, 5.8)
Hemiplegic migraine	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hyperaesthesia	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypersomnia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoaesthesia	5	0.1	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Hypogeusia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hyposmia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Idiopathic intracranial hypertension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intraventricular haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ischaemic stroke	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lethargy	25	0.3	(0.2, 0.5)	6	0.1	(0.0, 0.2)
Mental impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Migraine	25	0.3	(0.2, 0.5)	12	0.2	(0.1, 0.3)
Migraine with aura	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Migraine without aura	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Morton's neuralgia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Motor dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Muscle spasticity	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Myoclonus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nerve compression	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Neuralgia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neuritis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Neuropathy peripheral	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Nystagmus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Paraesthesia	23	0.3	(0.2, 0.4)	24	0.3	(0.2, 0.5)
Paraparesis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Parkinsonism	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Parosmia	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Periodic limb movement disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peripheral nerve lesion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Peripheral sensory neuropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Piriformis syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post herpetic neuralgia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Presyncope	7	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Radiculopathy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Restless legs syndrome	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sciatic nerve neuropathy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Sciatica	13	0.2	(0.1, 0.3)	11	0.1	(0.1, 0.2)
Seizure	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinus headache	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Somnolence	8	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Spinal cord compression	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subarachnoid haemorrhage	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Syncope	14	0.2	(0.1, 0.3)	13	0.2	(0.1, 0.3)
Taste disorder	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tension headache	11	0.1	(0.1, 0.2)	8	0.1	(0.0, 0.2)
Thoracic radiculopathy	0	0.0	(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, 0.0)
Transient ischaemic attack	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Tremor	9	0.1	(0.1, 0.2)	6	0.1	(0.0, 0.2)
Trigeminal neuralgia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
VIth nerve paralysis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Abortion incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abortion spontaneous	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
PRODUCT ISSUES	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Device breakage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Device connection issue	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	108	1.3	(1.1, 1.6)	107	1.4	(1.1, 1.6)
Abnormal dreams	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adjustment disorder with depressed mood	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Alcohol abuse	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Alcohol withdrawal syndrome	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Anxiety	26	0.3	(0.2, 0.5)	31	0.4	(0.3, 0.6)
Anxiety disorder	4	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Attention deficit hyperactivity disorder	4	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Bipolar disorder	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Bruxism	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Confusional state	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cyclothymic disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Depressed mood	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Depression	22	0.3	(0.2, 0.4)	25	0.3	(0.2, 0.5)
Depression suicidal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Disorientation	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dysphemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastrointestinal somatic symptom disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Generalised anxiety disorder	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Insomnia	24	0.3	(0.2, 0.4)	13	0.2	(0.1, 0.3)
Irritability	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Libido decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Libido increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Listless	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Major depression	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mental disorder	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Mental fatigue	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mental status changes	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Mood swings	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nightmare	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Panic attack	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Panic disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Panic reaction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Paranoia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post-traumatic stress disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Restlessness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Schizophrenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sleep disorder	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Stress	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Substance abuse	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Suicidal ideation	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Suicide attempt	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	52	0.6	(0.5, 0.8)	48	0.6	(0.4, 0.8)
Acute kidney injury	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Bladder spasm	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chronic kidney disease	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Costovertebral angle tenderness	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dysuria	8	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Haematuria	5	0.1	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Hydronephrosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypertonic bladder	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Micturition urgency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Nephrolithiasis	14	0.2	(0.1, 0.3)	15	0.2	(0.1, 0.3)
Nocturia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Obstructive nephropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oedematous kidney	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Perinephric oedema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pollakiuria	5	0.1	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Polyuria	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Renal atrophy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Renal colic	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Renal cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Renal cyst haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Renal failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subcapsular renal haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ureterolithiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urethral discharge	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Urethral stenosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urinary bladder polyp	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Urinary retention	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Urinary tract obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urine odour abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vesical fistula	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	48	0.6	(0.4, 0.8)	55	0.7	(0.5, 0.9)
Adenomyosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Adnexal torsion	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Amenorrhoea	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Benign prostatic hyperplasia	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Breast calcifications	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Breast cyst	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Breast hyperplasia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Breast mass	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Breast pain	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cervical dysplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cervical polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dysfunctional uterine bleeding	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dysmenorrhoea	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Ejaculation disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Endometriosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Erectile dysfunction	0	0.0	(0.0, 0.0)	6	0.1	(0.0, 0.2)
Genital erythema	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haematospermia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haemorrhagic ovarian cyst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mammary duct ectasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Menometrorrhagia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Menorrhagia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Menstruation delayed	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Menstruation irregular	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metrorrhagia	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Nipple pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ovarian cyst	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ovarian mass	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pelvic pain	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Penile vein thrombosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Polycystic ovaries	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Postmenopausal haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Premenstrual syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Prostatitis	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Prostatomegaly	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pruritus genital	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectocele	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Scrotal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Testicular pain	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Testicular torsion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Uterine haemorrhage	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Uterine inflammation	0	0.0	(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, 0.0)
Vaginal discharge	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vaginal haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaginal prolapse	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vulvovaginal pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	218	2.7	(2.4, 3.1)	188	2.4	(2.0, 2.7)
Acute respiratory failure	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Allergic respiratory disease	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Allergic sinusitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Asthma	15	0.2	(0.1, 0.3)	9	0.1	(0.1, 0.2)
Asthma exercise induced	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Asthmatic crisis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atelectasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bronchospasm	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	6	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cough	20	0.2	(0.2, 0.4)	15	0.2	(0.1, 0.3)
Dry throat	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dysphonia	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Dyspnoea	6	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Dyspnoea exertional	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Emphysema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Epistaxis	6	0.1	(0.0, 0.2)	9	0.1	(0.1, 0.2)
Haemoptysis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hiccups	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypoxia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Interstitial lung disease	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lung infiltration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nasal congestion	29	0.4	(0.2, 0.5)	32	0.4	(0.3, 0.6)
Nasal discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Nasal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Nasal polyps	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal septum deviation	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal turbinate hypertrophy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nasal valve collapse	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nasopharyngeal polyp	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oropharyngeal discomfort	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Oropharyngeal pain	35	0.4	(0.3, 0.6)	29	0.4	(0.2, 0.5)
Paranasal sinus discomfort	4	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Paranasal sinus hypersecretion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pharyngeal lesion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pharyngeal swelling	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Pleurisy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pleuritic pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pneumonia aspiration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pneumothorax	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Productive cough	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pulmonary embolism	7	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Pulmonary hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pulmonary mass	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Pulmonary oedema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pulmonary pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Reflux laryngitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Respiratory failure	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory tract congestion	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Rhinalgia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rhinitis allergic	13	0.2	(0.1, 0.3)	13	0.2	(0.1, 0.3)
Rhinitis perennial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rhinorrhoea	21	0.3	(0.2, 0.4)	11	0.1	(0.1, 0.2)
Sinus congestion	6	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Sinus disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Sleep apnoea syndrome	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Sneezing	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Snoring	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sputum discoloured	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Throat irritation	7	0.1	(0.0, 0.2)	9	0.1	(0.1, 0.2)
Tonsillar hypertrophy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Upper respiratory tract congestion	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper-airway cough syndrome	8	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Wheezing	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	249	3.1	(2.7, 3.5)	187	2.4	(2.0, 2.7)
Acne	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Acne cystic	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Actinic keratosis	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Alopecia	5	0.1	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Alopecia areata	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Angioedema	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blister	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Cold sweat	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dermal cyst	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis	5	0.1	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Dermatitis acneiform	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dermatitis allergic	3	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Dermatitis atopic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dermatitis bullous	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dermatitis contact	14	0.2	(0.1, 0.3)	21	0.3	(0.2, 0.4)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dermatitis exfoliative	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diabetic foot	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug eruption	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Dyshidrotic eczema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ecchymosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Eczema	7	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Erythema	9	0.1	(0.1, 0.2)	2	0.0	(0.0, 0.1)
Erythema nodosum	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fixed eruption	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hand dermatitis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hangnail	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hidradenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperhidrosis	31	0.4	(0.3, 0.5)	9	0.1	(0.1, 0.2)
Ingrowing nail	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Lipodystrophy acquired	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Livedo reticularis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Macule	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mechanical urticaria	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Night sweats	17	0.2	(0.1, 0.3)	3	0.0	(0.0, 0.1)
Onycholysis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Onychomadesis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pain of skin	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peau d'orange	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Perioral dermatitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pityriasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pityriasis rosea	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Pruritus	23	0.3	(0.2, 0.4)	18	0.2	(0.1, 0.4)
Pruritus allergic	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Pseudofolliculitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Psoriasis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Purpura	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Rash	61	0.8	(0.6, 1.0)	51	0.6	(0.5, 0.8)
Rash erythematous	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Rash maculo-papular	7	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.1)
Rash papular	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rash pruritic	8	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Rosacea	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Seborrhoeic dermatitis	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Skin discolouration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin induration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Skin irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin lesion	3	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Skin mass	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Stasis dermatitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Urticaria	18	0.2	(0.1, 0.4)	15	0.2	(0.1, 0.3)
Urticaria contact	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
High risk sexual behaviour	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Menopause	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Miscarriage of partner	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	33	0.4	(0.3, 0.6)	26	0.3	(0.2, 0.5)
Abortion induced	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Apicectomy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Botulinum toxin injection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac pacemaker replacement	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardioversion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Carpal tunnel decompression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cataract operation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Chondroplasty	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dental care	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Dental implantation	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Drug titration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Endodontic procedure	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facet joint block	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Finger amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Gingival operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Inguinal hernia repair	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lacrimal duct procedure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lens extraction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mammoplasty	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Medical device implantation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nasal polypectomy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Open reduction of fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Postoperative care	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Retinal operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Rhinoplasty	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rotator cuff repair	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sclerotherapy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin neoplasm excision	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Toe amputation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Toe operation	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Tonsillectomy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tooth extraction	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Vasectomy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Wisdom teeth removal	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Wound drainage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
VASCULAR DISORDERS	106	1.3	(1.1, 1.6)	115	1.5	(1.2, 1.7)
Accelerated hypertension	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Aortic aneurysm	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Aortic dilatation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Aortic rupture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Aortic stenosis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Arteriosclerosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blood pressure inadequately controlled	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Deep vein thrombosis	6	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Diastolic hypertension	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Essential hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Flushing	11	0.1	(0.1, 0.2)	2	0.0	(0.0, 0.1)
Haematoma	4	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hot flush	7	0.1	(0.0, 0.2)	9	0.1	(0.1, 0.2)
Hypertension	57	0.7	(0.5, 0.9)	66	0.8	(0.6, 1.1)
Hypertensive crisis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertensive emergency	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypertensive urgency	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypotension	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Intermittent claudication	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphoedema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lymphorrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Orthostatic hypotension	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Pallor	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Peripheral arterial occlusive disease	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Peripheral artery stenosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Phlebitis superficial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Phlebolith	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Raynaud's phenomenon	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subgaleal haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Systolic hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Thrombophlebitis superficial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Varicose vein	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Venous thrombosis limb	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.123. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 unb base p3 saf

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	1853	78.4	(74.9, 82.0)	1127	47.9	(45.1, 50.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	42	1.8	(1.3, 2.4)	9	0.4	(0.2, 0.7)
Anaemia	2	0.1	(0.0, 0.3)	4	0.2	(0.0, 0.4)
Iron deficiency anaemia	4	0.2	(0.0, 0.4)	2	0.1	(0.0, 0.3)
Leukopenia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Lymph node pain	3	0.1	(0.0, 0.4)	0	0.0	(0.0, 0.2)
Lymphadenopathy	32	1.4	(0.9, 1.9)	3	0.1	(0.0, 0.4)
Lymphadenopathy mediastinal	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
CARDIAC DISORDERS	19	0.8	(0.5, 1.3)	22	0.9	(0.6, 1.4)
Acute coronary syndrome	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Acute myocardial infarction	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Angina pectoris	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Angina unstable	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Aortic valve incompetence	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Arrhythmia	0	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.4)
Arrhythmia supraventricular	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Arteriosclerosis coronary artery	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Atrial fibrillation	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Bundle branch block right	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Cardiac disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Cardio-respiratory arrest	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Coronary artery disease	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Myocarditis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Palpitations	4	0.2	(0.0, 0.4)	8	0.3	(0.1, 0.7)
Pericarditis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Sinus tachycardia	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Supraventricular tachycardia	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Tachycardia	3	0.1	(0.0, 0.4)	2	0.1	(0.0, 0.3)
Tricuspid valve incompetence	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Ventricular extrasystoles	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Arnold-Chiari malformation	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Congenital bladder neck obstruction	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
EAR AND LABYRINTH DISORDERS	27	1.1	(0.8, 1.7)	19	0.8	(0.5, 1.3)
Allergic otitis media	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Cerumen impaction	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Deafness	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Deafness neurosensory	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Deafness unilateral	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Ear pain	5	0.2	(0.1, 0.5)	0	0.0	(0.0, 0.2)
Eustachian tube dysfunction	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Meniere's disease	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Otorrhoea	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Sudden hearing loss	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Tinnitus	4	0.2	(0.0, 0.4)	5	0.2	(0.1, 0.5)
Tympanic membrane perforation	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Vertigo	8	0.3	(0.1, 0.7)	9	0.4	(0.2, 0.7)
Vertigo positional	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
ENDOCRINE DISORDERS	8	0.3	(0.1, 0.7)	4	0.2	(0.0, 0.4)
Hyperprolactinaemia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Hypothyroidism	5	0.2	(0.1, 0.5)	3	0.1	(0.0, 0.4)
Thyroid mass	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
EYE DISORDERS	18	0.8	(0.5, 1.2)	23	1.0	(0.6, 1.5)
Asthenopia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Astigmatism	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Blepharitis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Blepharospasm	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Cataract	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Chalazion	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Choroidal neovascularisation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Conjunctival haemorrhage	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Conjunctivitis allergic	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Dacryostenosis acquired	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dry eye	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Episcleritis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Eye allergy	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Eye irritation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Eye pain	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Eyelid haematoma	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Eyelid oedema	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Eyelid pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Eyelids pruritus	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Glaucoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Hypermetropia	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Iritis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Keratitis	0	0.0	(0.0, 0.2)	4	0.2	(0.0, 0.4)
Lacrimation increased	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Macular oedema	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Ocular discomfort	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Ocular hyperaemia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Ulcerative keratitis	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Vitreous detachment	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	208	8.8	(7.6, 10.1)	163	6.9	(5.9, 8.1)
Abdominal discomfort	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Abdominal distension	3	0.1	(0.0, 0.4)	1	0.0	(0.0, 0.2)
Abdominal hernia	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Abdominal pain	9	0.4	(0.2, 0.7)	12	0.5	(0.3, 0.9)
Abdominal pain upper	14	0.6	(0.3, 1.0)	5	0.2	(0.1, 0.5)
Acute abdomen	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Anal pruritus	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Angular cheilitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Aphthous ulcer	4	0.2	(0.0, 0.4)	0	0.0	(0.0, 0.2)
Colitis ulcerative	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Constipation	2	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.3)
Dental caries	8	0.3	(0.1, 0.7)	3	0.1	(0.0, 0.4)
Diarrhoea	70	3.0	(2.3, 3.7)	47	2.0	(1.5, 2.7)
Diverticular perforation	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Diverticulum	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Diverticulum intestinal	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Dry mouth	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Dyspepsia	6	0.3	(0.1, 0.6)	8	0.3	(0.1, 0.7)
Dysphagia	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Epiploic appendagitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Faeces soft	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Flatulence	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Food poisoning	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Gastritis	3	0.1	(0.0, 0.4)	11	0.5	(0.2, 0.8)
Gastritis erosive	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Gastrointestinal disorder	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Gastrooesophageal reflux disease	8	0.3	(0.1, 0.7)	11	0.5	(0.2, 0.8)
Gingival bleeding	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Gingival pain	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Glossitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Glossodynia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Haemorrhoids	1	0.0	(0.0, 0.2)	5	0.2	(0.1, 0.5)
Incarcerated inguinal hernia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Inguinal hernia	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Intestinal perforation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Intestinal polyp	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Intra-abdominal fluid collection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Irritable bowel syndrome	4	0.2	(0.0, 0.4)	3	0.1	(0.0, 0.4)
Large intestine polyp	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Lip oedema	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Loose tooth	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Nausea	48	2.0	(1.5, 2.7)	17	0.7	(0.4, 1.2)
Odynophagia	10	0.4	(0.2, 0.8)	6	0.3	(0.1, 0.6)
Oesophageal food impaction	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Oesophageal spasm	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Oral lichenoid reaction	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Oral mucosa haematoma	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Oral pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Palatal disorder	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pancreatic cyst	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pancreatitis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pancreatitis acute	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Paraesthesia oral	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Parotid duct obstruction	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Precancerous lesion of digestive tract	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Proctalgia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Rectal haemorrhage	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Salivary gland mucocoele	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Small intestinal obstruction	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Stomatitis	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.4)
Tongue discolouration	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Tooth disorder	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Toothache	9	0.4	(0.2, 0.7)	16	0.7	(0.4, 1.1)
Umbilical hernia	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Vomiting	13	0.5	(0.3, 0.9)	9	0.4	(0.2, 0.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1092	46.2	(43.5, 49.0)	243	10.3	(9.1, 11.7)
Application site erythema	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Application site pain	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Application site pruritus	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Application site rash	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Application site reaction	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Asthenia	50	2.1	(1.6, 2.8)	20	0.8	(0.5, 1.3)
Axillary pain	6	0.3	(0.1, 0.6)	1	0.0	(0.0, 0.2)
Capsular contracture associated with breast implant	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Chest pain	7	0.3	(0.1, 0.6)	4	0.2	(0.0, 0.4)
Chills	236	10.0	(8.7, 11.3)	29	1.2	(0.8, 1.8)
Cyst	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Discomfort	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Face oedema	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Fatigue	273	11.5	(10.2, 13.0)	91	3.9	(3.1, 4.7)
Feeling hot	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Illness	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Influenza like illness	8	0.3	(0.1, 0.7)	1	0.0	(0.0, 0.2)
Injection site bruising	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Injection site discomfort	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Injection site erythema	48	2.0	(1.5, 2.7)	7	0.3	(0.1, 0.6)
Injection site haematoma	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Injection site haemorrhage	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Injection site induration	3	0.1	(0.0, 0.4)	0	0.0	(0.0, 0.2)
Injection site lymphadenopathy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Injection site oedema	11	0.5	(0.2, 0.8)	0	0.0	(0.0, 0.2)
Injection site pain	632	26.7	(24.7, 28.9)	86	3.7	(2.9, 4.5)
Injection site papule	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Injection site pruritus	6	0.3	(0.1, 0.6)	3	0.1	(0.0, 0.4)
Injection site reaction	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Injection site swelling	22	0.9	(0.6, 1.4)	5	0.2	(0.1, 0.5)
Injection site warmth	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Malaise	30	1.3	(0.9, 1.8)	1	0.0	(0.0, 0.2)
Medical device site granuloma	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Nodule	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Non-cardiac chest pain	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Oedema peripheral	3	0.1	(0.0, 0.4)	2	0.1	(0.0, 0.3)
Pain	101	4.3	(3.5, 5.2)	15	0.6	(0.4, 1.1)
Peripheral swelling	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Pyrexia	376	15.9	(14.3, 17.6)	15	0.6	(0.4, 1.1)
Sensation of foreign body	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Swelling	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Swelling face	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Thirst	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Vascular stent occlusion	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Vessel puncture site haematoma	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	9	0.4	(0.2, 0.7)	6	0.3	(0.1, 0.6)
Bile duct stone	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Biliary colic	3	0.1	(0.0, 0.4)	0	0.0	(0.0, 0.2)
Biliary dyskinesia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Cholecystitis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Cholecystitis acute	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Cholecystitis chronic	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Cholelithiasis	3	0.1	(0.0, 0.4)	3	0.1	(0.0, 0.4)
Hepatic cirrhosis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	4	0.2	(0.0, 0.4)	13	0.6	(0.3, 0.9)
Allergy to arthropod bite	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Drug hypersensitivity	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.4)
Food allergy	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hypersensitivity	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Jarisch-Herxheimer reaction	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Seasonal allergy	1	0.0	(0.0, 0.2)	6	0.3	(0.1, 0.6)
INFECTIONS AND INFESTATIONS	134	5.7	(4.7, 6.7)	162	6.9	(5.9, 8.0)
Abdominal abscess	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Abscess limb	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Acarodermatitis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Acute sinusitis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Anal fistula infection	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Appendicitis	7	0.3	(0.1, 0.6)	5	0.2	(0.1, 0.5)
Arthritis bacterial	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Bacterial vulvovaginitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Balanitis candida	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Bartholinitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Bone abscess	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Bronchitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
COVID-19	0	0.0	(0.0, 0.2)	6	0.3	(0.1, 0.6)
Cellulitis	1	0.0	(0.0, 0.2)	8	0.3	(0.1, 0.7)
Chlamydial infection	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Complicated appendicitis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Conjunctivitis	4	0.2	(0.0, 0.4)	3	0.1	(0.0, 0.4)
Conjunctivitis bacterial	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Cystitis	1	0.0	(0.0, 0.2)	6	0.3	(0.1, 0.6)
Dental fistula	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Device related infection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Diverticulitis	1	0.0	(0.0, 0.2)	4	0.2	(0.0, 0.4)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Ear infection	3	0.1	(0.0, 0.4)	6	0.3	(0.1, 0.6)
Emphysematous cholecystitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Erysipelas	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Extradural abscess	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Eye infection	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Eye infection bacterial	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Folliculitis	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Furuncle	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Gangrene	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Gastroenteritis	2	0.1	(0.0, 0.3)	5	0.2	(0.1, 0.5)
Genital herpes	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Genital herpes simplex	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Genitourinary chlamydia infection	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Gingivitis	6	0.3	(0.1, 0.6)	2	0.1	(0.0, 0.3)
Gonorrhoea	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Helicobacter gastritis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Helicobacter infection	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Hepatitis A	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Herpes simplex	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Herpes zoster	3	0.1	(0.0, 0.4)	5	0.2	(0.1, 0.5)
Herpes zoster cutaneous disseminated	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hordeolum	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Infected dermal cyst	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Influenza	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Laryngitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Mastitis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Onychomycosis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Ophthalmic herpes zoster	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Oral candidiasis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Oral herpes	2	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.4)
Orchitis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Otitis externa	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Otitis media	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Otitis media acute	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Papilloma viral infection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Paronychia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Parotitis	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Penile infection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Periodontitis	3	0.1	(0.0, 0.4)	3	0.1	(0.0, 0.4)
Peritonitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Pharyngitis	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Pharyngitis bacterial	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pharyngitis streptococcal	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Pharyngotonsillitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Pilonidal cyst	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Pneumonia	1	0.0	(0.0, 0.2)	4	0.2	(0.0, 0.4)
Postoperative wound infection	2	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.3)
Primary syphilis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pustule	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Pyelonephritis	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Rash pustular	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Renal abscess	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Rhinitis	5	0.2	(0.1, 0.5)	6	0.3	(0.1, 0.6)
Sepsis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Septic shock	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Shigella sepsis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Sialoadenitis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Sinusitis	3	0.1	(0.0, 0.4)	4	0.2	(0.0, 0.4)
Sinusitis bacterial	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Skin infection	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Soft tissue infection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Staphylococcal sepsis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Subacute endocarditis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Tinea versicolour	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Tonsillitis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Tonsillitis bacterial	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Tooth abscess	4	0.2	(0.0, 0.4)	2	0.1	(0.0, 0.3)
Tooth infection	17	0.7	(0.4, 1.2)	23	1.0	(0.6, 1.5)
Upper respiratory tract infection	2	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.3)
Urinary tract infection	18	0.8	(0.5, 1.2)	16	0.7	(0.4, 1.1)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Urosepsis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Vaginal infection	0	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.4)
Viral upper respiratory tract infection	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Vulvovaginal candidiasis	3	0.1	(0.0, 0.4)	1	0.0	(0.0, 0.2)
Vulvovaginal mycotic infection	3	0.1	(0.0, 0.4)	2	0.1	(0.0, 0.3)
Vulvovaginitis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	64	2.7	(2.1, 3.5)	115	4.9	(4.0, 5.9)
Animal bite	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Ankle fracture	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Arthropod bite	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Arthropod sting	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Bone fissure	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Burns first degree	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Burns second degree	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Cervical vertebral fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Chest injury	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Concussion	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Contusion	4	0.2	(0.0, 0.4)	7	0.3	(0.1, 0.6)
Corneal abrasion	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Craniocerebral injury	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Dental restoration failure	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Epicondylitis	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Exposure during pregnancy	11	0.5	(0.2, 0.8)	19	0.8	(0.5, 1.3)
Eyelid injury	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Facial bones fracture	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Fall	12	0.5	(0.3, 0.9)	13	0.6	(0.3, 0.9)
Femur fracture	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Fibula fracture	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Foot fracture	2	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.4)
Forearm fracture	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Foreign body aspiration	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hand fracture	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Head injury	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Heat stroke	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Humerus fracture	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Joint dislocation	3	0.1	(0.0, 0.4)	1	0.0	(0.0, 0.2)
Joint injury	0	0.0	(0.0, 0.2)	6	0.3	(0.1, 0.6)
Ligament injury	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Ligament rupture	0	0.0	(0.0, 0.2)	4	0.2	(0.0, 0.4)
Ligament sprain	2	0.1	(0.0, 0.3)	9	0.4	(0.2, 0.7)
Limb injury	4	0.2	(0.0, 0.4)	6	0.3	(0.1, 0.6)
Lumbar vertebral fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Maternal exposure during pregnancy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Meniscus injury	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.4)
Multiple injuries	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Muscle rupture	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Muscle strain	3	0.1	(0.0, 0.4)	4	0.2	(0.0, 0.4)
Patella fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Penis injury	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Pharyngeal perforation	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Post procedural discomfort	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Post procedural haemorrhage	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Postoperative ileus	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Procedural dizziness	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Procedural haemorrhage	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Procedural hypotension	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Procedural pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Radius fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Road traffic accident	6	0.3	(0.1, 0.6)	6	0.3	(0.1, 0.6)
Skin abrasion	2	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.3)
Skin injury	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Skin laceration	2	0.1	(0.0, 0.3)	5	0.2	(0.1, 0.5)
Spinal compression fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Spinal cord injury cervical	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Stress fracture	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Tendon injury	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Thermal burn	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Tibia fracture	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Tooth fracture	1	0.0	(0.0, 0.2)	7	0.3	(0.1, 0.6)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Ulna fracture	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Vulvovaginal injury	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Wound	2	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.3)
Wrist fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
INVESTIGATIONS	46	1.9	(1.4, 2.6)	10	0.4	(0.2, 0.8)
Alanine aminotransferase increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Aspartate aminotransferase increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Blood cholesterol increased	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Blood glucose abnormal	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Blood glucose increased	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Blood immunoglobulin E increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Body temperature	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Body temperature increased	36	1.5	(1.1, 2.1)	7	0.3	(0.1, 0.6)
C-reactive protein	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Electrocardiogram QT prolonged	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Heart rate increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Low density lipoprotein increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
SARS-CoV-2 antibody test positive	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Weight decreased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	39	1.6	(1.2, 2.3)	49	2.1	(1.5, 2.8)
Decreased appetite	7	0.3	(0.1, 0.6)	1	0.0	(0.0, 0.2)
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Dyslipidaemia	4	0.2	(0.0, 0.4)	7	0.3	(0.1, 0.6)
Glucose tolerance impaired	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Gout	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hypercholesterolaemia	4	0.2	(0.0, 0.4)	11	0.5	(0.2, 0.8)
Hyperglycaemia	2	0.1	(0.0, 0.3)	4	0.2	(0.0, 0.4)
Hyperlipidaemia	4	0.2	(0.0, 0.4)	1	0.0	(0.0, 0.2)
Hypertriglyceridaemia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Hyperuricaemia	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Hypocalcaemia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Hypocholesterolaemia	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hypoglycaemia	2	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.3)
Hypokalaemia	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hyponatraemia	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Insulin resistance	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Polydipsia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Type 2 diabetes mellitus	5	0.2	(0.1, 0.5)	5	0.2	(0.1, 0.5)
Vitamin B12 deficiency	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Vitamin D deficiency	5	0.2	(0.1, 0.5)	7	0.3	(0.1, 0.6)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	513	21.7	(19.9, 23.7)	219	9.3	(8.1, 10.6)
Arthralgia	76	3.2	(2.5, 4.0)	42	1.8	(1.3, 2.4)
Arthritis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Arthritis reactive	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Arthropathy	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Back pain	50	2.1	(1.6, 2.8)	50	2.1	(1.6, 2.8)
Bone swelling	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Bursitis	4	0.2	(0.0, 0.4)	1	0.0	(0.0, 0.2)
Coccydynia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Costochondritis	3	0.1	(0.0, 0.4)	0	0.0	(0.0, 0.2)
Exostosis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Flank pain	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Groin pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Intervertebral disc degeneration	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Intervertebral disc protrusion	4	0.2	(0.0, 0.4)	4	0.2	(0.0, 0.4)
Joint swelling	2	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.3)
Limb discomfort	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Muscle contracture	4	0.2	(0.0, 0.4)	8	0.3	(0.1, 0.7)
Muscle spasms	9	0.4	(0.2, 0.7)	3	0.1	(0.0, 0.4)
Muscular weakness	4	0.2	(0.0, 0.4)	0	0.0	(0.0, 0.2)
Musculoskeletal chest pain	3	0.1	(0.0, 0.4)	3	0.1	(0.0, 0.4)
Musculoskeletal discomfort	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Myalgia	323	13.7	(12.2, 15.2)	68	2.9	(2.2, 3.7)
Neck pain	13	0.5	(0.3, 0.9)	17	0.7	(0.4, 1.2)
Osteitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Osteoarthritis	0	0.0	(0.0, 0.2)	5	0.2	(0.1, 0.5)
Osteochondritis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Osteopenia	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Osteoporosis	0	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.4)
Pain in extremity	47	2.0	(1.5, 2.6)	9	0.4	(0.2, 0.7)
Pain in jaw	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Periarthritis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Plantar fasciitis	2	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.4)
Rhabdomyolysis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Rheumatoid arthritis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Rotator cuff syndrome	3	0.1	(0.0, 0.4)	3	0.1	(0.0, 0.4)
Spinal osteoarthritis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Spondylitis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Synovial cyst	2	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.3)
Synovitis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Systemic lupus erythematosus	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Temporomandibular joint syndrome	0	0.0	(0.0, 0.2)	4	0.2	(0.0, 0.4)
Tendon disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Tendonitis	3	0.1	(0.0, 0.4)	2	0.1	(0.0, 0.3)
Tenosynovitis stenosans	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Torticollis	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Trigger finger	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	22	0.9	(0.6, 1.4)	8	0.3	(0.1, 0.7)
Acrochordon	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Adenocarcinoma of colon	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Benign breast neoplasm	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Benign hydatidiform mole	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Benign pancreatic neoplasm	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Benign uterine neoplasm	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Breast cancer	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Carcinoid tumour of the stomach	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Chondroma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Colon adenoma	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Gastric cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Invasive ductal breast carcinoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Leydig cell tumour of the testis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Lipoma	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Lymphoproliferative disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Malignant melanoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Metastases to central nervous system	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Non-Hodgkin's lymphoma recurrent	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Papillary thyroid cancer	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Plasma cell myeloma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Polycythaemia vera	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Prostate cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Prostate cancer metastatic	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Squamous cell carcinoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Transitional cell carcinoma	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Uterine leiomyoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	408	17.3	(15.6, 19.0)	226	9.6	(8.4, 10.9)
Amyotrophic lateral sclerosis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Burning sensation	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Carpal tunnel syndrome	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.4)
Cervical radiculopathy	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Diabetic neuropathy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Dizziness	20	0.8	(0.5, 1.3)	12	0.5	(0.3, 0.9)
Dysgeusia	3	0.1	(0.0, 0.4)	0	0.0	(0.0, 0.2)
Facial paralysis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Facial paresis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Haemorrhagic stroke	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Head discomfort	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Headache	333	14.1	(12.6, 15.7)	162	6.9	(5.9, 8.0)
Hemiparaesthesia	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hyperaesthesia	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Hypersomnia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Hypoaesthesia	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Idiopathic intracranial hypertension	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Ischaemic stroke	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Lethargy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Migraine	7	0.3	(0.1, 0.6)	4	0.2	(0.0, 0.4)
Migraine with aura	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Myoclonus	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Nerve compression	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Neuritis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Neuropathy peripheral	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Optic neuritis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Paraesthesia	10	0.4	(0.2, 0.8)	11	0.5	(0.2, 0.8)
Parosmia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Peripheral nerve lesion	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Presyncope	4	0.2	(0.0, 0.4)	2	0.1	(0.0, 0.3)
Restless legs syndrome	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Sciatica	7	0.3	(0.1, 0.6)	5	0.2	(0.1, 0.5)
Seizure	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Somnolence	2	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.4)
Subarachnoid haemorrhage	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Syncope	8	0.3	(0.1, 0.7)	3	0.1	(0.0, 0.4)
Tension headache	3	0.1	(0.0, 0.4)	4	0.2	(0.0, 0.4)
Transient ischaemic attack	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Tremor	3	0.1	(0.0, 0.4)	3	0.1	(0.0, 0.4)
Trigeminal neuralgia	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.3)
Abortion incomplete	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Abortion spontaneous	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
PRODUCT ISSUES	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Device breakage	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
PSYCHIATRIC DISORDERS	26	1.1	(0.7, 1.6)	39	1.7	(1.2, 2.3)
Adjustment disorder with depressed mood	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Anxiety	6	0.3	(0.1, 0.6)	8	0.3	(0.1, 0.7)
Anxiety disorder	2	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.4)
Attention deficit hyperactivity disorder	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Bipolar disorder	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Bruxism	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Confusional state	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Depression	3	0.1	(0.0, 0.4)	10	0.4	(0.2, 0.8)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Generalised anxiety disorder	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Insomnia	4	0.2	(0.0, 0.4)	7	0.3	(0.1, 0.6)
Irritability	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Mental disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Nightmare	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Panic attack	2	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.4)
Panic disorder	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Panic reaction	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Schizophrenia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Sleep disorder	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Stress	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
RENAL AND URINARY DISORDERS	15	0.6	(0.4, 1.0)	19	0.8	(0.5, 1.3)
Acute kidney injury	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Bladder spasm	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Chronic kidney disease	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Costovertebral angle tenderness	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Dysuria	3	0.1	(0.0, 0.4)	4	0.2	(0.0, 0.4)
Haematuria	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Hydronephrosis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Nephrolithiasis	2	0.1	(0.0, 0.3)	7	0.3	(0.1, 0.6)
Pollakiuria	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Renal colic	2	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.3)
Renal cyst	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Renal failure	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Subcapsular renal haematoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Ureterolithiasis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Urethral discharge	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Urinary bladder polyp	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Urinary retention	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	24	1.0	(0.7, 1.5)	26	1.1	(0.7, 1.6)
Amenorrhoea	2	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.3)
Benign prostatic hyperplasia	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Breast calcifications	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Breast cyst	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Breast hyperplasia	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Breast pain	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Cervical dysplasia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Dysmenorrhoea	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Ejaculation disorder	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Erectile dysfunction	0	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.4)
Genital erythema	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Haematospermia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Haemorrhagic ovarian cyst	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Mammary duct ectasia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Menorrhagia	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Menstruation delayed	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Menstruation irregular	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Metrorrhagia	2	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.3)
Ovarian cyst	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Pelvic pain	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Penile vein thrombosis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Premenstrual syndrome	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pruritus genital	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Rectocele	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Scrotal pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Testicular pain	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Testicular torsion	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Uterine prolapse	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Vaginal discharge	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Vaginal haemorrhage	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Vaginal prolapse	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Vulvovaginal pruritus	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	59	2.5	(1.9, 3.2)	59	2.5	(1.9, 3.2)
Acute respiratory failure	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Allergic sinusitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Asthma	3	0.1	(0.0, 0.4)	3	0.1	(0.0, 0.4)
Asthmatic crisis	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Bronchospasm	3	0.1	(0.0, 0.4)	1	0.0	(0.0, 0.2)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Cough	4	0.2	(0.0, 0.4)	2	0.1	(0.0, 0.3)
Dysphonia	2	0.1	(0.0, 0.3)	4	0.2	(0.0, 0.4)
Dyspnoea	2	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.4)
Dyspnoea exertional	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Emphysema	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Epistaxis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Interstitial lung disease	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Nasal congestion	7	0.3	(0.1, 0.6)	6	0.3	(0.1, 0.6)
Nasal discomfort	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Nasal polyps	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Nasal septum deviation	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Nasal turbinate hypertrophy	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Nasal valve collapse	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Nasopharyngeal polyp	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Oropharyngeal discomfort	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Oropharyngeal pain	11	0.5	(0.2, 0.8)	2	0.1	(0.0, 0.3)
Paranasal sinus discomfort	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Pharyngeal swelling	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pleuritic pain	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pneumonitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Productive cough	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pulmonary embolism	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Pulmonary mass	0	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.4)
Rhinitis allergic	6	0.3	(0.1, 0.6)	10	0.4	(0.2, 0.8)
Rhinorrhoea	5	0.2	(0.1, 0.5)	6	0.3	(0.1, 0.6)
Sinus disorder	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Sleep apnoea syndrome	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Sneezing	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Snoring	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Throat irritation	2	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.4)
Tonsillar hypertrophy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Upper-airway cough syndrome	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Wheezing	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	65	2.7	(2.1, 3.5)	63	2.7	(2.1, 3.4)
Acne	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Alopecia	1	0.0	(0.0, 0.2)	4	0.2	(0.0, 0.4)
Blister	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Dermal cyst	3	0.1	(0.0, 0.4)	0	0.0	(0.0, 0.2)
Dermatitis	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Dermatitis allergic	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Dermatitis bullous	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Dermatitis contact	2	0.1	(0.0, 0.3)	4	0.2	(0.0, 0.4)
Dermatitis exfoliative	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Eczema	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Erythema	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Erythema nodosum	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Hand dermatitis	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Hyperhidrosis	5	0.2	(0.1, 0.5)	2	0.1	(0.0, 0.3)
Mechanical urticaria	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Night sweats	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pain of skin	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Papule	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Peau d'orange	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pityriasis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Pityriasis rosea	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Pruritus	12	0.5	(0.3, 0.9)	6	0.3	(0.1, 0.6)
Pruritus allergic	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Psoriasis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Rash	14	0.6	(0.3, 1.0)	19	0.8	(0.5, 1.3)
Rash erythematous	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Rash maculo-papular	2	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.4)
Rash papular	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Rash pruritic	4	0.2	(0.0, 0.4)	5	0.2	(0.1, 0.5)
Rosacea	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Seborrhoeic dermatitis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Skin irritation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Skin lesion	2	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.4)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Skin mass	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Urticaria	6	0.3	(0.1, 0.6)	3	0.1	(0.0, 0.4)
Urticaria contact	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
SOCIAL CIRCUMSTANCES	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
High risk sexual behaviour	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
SURGICAL AND MEDICAL PROCEDURES	16	0.7	(0.4, 1.1)	18	0.8	(0.5, 1.2)
Botulinum toxin injection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Cardiac pacemaker replacement	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Cataract operation	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Dental care	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Dental implantation	3	0.1	(0.0, 0.4)	2	0.1	(0.0, 0.3)
Drug titration	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Endodontic procedure	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Finger amputation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Lacrimal duct procedure	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Lens extraction	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Medical device implantation	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Rhinoplasty	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Rotator cuff repair	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Toe operation	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Tonsillectomy	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Tooth extraction	4	0.2	(0.0, 0.4)	5	0.2	(0.1, 0.5)
Vasectomy	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Wisdom teeth removal	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Wound drainage	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
VASCULAR DISORDERS	33	1.4	(1.0, 2.0)	35	1.5	(1.0, 2.1)
Aortic stenosis	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Arteriosclerosis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Blood pressure inadequately controlled	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Deep vein thrombosis	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Diastolic hypertension	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Haematoma	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Hot flush	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Hypertension	18	0.8	(0.5, 1.2)	22	0.9	(0.6, 1.4)

14.124. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hypertensive crisis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hypertensive emergency	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hypertensive urgency	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Hypotension	4	0.2	(0.0, 0.4)	0	0.0	(0.0, 0.2)
Intermittent claudication	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Orthostatic hypotension	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Phlebitis superficial	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Raynaud's phenomenon	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Subgaleal haematoma	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Systolic hypertension	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Varicose vein	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Venous thrombosis limb	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 unb eth p3 saf

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	5073	85.4	(83.1, 87.8)	2422	41.6	(40.0, 43.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	76	1.3	(1.0, 1.6)	22	0.4	(0.2, 0.6)
Anaemia	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Blood loss anaemia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coagulopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypochromic anaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Iron deficiency anaemia	5	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Leukocytosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Leukopenia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymph node pain	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Lymphadenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphadenopathy	55	0.9	(0.7, 1.2)	5	0.1	(0.0, 0.2)
Lymphocytosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphopenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Microcytic anaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Monoclonal B-cell lymphocytosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neutropenia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Splenomegaly	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thrombocytopenia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Thrombocytosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
CARDIAC DISORDERS	68	1.1	(0.9, 1.5)	56	1.0	(0.7, 1.3)
Acute coronary syndrome	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Acute left ventricular failure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Acute myocardial infarction	6	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Angina pectoris	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Angina unstable	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Aortic valve incompetence	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arrhythmia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arteriospasm coronary	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrial fibrillation	11	0.2	(0.1, 0.3)	16	0.3	(0.2, 0.4)
Atrial flutter	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Atrioventricular block complete	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrioventricular block first degree	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Bradycardia	3	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bundle branch block left	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac arrest	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Cardiac failure acute	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	5	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiomegaly	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiovascular disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Coronary artery disease	4	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Coronary artery dissection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Coronary artery occlusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertensive heart disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Left atrial enlargement	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Left ventricular dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Left ventricular hypertrophy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mitral valve incompetence	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Mitral valve prolapse	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myocardial infarction	4	0.1	(0.0, 0.2)	8	0.1	(0.1, 0.3)
Myocardial ischaemia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Palpitations	3	0.1	(0.0, 0.1)	8	0.1	(0.1, 0.3)
Pericardial effusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Postural orthostatic tachycardia syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinus bradycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinus tachycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Supraventricular tachycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tachyarrhythmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tachycardia	12	0.2	(0.1, 0.4)	5	0.1	(0.0, 0.2)
Tricuspid valve incompetence	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ventricular arrhythmia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ventricular extrasystoles	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ventricular tachycardia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Congenital cystic kidney disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Congenital ureteropelvic junction obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Developmental hip dysplasia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal arteriovenous malformation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Heart disease congenital	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Protein S deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Type V hyperlipidaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	49	0.8	(0.6, 1.1)	42	0.7	(0.5, 1.0)
Cerumen impaction	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deafness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deafness neurosensory	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Deafness unilateral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear discomfort	3	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear disorder	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Ear pain	8	0.1	(0.1, 0.3)	11	0.2	(0.1, 0.3)
Ear pruritus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyperacusis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypoacusis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Tinnitus	5	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Vertigo	23	0.4	(0.2, 0.6)	17	0.3	(0.2, 0.5)
Vertigo positional	6	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
ENDOCRINE DISORDERS	9	0.2	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Autoimmune thyroiditis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Goitre	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperthyroidism	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypogonadism	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypothyroidism	3	0.1	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Oestrogen deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Thyroid cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thyroid mass	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
EYE DISORDERS	52	0.9	(0.7, 1.1)	42	0.7	(0.5, 1.0)
Amaurosis fugax	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angle closure glaucoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthenopia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blepharitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blepharospasm	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cataract	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Chalazion	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Conjunctival haemorrhage	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Conjunctival hyperaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Conjunctival oedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Conjunctivitis allergic	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Corneal irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diabetic retinopathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diplopia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dry age-related macular degeneration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dry eye	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Eye haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye inflammation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye irritation	5	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Eye pain	5	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Eye pruritus	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Glaucoma	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Keratitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lacrimation increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Macular oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ocular hyperaemia	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Photophobia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal artery occlusion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal detachment	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Retinal tear	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Scleral discolouration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Swelling of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Uveitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vision blurred	7	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Visual acuity reduced	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Visual impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vitreous detachment	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Vitreous floaters	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
GASTROINTESTINAL DISORDERS	540	9.1	(8.3, 9.9)	344	5.9	(5.3, 6.6)
Abdominal adhesions	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abdominal discomfort	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Abdominal distension	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Abdominal hernia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abdominal pain	14	0.2	(0.1, 0.4)	10	0.2	(0.1, 0.3)
Abdominal pain lower	3	0.1	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Abdominal pain upper	13	0.2	(0.1, 0.4)	10	0.2	(0.1, 0.3)
Abdominal rigidity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abnormal faeces	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aphthous ulcer	5	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Appendix disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cheilitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Chronic gastritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coeliac artery aneurysm	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coeliac disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colitis ischaemic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colitis microscopic	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colitis ulcerative	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Constipation	8	0.1	(0.1, 0.3)	11	0.2	(0.1, 0.3)
Crohn's disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dental caries	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Diarrhoea	185	3.1	(2.7, 3.6)	141	2.4	(2.0, 2.9)
Diverticulum	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diverticulum intestinal	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Diverticulum intestinal haemorrhagic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dry mouth	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Duodenal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Duodenal ulcer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dyspepsia	9	0.2	(0.1, 0.3)	6	0.1	(0.0, 0.2)
Dysphagia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Enterocolitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eructation	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Faeces soft	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Femoral hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Flatulence	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Food poisoning	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Frequent bowel movements	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastric antral vascular ectasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastric polyps	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastric ulcer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastric ulcer haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastritis	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Gastrointestinal disorder	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal haemorrhage	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal mucosa hyperaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastrointestinal sounds abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrooesophageal reflux disease	7	0.1	(0.0, 0.2)	12	0.2	(0.1, 0.4)
Gingival discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gingival pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gingival swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Glossodynia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haematemesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haematochezia	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haemorrhoidal haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haemorrhoids	4	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Hiatus hernia	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Hypoaesthesia oral	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypoaesthesia teeth	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ileus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Impaired gastric emptying	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Inguinal hernia	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Internal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intestinal obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal strangulation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Irritable bowel syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Large intestine perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Large intestine polyp	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Lip swelling	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mouth ulceration	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Nausea	229	3.9	(3.4, 4.4)	70	1.2	(0.9, 1.5)
Noninfective gingivitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Obstructive pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Odynophagia	3	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Oesophageal ulcer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oesophageal varices haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oesophagitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Oral discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oral pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pancreatic failure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis acute	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Paraesthesia oral	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Parotid duct obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peptic ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Proctalgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectal haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rectal polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Retching	3	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retroperitoneal haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Salivary gland calculus	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Small intestinal obstruction	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Stomatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Swollen tongue	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Teething	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tongue discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tongue oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tongue pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tongue ulceration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tooth impacted	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Toothache	17	0.3	(0.2, 0.5)	12	0.2	(0.1, 0.4)
Umbilical hernia	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Varices oesophageal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Volvulus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vomiting	55	0.9	(0.7, 1.2)	26	0.4	(0.3, 0.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3644	61.4	(59.4, 63.4)	763	13.1	(12.2, 14.1)
Adverse drug reaction	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthenia	27	0.5	(0.3, 0.7)	5	0.1	(0.0, 0.2)
Axillary pain	8	0.1	(0.1, 0.3)	2	0.0	(0.0, 0.1)
Chest discomfort	5	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Chest pain	10	0.2	(0.1, 0.3)	12	0.2	(0.1, 0.4)
Chills	1127	19.0	(17.9, 20.1)	92	1.6	(1.3, 1.9)
Chronic fatigue syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cyst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug withdrawal syndrome	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Effusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Exercise tolerance decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Face oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Facial pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fatigue	1190	20.0	(18.9, 21.2)	285	4.9	(4.3, 5.5)
Feeling abnormal	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Feeling cold	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Feeling hot	6	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gait disturbance	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Induration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Inflammation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Influenza like illness	15	0.3	(0.1, 0.4)	3	0.1	(0.0, 0.2)
Injection site bruising	11	0.2	(0.1, 0.3)	17	0.3	(0.2, 0.5)
Injection site dermatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site discolouration	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site discomfort	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Injection site erythema	137	2.3	(1.9, 2.7)	22	0.4	(0.2, 0.6)
Injection site haematoma	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Injection site haemorrhage	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Injection site hyperaesthesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site induration	7	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site macule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site mass	3	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site nodule	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site pain	2278	38.4	(36.8, 40.0)	313	5.4	(4.8, 6.0)
Injection site papule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site paraesthesia	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Injection site plaque	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site pruritus	32	0.5	(0.4, 0.8)	3	0.1	(0.0, 0.2)
Injection site rash	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site reaction	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Injection site swelling	118	2.0	(1.6, 2.4)	18	0.3	(0.2, 0.5)
Injection site urticaria	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site warmth	12	0.2	(0.1, 0.4)	4	0.1	(0.0, 0.2)
Injury associated with device	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Malaise	100	1.7	(1.4, 2.0)	21	0.4	(0.2, 0.6)
Mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Medical device pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mucosal disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nodule	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Non-cardiac chest pain	5	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Oedema peripheral	5	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Pain	524	8.8	(8.1, 9.6)	45	0.8	(0.6, 1.0)
Peripheral swelling	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Pyrexia	1139	19.2	(18.1, 20.3)	63	1.1	(0.8, 1.4)
Sensation of foreign body	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Shoulder injury related to vaccine administration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sluggishness	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sudden cardiac death	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Swelling	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Swelling face	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Temperature intolerance	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Therapeutic response unexpected	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thirst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vaccination site induration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vaccination site pain	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vaccination site swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vessel puncture site bruise	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vessel puncture site haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vessel puncture site induration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	15	0.3	(0.1, 0.4)	10	0.2	(0.1, 0.3)
Bile duct stone	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary colic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary dyskinesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholecystitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholecystitis acute	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Cholelithiasis	8	0.1	(0.1, 0.3)	2	0.0	(0.0, 0.1)
Cirrhosis alcoholic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gallbladder disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hepatic cyst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatic steatosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hepatocellular injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nonalcoholic fatty liver disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	19	0.3	(0.2, 0.5)	21	0.4	(0.2, 0.6)
Allergy to animal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Allergy to arthropod bite	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Allergy to arthropod sting	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anaphylactic shock	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug hypersensitivity	6	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Food allergy	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypersensitivity	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Milk allergy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Seasonal allergy	7	0.1	(0.0, 0.2)	10	0.2	(0.1, 0.3)
INFECTIONS AND INFESTATIONS	280	4.7	(4.2, 5.3)	337	5.8	(5.2, 6.4)
Abscess	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Abscess intestinal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abscess jaw	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess limb	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abscess neck	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abscess oral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Acarodermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Acute sinusitis	1	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Anal abscess	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Appendicitis	7	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Appendicitis perforated	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bacterial blepharitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bacterial infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bacterial rhinitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bacterial sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bacterial vaginosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bacterial vulvovaginitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bartholin's abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blister infected	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Brain abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bronchitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Campylobacter infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Carbuncle	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Catheter site infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cellulitis	14	0.2	(0.1, 0.4)	12	0.2	(0.1, 0.4)
Cellulitis orbital	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chronic sinusitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clostridium difficile infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Complicated appendicitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Conjunctivitis	8	0.1	(0.1, 0.3)	8	0.1	(0.1, 0.3)
Conjunctivitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coxsackie viral infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cystitis	7	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Dermatitis infected	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Device related infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diabetic foot infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulitis	9	0.2	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Ear infection	8	0.1	(0.1, 0.3)	11	0.2	(0.1, 0.3)
Empyema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Escherichia sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Escherichia urinary tract infection	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Folliculitis	5	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Fungal infection	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Fungal skin infection	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Furuncle	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Gastroenteritis	4	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Gastroenteritis viral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Genital herpes	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Gingival abscess	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Gingivitis	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Gonorrhoea	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Groin abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Helicobacter gastritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Helicobacter infection	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hepatitis C	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Herpes simplex	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Herpes virus infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Herpes zoster	15	0.3	(0.1, 0.4)	11	0.2	(0.1, 0.3)
Herpes zoster oticus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hordeolum	6	0.1	(0.0, 0.2)	11	0.2	(0.1, 0.3)
Impetigo	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Infected bite	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Infected dermal cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Infectious mononucleosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Influenza	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Kidney infection	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Labyrinthitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Laryngitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Localised infection	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Lyme disease	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Mastoiditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Meningitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nail infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasopharyngitis	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Onychomycosis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Oral candidiasis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oral fungal infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral herpes	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Oral infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Orchitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteomyelitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Otitis externa	4	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Otitis media	9	0.2	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Otitis media acute	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Otitis media bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papilloma viral infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Parasitic gastroenteritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paronychia	3	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Parotitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pelvic inflammatory disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peritonitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritonsillar abscess	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pharyngitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pharyngitis streptococcal	3	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pharyngotonsillitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonia	3	0.1	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Post procedural infection	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Postoperative wound infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pulmonary tuberculosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Puncture site infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pustule	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pyelonephritis	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Pyelonephritis acute	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Respiratory tract infection viral	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rhinitis	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Sepsis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Septic shock	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sinusitis	17	0.3	(0.2, 0.5)	27	0.5	(0.3, 0.7)
Sinusitis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin bacterial infection	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Skin infection	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Staphylococcal infection	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Subcutaneous abscess	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Syphilis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tinea cruris	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tinea infection	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Tinea versicolour	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tonsillitis	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Tooth abscess	8	0.1	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Tooth infection	8	0.1	(0.1, 0.3)	10	0.2	(0.1, 0.3)
Trichomoniasis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper respiratory tract infection	8	0.1	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Ureaplasma infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urinary tract infection	56	0.9	(0.7, 1.2)	66	1.1	(0.9, 1.4)
Vaginal infection	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Varicella	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Viral infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vulval abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vulvovaginal candidiasis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vulvovaginal mycotic infection	3	0.1	(0.0, 0.1)	8	0.1	(0.1, 0.3)
Vulvovaginitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Wound infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	228	3.8	(3.4, 4.4)	259	4.5	(3.9, 5.0)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Administration related reaction	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Alcohol poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anaemia postoperative	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Animal bite	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Ankle fracture	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Arthropod bite	12	0.2	(0.1, 0.4)	6	0.1	(0.0, 0.2)
Arthropod sting	3	0.1	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Back injury	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bone contusion	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bone fissure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Brain contusion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Burn oral cavity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Burns second degree	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cartilage injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cervical vertebral fracture	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chest injury	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Chillblains	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clavicle fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colon injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Concussion	5	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Contusion	10	0.2	(0.1, 0.3)	15	0.3	(0.1, 0.4)
Corneal abrasion	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Craniocerebral injury	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Delayed recovery from anaesthesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear canal abrasion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Epicondylitis	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Exposure during pregnancy	19	0.3	(0.2, 0.5)	22	0.4	(0.2, 0.6)
Exposure to communicable disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye contusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial bones fracture	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Fall	49	0.8	(0.6, 1.1)	62	1.1	(0.8, 1.4)
Fibula fracture	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Flail chest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foot fracture	5	0.1	(0.0, 0.2)	8	0.1	(0.1, 0.3)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Forearm fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foreign body	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Foreign body in eye	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fractured sacrum	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hand fracture	3	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Head injury	3	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hip fracture	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Humerus fracture	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Jaw fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Joint dislocation	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Joint injury	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Ligament injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ligament rupture	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Ligament sprain	19	0.3	(0.2, 0.5)	18	0.3	(0.2, 0.5)
Limb fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Limb injury	4	0.1	(0.0, 0.2)	10	0.2	(0.1, 0.3)
Limb traumatic amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lip injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lower limb fracture	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Lumbar vertebral fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Maternal exposure before pregnancy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Maternal exposure during breast feeding	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Maternal exposure during pregnancy	3	0.1	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Meniscus injury	5	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Mouth injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle contusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Muscle injury	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Muscle rupture	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Muscle strain	15	0.3	(0.1, 0.4)	13	0.2	(0.1, 0.4)
Overdose	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Patella fracture	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pelvic fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post concussion syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post procedural haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Post procedural swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post-traumatic pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Procedural pain	8	0.1	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Radius fracture	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Respiratory fume inhalation disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rib fracture	3	0.1	(0.0, 0.1)	8	0.1	(0.1, 0.3)
Road traffic accident	10	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.4)
Scapula fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Scar	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin abrasion	6	0.1	(0.0, 0.2)	13	0.2	(0.1, 0.4)
Skin injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin laceration	16	0.3	(0.2, 0.4)	19	0.3	(0.2, 0.5)
Skull fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Soft tissue injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal column injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal compression fracture	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Spinal fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Stab wound	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Stoma site rash	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Stress fracture	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Subdural haematoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sunburn	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tendon injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tendon rupture	0	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Thermal burn	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Tibia fracture	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tooth fracture	8	0.1	(0.1, 0.3)	3	0.1	(0.0, 0.2)
Tooth injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Toxicity to various agents	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Traumatic haemothorax	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ulna fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper limb fracture	3	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vaccination complication	5	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Venom poisoning	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Wound	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Wrist fracture	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
INVESTIGATIONS	136	2.3	(1.9, 2.7)	41	0.7	(0.5, 1.0)
Alanine aminotransferase increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Autoantibody positive	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Biopsy breast normal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood chloride decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood cholesterol increased	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Blood creatinine decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood creatinine increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood glucose abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood glucose fluctuation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood glucose increased	6	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Blood iron decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood potassium decreased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood pressure abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood pressure diastolic increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood pressure increased	6	0.1	(0.0, 0.2)	10	0.2	(0.1, 0.3)
Blood pressure systolic increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood sodium decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood testosterone decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood testosterone increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood thyroid stimulating hormone increased	3	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood triglycerides increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood urea increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Body temperature decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Body temperature increased	84	1.4	(1.1, 1.8)	6	0.1	(0.0, 0.2)
Cardiac stress test abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fractional exhaled nitric oxide increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glomerular filtration rate decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haemoglobin decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Heart rate increased	3	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Heart rate irregular	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatic enzyme increased	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hepatitis C antibody positive	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Herpes simplex test positive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
High density lipoprotein increased	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Intraocular pressure increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Liver function test increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Low density lipoprotein increased	3	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymphocyte count decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mammogram abnormal	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mean cell haemoglobin decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mean cell volume decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mean cell volume increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Monocyte count increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Platelet count decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Platelet count increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Prostatic specific antigen increased	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Red blood cell morphology abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory rate increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
SARS-CoV-2 antibody test positive	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Serum ferritin decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thyroid function test abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Troponin increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urine ketone body present	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Weight decreased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Weight increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
White blood cell count increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
White blood cells urine positive	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	89	1.5	(1.2, 1.8)	68	1.2	(0.9, 1.5)
Decreased appetite	32	0.5	(0.4, 0.8)	8	0.1	(0.1, 0.3)
Dehydration	3	0.1	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Diabetes mellitus	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diabetes mellitus inadequate control	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Diabetic ketoacidosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dyslipidaemia	3	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Fluid retention	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Folate deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Food intolerance	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glucose tolerance impaired	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Gout	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Hypercholesterolaemia	2	0.0	(0.0, 0.1)	10	0.2	(0.1, 0.3)
Hyperglycaemia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hyperkalaemia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperlipidaemia	5	0.1	(0.0, 0.2)	10	0.2	(0.1, 0.3)
Hypernatraemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypertriglyceridaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypocalcaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypocholesterolaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypoglycaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypokalaemia	8	0.1	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Hypomagnesaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyponatraemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypovolaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Impaired fasting glucose	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Increased appetite	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Insulin resistance	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Iron deficiency	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lactic acidosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Obesity	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Polydipsia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Type 2 diabetes mellitus	9	0.2	(0.1, 0.3)	8	0.1	(0.1, 0.3)
Vitamin B12 deficiency	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Vitamin D deficiency	7	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1340	22.6	(21.4, 23.8)	398	6.8	(6.2, 7.5)
Arthralgia	205	3.5	(3.0, 4.0)	78	1.3	(1.1, 1.7)
Arthritis	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Arthropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Axillary mass	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Back pain	54	0.9	(0.7, 1.2)	48	0.8	(0.6, 1.1)
Bone disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bone pain	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Bursitis	7	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Coccydynia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Costochondritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dupuytren's contracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Exostosis	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Fibromyalgia	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Flank pain	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Groin pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc compression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intervertebral disc degeneration	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Intervertebral disc disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	6	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Joint effusion	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Joint instability	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Joint range of motion decreased	5	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Joint stiffness	5	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Joint swelling	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Limb discomfort	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metatarsalgia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Mobility decreased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Muscle discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle fatigue	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Muscle spasms	19	0.3	(0.2, 0.5)	13	0.2	(0.1, 0.4)
Muscle tightness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Muscle twitching	3	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscular weakness	9	0.2	(0.1, 0.3)	3	0.1	(0.0, 0.2)
Musculoskeletal chest pain	8	0.1	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Musculoskeletal discomfort	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Musculoskeletal pain	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Musculoskeletal stiffness	11	0.2	(0.1, 0.3)	6	0.1	(0.0, 0.2)
Myalgia	919	15.5	(14.5, 16.5)	102	1.8	(1.4, 2.1)
Myalgia intercostal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neck pain	21	0.4	(0.2, 0.5)	19	0.3	(0.2, 0.5)
Osteitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteoarthritis	15	0.3	(0.1, 0.4)	18	0.3	(0.2, 0.5)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Osteochondrosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteopenia	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Osteoporosis	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Pain in extremity	141	2.4	(2.0, 2.8)	42	0.7	(0.5, 1.0)
Pain in jaw	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Patellofemoral pain syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Periarthritis	3	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Plantar fasciitis	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Polyarthritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Psoriatic arthropathy	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Rhabdomyolysis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rheumatoid arthritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rotator cuff syndrome	2	0.0	(0.0, 0.1)	10	0.2	(0.1, 0.3)
Scoliosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Sinus tarsi syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal osteoarthritis	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Spinal stenosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spondylitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Spondylolisthesis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Synovial cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Synovitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Temporomandibular joint syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tendon disorder	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tendon pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tendonitis	9	0.2	(0.1, 0.3)	8	0.1	(0.1, 0.3)
Tenosynovitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tenosynovitis stenosans	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Trigger finger	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	45	0.8	(0.6, 1.0)	61	1.0	(0.8, 1.3)
Acrochordon	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Acute myeloid leukaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenocarcinoma pancreas	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Adenoma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adrenal gland cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
B-cell lymphoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Basal cell carcinoma	3	0.1	(0.0, 0.1)	11	0.2	(0.1, 0.3)
Biliary cancer metastatic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bladder cancer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Borderline serous tumour of ovary	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cancer	1	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Breast cancer in situ	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cancer stage I	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colon adenoma	3	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Fibroadenoma of breast	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Gallbladder cancer stage II	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glomus tumour	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haemangioma of skin	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Infected naevus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Invasive ductal breast carcinoma	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lipoma	4	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Lobular breast carcinoma in situ	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lung adenocarcinoma	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Malignant melanoma	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Malignant melanoma of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Meningioma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Meningioma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to liver	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.1)	2	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, 0.1)
Oropharyngeal cancer recurrent	0	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, 0.1)
Ovarian germ cell teratoma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pancreatic carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Papillary serous endometrial carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Penile neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Penile squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Prostate cancer	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Seborrhoeic keratosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin papilloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Squamous cell carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Squamous cell carcinoma of head and neck	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Squamous cell carcinoma of skin	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Teratoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thyroid cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tonsil cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transitional cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Uterine cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uterine leiomyoma	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	1190	20.0	(18.9, 21.2)	408	7.0	(6.3, 7.7)
Ageusia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Amnesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aphasia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Balance disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Burning sensation	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Carpal tunnel syndrome	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Cerebellar infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebral atrophy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebral capillary telangiectasia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebral infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebrovascular accident	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cervical radiculopathy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cervicogenic headache	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dementia Alzheimer's type	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depressed level of consciousness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diabetic neuropathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Disturbance in attention	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dizziness	61	1.0	(0.8, 1.3)	51	0.9	(0.7, 1.2)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dizziness postural	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug withdrawal headache	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dysgeusia	9	0.2	(0.1, 0.3)	8	0.1	(0.1, 0.3)
Dyskinesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dystonia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial paralysis	3	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Generalised tonic-clonic seizure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Guillain-Barre syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Head discomfort	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Headache	1012	17.0	(16.0, 18.1)	267	4.6	(4.1, 5.2)
Hemiplegic migraine	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyperaesthesia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypersomnia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoaesthesia	4	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Hypogeusia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyposmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Idiopathic intracranial hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intraventricular haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ischaemic stroke	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lethargy	24	0.4	(0.3, 0.6)	6	0.1	(0.0, 0.2)
Mental impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Migraine	18	0.3	(0.2, 0.5)	9	0.2	(0.1, 0.3)
Migraine with aura	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Migraine without aura	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Morton's neuralgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Motor dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Muscle spasticity	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nerve compression	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Neuralgia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neuropathy peripheral	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nystagmus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Optic neuritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paraesthesia	13	0.2	(0.1, 0.4)	13	0.2	(0.1, 0.4)
Paraparesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Parkinsonism	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Parosmia	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Periodic limb movement disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peripheral sensory neuropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Piriformis syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post herpetic neuralgia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Presyncope	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Radiculopathy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Restless legs syndrome	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sciatic nerve neuropathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sciatica	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Seizure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sinus headache	3	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Somnolence	7	0.1	(0.0, 0.2)	8	0.1	(0.1, 0.3)
Spinal cord compression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subarachnoid haemorrhage	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Syncope	6	0.1	(0.0, 0.2)	10	0.2	(0.1, 0.3)
Taste disorder	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tension headache	8	0.1	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Thoracic radiculopathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Toxic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transient global amnesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transient ischaemic attack	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tremor	6	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
VIth nerve paralysis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Abortion spontaneous	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retained products of conception	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PRODUCT ISSUES	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Device connection issue	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	86	1.4	(1.2, 1.8)	68	1.2	(0.9, 1.5)
Abnormal dreams	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Alcohol abuse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Alcohol withdrawal syndrome	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Anxiety	21	0.4	(0.2, 0.5)	23	0.4	(0.3, 0.6)
Anxiety disorder	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Attention deficit hyperactivity disorder	3	0.1	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Bipolar disorder	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bruxism	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cyclothymic disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depressed mood	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Depression	20	0.3	(0.2, 0.5)	16	0.3	(0.2, 0.4)
Disorientation	5	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dysphemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal somatic symptom disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Generalised anxiety disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Insomnia	21	0.4	(0.2, 0.5)	6	0.1	(0.0, 0.2)
Irritability	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Libido decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Libido increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Listless	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Major depression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mental disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mental fatigue	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mental status changes	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mood swings	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nightmare	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Panic attack	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Paranoia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post-traumatic stress disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Restlessness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sleep disorder	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Substance abuse	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Suicidal ideation	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Suicide attempt	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	37	0.6	(0.4, 0.9)	29	0.5	(0.3, 0.7)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Acute kidney injury	5	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Bladder spasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chronic kidney disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dysuria	5	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Haematuria	4	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Hydronephrosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertonic bladder	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Micturition urgency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nephrolithiasis	12	0.2	(0.1, 0.4)	8	0.1	(0.1, 0.3)
Nocturia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Obstructive nephropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oedematous kidney	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Perinephric oedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pollakiuria	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Polyuria	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Renal atrophy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Renal cyst haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urethral stenosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urinary retention	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urinary tract obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urine odour abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vesical fistula	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	26	0.4	(0.3, 0.6)	32	0.6	(0.4, 0.8)
Adenomyosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Adnexal torsion	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Amenorrhoea	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Benign prostatic hyperplasia	3	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Breast cyst	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Breast hyperplasia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Breast mass	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Breast pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cervical polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dysfunctional uterine bleeding	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dysmenorrhoea	3	0.1	(0.0, 0.1)	3	0.1	(0.0, 0.2)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Endometriosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Erectile dysfunction	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Menometrorrhagia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Menorrhagia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Menstruation irregular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nipple pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ovarian cyst	3	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ovarian mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pelvic pain	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Polycystic ovaries	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Postmenopausal haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Prostatitis	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Prostatomegaly	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uterine haemorrhage	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Uterine inflammation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaginal haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	165	2.8	(2.4, 3.2)	136	2.3	(2.0, 2.8)
Acute respiratory failure	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Allergic respiratory disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Allergic sinusitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthma	12	0.2	(0.1, 0.4)	6	0.1	(0.0, 0.2)
Asthma exercise induced	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Atelectasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bronchospasm	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	5	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cough	19	0.3	(0.2, 0.5)	13	0.2	(0.1, 0.4)
Dry throat	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dyspnoea	4	0.1	(0.0, 0.2)	8	0.1	(0.1, 0.3)
Dyspnoea exertional	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Epistaxis	5	0.1	(0.0, 0.2)	8	0.1	(0.1, 0.3)
Haemoptysis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hiccups	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypoxia	0	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)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Lung infiltration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal congestion	23	0.4	(0.2, 0.6)	27	0.5	(0.3, 0.7)
Nasal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nasal polyps	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nasal septum deviation	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oropharyngeal discomfort	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oropharyngeal pain	25	0.4	(0.3, 0.6)	29	0.5	(0.3, 0.7)
Paranasal sinus discomfort	3	0.1	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Paranasal sinus hypersecretion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pharyngeal lesion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pharyngeal swelling	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pleurisy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumonia aspiration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumothorax	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Productive cough	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pulmonary embolism	7	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Pulmonary hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pulmonary oedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pulmonary pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Reflux laryngitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory failure	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory tract congestion	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Rhinalgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rhinitis allergic	7	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Rhinitis perennial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rhinorrhoea	16	0.3	(0.2, 0.4)	7	0.1	(0.0, 0.2)
Sinus congestion	6	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Sleep apnoea syndrome	5	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Sneezing	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Snoring	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sputum discoloured	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Throat irritation	5	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Upper respiratory tract congestion	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Upper-airway cough syndrome	7	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Wheezing	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	188	3.2	(2.7, 3.7)	130	2.2	(1.9, 2.7)
Acne	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Acne cystic	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Actinic keratosis	3	0.1	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Alopecia	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Alopecia areata	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angioedema	3	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blister	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Cold sweat	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dermal cyst	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Dermatitis acneiform	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dermatitis allergic	3	0.1	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Dermatitis atopic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis contact	12	0.2	(0.1, 0.4)	17	0.3	(0.2, 0.5)
Diabetic foot	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug eruption	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Dry skin	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dyshidrotic eczema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ecchymosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Eczema	5	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Erythema	8	0.1	(0.1, 0.3)	2	0.0	(0.0, 0.1)
Fixed eruption	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hand dermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hangnail	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hidradenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperhidrosis	26	0.4	(0.3, 0.6)	7	0.1	(0.0, 0.2)
Ingrowing nail	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Intertrigo	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lipodystrophy acquired	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Livedo reticularis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Macule	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Night sweats	17	0.3	(0.2, 0.5)	2	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Onycholysis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Onychomadesis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pain of skin	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Papule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Perioral dermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pityriasis rosea	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pruritus	12	0.2	(0.1, 0.4)	14	0.2	(0.1, 0.4)
Pruritus allergic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pseudofolliculitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Psoriasis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Purpura	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rash	47	0.8	(0.6, 1.1)	33	0.6	(0.4, 0.8)
Rash erythematous	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Rash maculo-papular	5	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Rash papular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rash pruritic	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Rosacea	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Seborrhoeic dermatitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Skin discolouration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin lesion	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Skin mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Stasis dermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Transient acantholytic dermatosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urticaria	12	0.2	(0.1, 0.4)	12	0.2	(0.1, 0.4)
Urticaria papular	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
High risk sexual behaviour	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Menopause	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Miscarriage of partner	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	17	0.3	(0.2, 0.5)	8	0.1	(0.1, 0.3)
Abortion induced	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Apicectomy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardioversion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Carpal tunnel decompression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chondroplasty	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dental implantation	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Endodontic procedure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facet joint block	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gingival operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Inguinal hernia repair	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mammoplasty	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nasal polypectomy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Open reduction of fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Postoperative care	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Retinal operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sclerotherapy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin neoplasm excision	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Toe amputation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Toe operation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tooth extraction	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Wisdom teeth removal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
VASCULAR DISORDERS	78	1.3	(1.0, 1.6)	81	1.4	(1.1, 1.7)
Accelerated hypertension	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Aortic aneurysm	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Aortic dilatation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Aortic rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arteriosclerosis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deep vein thrombosis	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Essential hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Flushing	11	0.2	(0.1, 0.3)	2	0.0	(0.0, 0.1)
Haematoma	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Hot flush	5	0.1	(0.0, 0.2)	9	0.2	(0.1, 0.3)
Hypertension	42	0.7	(0.5, 1.0)	45	0.8	(0.6, 1.0)
Hypertensive crisis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypertensive urgency	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypotension	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lymphoedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymphorrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.125. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Orthostatic hypotension	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Pallor	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peripheral arterial occlusive disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peripheral artery stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Phlebolith	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thrombophlebitis superficial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Varicose vein	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 unb eth p3 saf

14.126. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Not Reported

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=111, TE[b]=0.4)			Placebo (N[a]=113, TE[b]=0.4)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	21	49.4	(30.6, 75.5)	19	43.3	(26.1, 67.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
Anaemia	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
GASTROINTESTINAL DISORDERS	0	0.0	(0.0, 8.7)	4	9.1	(2.5, 23.4)
Diarrhoea	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
Diverticulum	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
Gingival discomfort	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
Large intestine polyp	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
Nausea	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	12	28.2	(14.6, 49.3)	4	9.1	(2.5, 23.4)
Chills	5	11.8	(3.8, 27.4)	0	0.0	(0.0, 8.4)
Fatigue	3	7.1	(1.5, 20.6)	3	6.8	(1.4, 20.0)
Influenza like illness	1	2.4	(0.1, 13.1)	0	0.0	(0.0, 8.4)
Injection site pain	7	16.5	(6.6, 33.9)	0	0.0	(0.0, 8.4)
Pain	3	7.1	(1.5, 20.6)	2	4.6	(0.6, 16.5)
Pyrexia	5	11.8	(3.8, 27.4)	0	0.0	(0.0, 8.4)
INFECTIONS AND INFESTATIONS	3	7.1	(1.5, 20.6)	0	0.0	(0.0, 8.4)
Chronic sinusitis	1	2.4	(0.1, 13.1)	0	0.0	(0.0, 8.4)
Herpes ophthalmic	1	2.4	(0.1, 13.1)	0	0.0	(0.0, 8.4)
Tooth infection	1	2.4	(0.1, 13.1)	0	0.0	(0.0, 8.4)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2	4.7	(0.6, 17.0)	4	9.1	(2.5, 23.4)
Exposure during pregnancy	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
Fall	1	2.4	(0.1, 13.1)	1	2.3	(0.1, 12.7)
Muscle rupture	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
Pelvic fracture	1	2.4	(0.1, 13.1)	0	0.0	(0.0, 8.4)
Tooth fracture	1	2.4	(0.1, 13.1)	0	0.0	(0.0, 8.4)
Wrist fracture	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
INVESTIGATIONS	1	2.4	(0.1, 13.1)	0	0.0	(0.0, 8.4)
Body temperature increased	1	2.4	(0.1, 13.1)	0	0.0	(0.0, 8.4)

14.126. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Not Reported

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=111, TE[b]=0.4)			Placebo (N[a]=113, TE[b]=0.4)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
METABOLISM AND NUTRITION DISORDERS	1	2.4	(0.1, 13.1)	0	0.0	(0.0, 8.4)
Hypercholesterolaemia	1	2.4	(0.1, 13.1)	0	0.0	(0.0, 8.4)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	6	14.1	(5.2, 30.7)	5	11.4	(3.7, 26.6)
Arthralgia	0	0.0	(0.0, 8.7)	2	4.6	(0.6, 16.5)
Arthritis	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
Back pain	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
Muscle spasms	1	2.4	(0.1, 13.1)	0	0.0	(0.0, 8.4)
Musculoskeletal pain	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
Musculoskeletal stiffness	1	2.4	(0.1, 13.1)	0	0.0	(0.0, 8.4)
Myalgia	3	7.1	(1.5, 20.6)	0	0.0	(0.0, 8.4)
Pain in extremity	1	2.4	(0.1, 13.1)	1	2.3	(0.1, 12.7)
NERVOUS SYSTEM DISORDERS	4	9.4	(2.6, 24.1)	1	2.3	(0.1, 12.7)
Dizziness	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
Headache	3	7.1	(1.5, 20.6)	0	0.0	(0.0, 8.4)
Migraine	1	2.4	(0.1, 13.1)	0	0.0	(0.0, 8.4)
PSYCHIATRIC DISORDERS	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
Depression suicidal	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1	2.4	(0.1, 13.1)	1	2.3	(0.1, 12.7)
Rash	1	2.4	(0.1, 13.1)	0	0.0	(0.0, 8.4)
Skin induration	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
VASCULAR DISORDERS	1	2.4	(0.1, 13.1)	2	4.6	(0.6, 16.5)
Hypertension	1	2.4	(0.1, 13.1)	1	2.3	(0.1, 12.7)
Hypotension	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)

14.126. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Not Reported

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=111, TE[b]=0.4)			Placebo (N[a]=113, TE[b]=0.4)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 unb eth p3 saf

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	5728	83.1	(81.0, 85.3)	2985	43.9	(42.3, 45.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	98	1.4	(1.2, 1.7)	28	0.4	(0.3, 0.6)
Anaemia	6	0.1	(0.0, 0.2)	8	0.1	(0.1, 0.2)
Blood loss anaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coagulopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Iron deficiency anaemia	8	0.1	(0.1, 0.2)	4	0.1	(0.0, 0.2)
Leukocytosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Leukopenia	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymph node pain	6	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Lymphadenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphadenopathy	73	1.1	(0.8, 1.3)	8	0.1	(0.1, 0.2)
Lymphadenopathy mediastinal	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymphocytosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphopenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Monoclonal B-cell lymphocytosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neutropenia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Splenomegaly	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thrombocytopenia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thrombocytosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
CARDIAC DISORDERS	80	1.2	(0.9, 1.4)	70	1.0	(0.8, 1.3)
Acute coronary syndrome	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Acute myocardial infarction	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Angina pectoris	4	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angina unstable	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Aortic valve incompetence	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Arrhythmia	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Arrhythmia supraventricular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arteriosclerosis coronary artery	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arteriospasm coronary	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrial fibrillation	13	0.2	(0.1, 0.3)	15	0.2	(0.1, 0.4)
Atrial flutter	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Atrioventricular block complete	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Atrioventricular block first degree	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bradycardia	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bundle branch block left	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bundle branch block right	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiac arrest	6	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cardiac disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiac failure congestive	4	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Cardio-respiratory arrest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiomegaly	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiovascular disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Coronary artery disease	4	0.1	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Coronary artery dissection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Coronary artery occlusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertensive heart disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Left atrial enlargement	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Left ventricular dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Left ventricular hypertrophy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mitral valve incompetence	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Mitral valve prolapse	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myocardial infarction	4	0.1	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Myocardial ischaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Myocarditis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Palpitations	6	0.1	(0.0, 0.2)	15	0.2	(0.1, 0.4)
Pericardial effusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pericarditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Postural orthostatic tachycardia syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinus tachycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Supraventricular tachycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tachyarrhythmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tachycardia	15	0.2	(0.1, 0.4)	7	0.1	(0.0, 0.2)
Tricuspid valve incompetence	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ventricular arrhythmia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ventricular extrasystoles	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ventricular tachycardia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Arnold-Chiari malformation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Congenital bladder neck obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Congenital cystic kidney disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Congenital ureteropelvic junction obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Developmental hip dysplasia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	66	1.0	(0.7, 1.2)	56	0.8	(0.6, 1.1)
Allergic otitis media	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerumen impaction	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deafness	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Deafness neurosensory	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Deafness unilateral	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear discomfort	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear disorder	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Ear pain	11	0.2	(0.1, 0.3)	10	0.1	(0.1, 0.3)
Eustachian tube dysfunction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyperacusis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypoacusis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Meniere's disease	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Otorrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sudden hearing loss	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tinnitus	9	0.1	(0.1, 0.2)	10	0.1	(0.1, 0.3)
Tympanic membrane perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vertigo	25	0.4	(0.2, 0.5)	24	0.4	(0.2, 0.5)
Vertigo positional	7	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
ENDOCRINE DISORDERS	17	0.2	(0.1, 0.4)	11	0.2	(0.1, 0.3)
Autoimmune thyroiditis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Goitre	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperprolactinaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperthyroidism	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypogonadism	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypothyroidism	8	0.1	(0.1, 0.2)	8	0.1	(0.1, 0.2)
Oestrogen deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Thyroid cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Thyroid mass	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EYE DISORDERS	61	0.9	(0.7, 1.1)	55	0.8	(0.6, 1.1)
Angle closure glaucoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthenopia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Astigmatism	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blepharitis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blepharospasm	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cataract	6	0.1	(0.0, 0.2)	8	0.1	(0.1, 0.2)
Chalazion	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Choroidal neovascularisation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Conjunctival haemorrhage	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Conjunctival hyperaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Conjunctivitis allergic	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dacryostenosis acquired	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diplopia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dry age-related macular degeneration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dry eye	1	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Episcleritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eye allergy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye inflammation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye irritation	5	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Eye pain	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Eye pruritus	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eyelid haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eyelid oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eyelid pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eyelids pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glaucoma	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypermetropia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Iritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Keratitis	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Lacrimation increased	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Macular oedema	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ocular discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ocular hyperaemia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Photophobia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal artery occlusion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal detachment	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Retinal tear	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Scleral discolouration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Swelling of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ulcerative keratitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vision blurred	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Visual acuity reduced	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Visual impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vitreous detachment	4	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vitreous floaters	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	621	9.0	(8.3, 9.7)	420	6.2	(5.6, 6.8)
Abdominal adhesions	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abdominal discomfort	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Abdominal distension	7	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Abdominal hernia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abdominal pain	19	0.3	(0.2, 0.4)	18	0.3	(0.2, 0.4)
Abdominal pain lower	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abdominal pain upper	19	0.3	(0.2, 0.4)	12	0.2	(0.1, 0.3)
Abdominal rigidity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Acute abdomen	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Anal pruritus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angular cheilitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Aphthous ulcer	8	0.1	(0.1, 0.2)	2	0.0	(0.0, 0.1)
Appendix disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cheilitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chronic gastritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coeliac artery aneurysm	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coeliac disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Colitis ischaemic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colitis microscopic	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colitis ulcerative	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Constipation	6	0.1	(0.0, 0.2)	12	0.2	(0.1, 0.3)
Crohn's disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dental caries	8	0.1	(0.1, 0.2)	7	0.1	(0.0, 0.2)
Diarrhoea	203	2.9	(2.6, 3.4)	158	2.3	(2.0, 2.7)
Diverticular perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulum	4	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulum intestinal	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Diverticulum intestinal haemorrhagic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dry mouth	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Duodenal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Duodenal ulcer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dyspepsia	10	0.1	(0.1, 0.3)	12	0.2	(0.1, 0.3)
Dysphagia	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Enterocolitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Epiploic appendagitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Faeces soft	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Flatulence	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Food poisoning	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastric polyps	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastric ulcer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastric ulcer haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastritis	4	0.1	(0.0, 0.1)	12	0.2	(0.1, 0.3)
Gastritis erosive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastrointestinal disorder	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastrointestinal sounds abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrooesophageal reflux disease	13	0.2	(0.1, 0.3)	19	0.3	(0.2, 0.4)
Gingival pain	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gingival swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Glossitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glossodynia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Haematemesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haematochezia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haemorrhoidal haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haemorrhoids	5	0.1	(0.0, 0.2)	10	0.1	(0.1, 0.3)
Hiatus hernia	4	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hypoaesthesia oral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoaesthesia teeth	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Impaired gastric emptying	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Incarcerated inguinal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Inguinal hernia	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Internal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intestinal obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal perforation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intestinal polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intestinal strangulation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Irritable bowel syndrome	5	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Large intestine perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Large intestine polyp	4	0.1	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Lip oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lip swelling	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mouth ulceration	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Nausea	236	3.4	(3.0, 3.9)	69	1.0	(0.8, 1.3)
Noninfective gingivitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Odynophagia	11	0.2	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Oesophageal food impaction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oesophageal spasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oesophageal ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oesophagitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Oral discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oral lichenoid reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oral mucosa haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Palatal disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatic cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pancreatitis acute	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Paraesthesia oral	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Parotid duct obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peptic ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Proctalgia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectal haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectal polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Retching	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Retroperitoneal haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Salivary gland calculus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Salivary gland mucocoele	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Small intestinal obstruction	4	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Stomatitis	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Swollen tongue	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Teething	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tongue discolouration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tongue discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tongue oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tongue pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tongue ulceration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tooth disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tooth impacted	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Toothache	23	0.3	(0.2, 0.5)	23	0.3	(0.2, 0.5)
Umbilical hernia	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Varices oesophageal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vomiting	54	0.8	(0.6, 1.0)	24	0.4	(0.2, 0.5)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3867	56.1	(54.3, 57.9)	771	11.3	(10.5, 12.2)
Adverse drug reaction	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Application site erythema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Application site pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Application site pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Application site rash	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Asthenia	62	0.9	(0.7, 1.2)	23	0.3	(0.2, 0.5)
Axillary pain	11	0.2	(0.1, 0.3)	3	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Capsular contracture associated with breast implant	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chest discomfort	3	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Chest pain	17	0.2	(0.1, 0.4)	11	0.2	(0.1, 0.3)
Chills	1144	16.6	(15.6, 17.6)	92	1.4	(1.1, 1.7)
Chronic fatigue syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cyst	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Drug withdrawal syndrome	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Effusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Exercise tolerance decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Face oedema	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Facial pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fatigue	1174	17.0	(16.1, 18.0)	291	4.3	(3.8, 4.8)
Feeling abnormal	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Feeling cold	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Feeling hot	5	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Gait disturbance	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Illness	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Induration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Inflammation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Influenza like illness	21	0.3	(0.2, 0.5)	2	0.0	(0.0, 0.1)
Injection site bruising	13	0.2	(0.1, 0.3)	18	0.3	(0.2, 0.4)
Injection site dermatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site discolouration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site discomfort	5	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Injection site erythema	158	2.3	(1.9, 2.7)	27	0.4	(0.3, 0.6)
Injection site haematoma	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Injection site haemorrhage	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Injection site hyperaesthesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site induration	9	0.1	(0.1, 0.2)	4	0.1	(0.0, 0.2)
Injection site irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site mass	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site nodule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site oedema	10	0.1	(0.1, 0.3)	0	0.0	(0.0, 0.1)
Injection site pain	2369	34.4	(33.0, 35.8)	291	4.3	(3.8, 4.8)
Injection site papule	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site paraesthesia	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Injection site plaque	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site pruritus	32	0.5	(0.3, 0.7)	6	0.1	(0.0, 0.2)
Injection site rash	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site reaction	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site swelling	111	1.6	(1.3, 1.9)	15	0.2	(0.1, 0.4)
Injection site urticaria	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site warmth	14	0.2	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Injury associated with device	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Malaise	112	1.6	(1.3, 2.0)	20	0.3	(0.2, 0.5)
Mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Medical device pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Medical device site granuloma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mucosal disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nodule	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Non-cardiac chest pain	5	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Oedema peripheral	8	0.1	(0.1, 0.2)	5	0.1	(0.0, 0.2)
Pain	531	7.7	(7.1, 8.4)	51	0.7	(0.6, 1.0)
Peripheral swelling	5	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Pyrexia	1223	17.7	(16.8, 18.8)	58	0.9	(0.6, 1.1)
Sensation of foreign body	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sluggishness	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sudden cardiac death	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Swelling	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Swelling face	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Temperature intolerance	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Therapeutic response unexpected	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thirst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaccination site induration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vaccination site pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Vaccination site swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vascular stent occlusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vessel puncture site bruise	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vessel puncture site haematoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vessel puncture site induration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	20	0.3	(0.2, 0.4)	15	0.2	(0.1, 0.4)
Bile duct stone	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary colic	4	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary dyskinesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholecystitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Cholecystitis acute	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Cholecystitis chronic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholelithiasis	10	0.1	(0.1, 0.3)	5	0.1	(0.0, 0.2)
Cirrhosis alcoholic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gallbladder disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hepatic cirrhosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatic cyst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatic steatosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatocellular injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nonalcoholic fatty liver disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	19	0.3	(0.2, 0.4)	25	0.4	(0.2, 0.5)
Allergy to arthropod bite	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Allergy to arthropod sting	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anaphylactic shock	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug hypersensitivity	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Food allergy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypersensitivity	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Jarisch-Herxheimer reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Milk allergy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Seasonal allergy	6	0.1	(0.0, 0.2)	13	0.2	(0.1, 0.3)
INFECTIONS AND INFESTATIONS	347	5.0	(4.5, 5.6)	443	6.5	(5.9, 7.1)
Abdominal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Abscess intestinal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abscess limb	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Abscess neck	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Acarodermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Acute sinusitis	1	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Anal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anal fistula infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Appendicitis	12	0.2	(0.1, 0.3)	9	0.1	(0.1, 0.3)
Appendicitis perforated	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arthritis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bacterial blepharitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bacterial infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bacterial sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bacterial vaginosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bacterial vulvovaginitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bartholin's abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bartholinitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blister infected	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bone abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Brain abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bronchitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.1)	13	0.2	(0.1, 0.3)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Carbuncle	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Catheter site infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cellulitis	10	0.1	(0.1, 0.3)	17	0.2	(0.1, 0.4)
Cellulitis orbital	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chlamydial infection	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Chronic sinusitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clostridium difficile infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Complicated appendicitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Conjunctivitis	9	0.1	(0.1, 0.2)	10	0.1	(0.1, 0.3)
Conjunctivitis bacterial	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Coxsackie viral infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cystitis	7	0.1	(0.0, 0.2)	12	0.2	(0.1, 0.3)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Device related infection	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diabetic foot infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulitis	10	0.1	(0.1, 0.3)	11	0.2	(0.1, 0.3)
Ear infection	8	0.1	(0.1, 0.2)	14	0.2	(0.1, 0.3)
Emphysematous cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Empyema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Erysipelas	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Escherichia sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Escherichia urinary tract infection	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Extradural abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye infection bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Folliculitis	5	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Fungal infection	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Fungal skin infection	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Furuncle	3	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Gangrene	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastroenteritis	5	0.1	(0.0, 0.2)	11	0.2	(0.1, 0.3)
Gastroenteritis viral	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Genital herpes	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Genital herpes simplex	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Genitourinary chlamydia infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gingival abscess	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gingivitis	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Gonorrhoea	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Groin abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Helicobacter gastritis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Helicobacter infection	0	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hepatitis A	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Herpes ophthalmic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Herpes simplex	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Herpes virus infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Herpes zoster	16	0.2	(0.1, 0.4)	15	0.2	(0.1, 0.4)
Herpes zoster oticus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hordeolum	7	0.1	(0.0, 0.2)	11	0.2	(0.1, 0.3)
Impetigo	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Infected bite	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Infected dermal cyst	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Influenza	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Kidney infection	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Labyrinthitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Laryngitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Localised infection	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Lyme disease	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Mastitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasopharyngitis	4	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Onychomycosis	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Ophthalmic herpes zoster	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral candidiasis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral fungal infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral herpes	5	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Oral infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Orchitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteomyelitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Otitis externa	5	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Otitis media	4	0.1	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Otitis media acute	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Otitis media bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papilloma viral infection	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paronychia	4	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Parotitis	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Penile infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Periodontitis	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peritonitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritonsillar abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pharyngitis	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Pharyngitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pharyngitis streptococcal	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pharyngotonsillitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pilonidal cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumonia	3	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Post procedural infection	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Postoperative wound infection	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Primary syphilis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Puncture site infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pustule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pyelonephritis	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Rash pustular	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Renal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory tract infection viral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rhinitis	4	0.1	(0.0, 0.1)	9	0.1	(0.1, 0.3)
Sepsis	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Septic shock	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Shigella sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sialoadenitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinusitis	18	0.3	(0.2, 0.4)	30	0.4	(0.3, 0.6)
Skin bacterial infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin infection	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Soft tissue infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Staphylococcal infection	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Staphylococcal sepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subacute endocarditis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subcutaneous abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tinea infection	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Tinea versicolour	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tonsillitis	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Tonsillitis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tooth abscess	12	0.2	(0.1, 0.3)	6	0.1	(0.0, 0.2)
Tooth infection	23	0.3	(0.2, 0.5)	30	0.4	(0.3, 0.6)
Trichomoniasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Upper respiratory tract infection	9	0.1	(0.1, 0.2)	9	0.1	(0.1, 0.3)
Ureaplasma infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Urinary tract infection	64	0.9	(0.7, 1.2)	76	1.1	(0.9, 1.4)
Urosepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaginal infection	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Viral infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Viral upper respiratory tract infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vulval abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vulvovaginal candidiasis	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Vulvovaginal mycotic infection	6	0.1	(0.0, 0.2)	8	0.1	(0.1, 0.2)
Vulvovaginitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	251	3.6	(3.2, 4.1)	319	4.7	(4.2, 5.2)
Administration related reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Alcohol poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Animal bite	1	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Ankle fracture	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Arthropod bite	11	0.2	(0.1, 0.3)	6	0.1	(0.0, 0.2)
Arthropod sting	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Back injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bone contusion	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bone fissure	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Brain contusion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Burn oral cavity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Burns first degree	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Burns second degree	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cartilage injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cervical vertebral fracture	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chest injury	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Chillblains	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clavicle fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colon injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Concussion	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Contusion	13	0.2	(0.1, 0.3)	19	0.3	(0.2, 0.4)
Corneal abrasion	4	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Craniocerebral injury	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Delayed recovery from anaesthesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dental restoration failure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear canal abrasion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Epicondylitis	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Exposure during pregnancy	22	0.3	(0.2, 0.5)	32	0.5	(0.3, 0.7)
Eye contusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eyelid injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Facial bones fracture	4	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Fall	56	0.8	(0.6, 1.1)	70	1.0	(0.8, 1.3)
Femur fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Fibula fracture	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Flail chest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foot fracture	7	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Forearm fracture	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Foreign body	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Foreign body aspiration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foreign body in eye	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fractured sacrum	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hand fracture	4	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Head injury	4	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Heat stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hip fracture	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Humerus fracture	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Jaw fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Joint dislocation	7	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Joint injury	5	0.1	(0.0, 0.2)	11	0.2	(0.1, 0.3)
Ligament injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ligament rupture	2	0.0	(0.0, 0.1)	10	0.1	(0.1, 0.3)
Ligament sprain	17	0.2	(0.1, 0.4)	22	0.3	(0.2, 0.5)
Limb fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Limb injury	8	0.1	(0.1, 0.2)	14	0.2	(0.1, 0.3)
Limb traumatic amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lip injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lower limb fracture	0	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Lumbar vertebral fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Maternal exposure before pregnancy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Maternal exposure during breast feeding	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Maternal exposure during pregnancy	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Meniscus injury	6	0.1	(0.0, 0.2)	9	0.1	(0.1, 0.3)
Mouth injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Multiple injuries	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle contusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Muscle injury	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Muscle rupture	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Muscle strain	18	0.3	(0.2, 0.4)	14	0.2	(0.1, 0.3)
Overdose	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Patella fracture	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pelvic fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Penis injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pharyngeal perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Post concussion syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post procedural haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Post procedural haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Post procedural swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post-traumatic pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Postoperative ileus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Procedural dizziness	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Procedural haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Procedural hypotension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Procedural pain	9	0.1	(0.1, 0.2)	5	0.1	(0.0, 0.2)
Radius fracture	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Respiratory fume inhalation disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rib fracture	3	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Road traffic accident	14	0.2	(0.1, 0.3)	16	0.2	(0.1, 0.4)
Scapula fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Scar	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin abrasion	8	0.1	(0.1, 0.2)	15	0.2	(0.1, 0.4)
Skin injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin laceration	17	0.2	(0.1, 0.4)	22	0.3	(0.2, 0.5)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Skull fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Soft tissue injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal compression fracture	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Spinal cord injury cervical	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Spinal fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Stoma site rash	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Stress fracture	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Subdural haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tendon injury	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Tendon rupture	0	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Thermal burn	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Tibia fracture	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tooth fracture	8	0.1	(0.1, 0.2)	10	0.1	(0.1, 0.3)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ulna fracture	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Upper limb fracture	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vaccination complication	4	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Venom poisoning	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vulvovaginal injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Wound	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Wrist fracture	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
INVESTIGATIONS	158	2.3	(1.9, 2.7)	41	0.6	(0.4, 0.8)
Alanine aminotransferase increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Aspartate aminotransferase increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Autoantibody positive	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood chloride decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood cholesterol increased	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blood creatinine increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood glucose abnormal	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood glucose fluctuation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood glucose increased	7	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Blood immunoglobulin E increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood potassium decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood pressure abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood pressure diastolic increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Blood pressure increased	5	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Blood pressure systolic increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood sodium decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood testosterone decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood testosterone increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood thyroid stimulating hormone increased	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood triglycerides increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood urea increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Body temperature	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Body temperature decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Body temperature increased	105	1.5	(1.2, 1.8)	10	0.1	(0.1, 0.3)
C-reactive protein	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Electrocardiogram QT prolonged	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fractional exhaled nitric oxide increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glomerular filtration rate decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Heart rate increased	4	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Heart rate irregular	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatic enzyme increased	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hepatitis C antibody positive	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Herpes simplex test positive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
High density lipoprotein increased	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Intraocular pressure increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Liver function test increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Low density lipoprotein increased	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymphocyte count decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mammogram abnormal	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mean cell haemoglobin decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mean cell volume decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mean cell volume increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Monocyte count increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Platelet count decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Platelet count increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Prostatic specific antigen increased	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Respiratory rate increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
SARS-CoV-2 antibody test positive	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Serum ferritin decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thyroid function test abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Troponin increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urine ketone body present	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Weight decreased	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Weight increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
White blood cell count increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
White blood cells urine positive	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	104	1.5	(1.2, 1.8)	107	1.6	(1.3, 1.9)
Decreased appetite	31	0.4	(0.3, 0.6)	8	0.1	(0.1, 0.2)
Dehydration	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Diabetes mellitus	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Diabetic ketoacidosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dyslipidaemia	6	0.1	(0.0, 0.2)	8	0.1	(0.1, 0.2)
Fluid retention	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Folate deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Food intolerance	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glucose tolerance impaired	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Gout	4	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hypercholesterolaemia	7	0.1	(0.0, 0.2)	20	0.3	(0.2, 0.5)
Hyperglycaemia	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Hyperkalaemia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperlipidaemia	9	0.1	(0.1, 0.2)	8	0.1	(0.1, 0.2)
Hypernatraemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypertriglyceridaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperuricaemia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypocalcaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypocholesterolaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoglycaemia	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hypokalaemia	6	0.1	(0.0, 0.2)	8	0.1	(0.1, 0.2)
Hypomagnesaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyponatraemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypovolaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Impaired fasting glucose	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Insulin resistance	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Iron deficiency	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lactic acidosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Obesity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Polydipsia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Type 2 diabetes mellitus	9	0.1	(0.1, 0.2)	11	0.2	(0.1, 0.3)
Vitamin B12 deficiency	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Vitamin D deficiency	9	0.1	(0.1, 0.2)	9	0.1	(0.1, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1548	22.5	(21.3, 23.6)	528	7.8	(7.1, 8.5)
Arthralgia	242	3.5	(3.1, 4.0)	99	1.5	(1.2, 1.8)
Arthritis	5	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Arthritis reactive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arthropathy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Axillary mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Back pain	84	1.2	(1.0, 1.5)	89	1.3	(1.1, 1.6)
Bone disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bone pain	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bone swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bursitis	11	0.2	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Coccydynia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Costochondritis	5	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dupuytren's contracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Exostosis	4	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Fibromyalgia	0	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Flank pain	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Groin pain	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc compression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intervertebral disc degeneration	4	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Intervertebral disc disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	9	0.1	(0.1, 0.2)	11	0.2	(0.1, 0.3)
Joint effusion	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Joint range of motion decreased	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Joint stiffness	4	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Joint swelling	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Limb discomfort	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Metatarsalgia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Mobility decreased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Muscle contracture	4	0.1	(0.0, 0.1)	8	0.1	(0.1, 0.2)
Muscle fatigue	4	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle spasms	26	0.4	(0.2, 0.6)	12	0.2	(0.1, 0.3)
Muscle tightness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Muscle twitching	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscular weakness	13	0.2	(0.1, 0.3)	2	0.0	(0.0, 0.1)
Musculoskeletal chest pain	8	0.1	(0.1, 0.2)	6	0.1	(0.0, 0.2)
Musculoskeletal discomfort	4	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Musculoskeletal pain	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Musculoskeletal stiffness	11	0.2	(0.1, 0.3)	6	0.1	(0.0, 0.2)
Myalgia	1022	14.8	(13.9, 15.8)	137	2.0	(1.7, 2.4)
Myalgia intercostal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neck pain	28	0.4	(0.3, 0.6)	35	0.5	(0.4, 0.7)
Osteitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteoarthritis	13	0.2	(0.1, 0.3)	22	0.3	(0.2, 0.5)
Osteochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Osteochondrosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteopenia	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Osteoporosis	0	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Pain in extremity	163	2.4	(2.0, 2.8)	38	0.6	(0.4, 0.8)
Pain in jaw	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Patellofemoral pain syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Periarthritis	4	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Plantar fasciitis	4	0.1	(0.0, 0.1)	8	0.1	(0.1, 0.2)
Polyarthritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Psoriatic arthropathy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rhabdomyolysis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rheumatoid arthritis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Rotator cuff syndrome	4	0.1	(0.0, 0.1)	12	0.2	(0.1, 0.3)
Scoliosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Sinus tarsi syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Spinal disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal osteoarthritis	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Spinal stenosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spondylitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spondylolisthesis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Synovial cyst	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Synovitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Systemic lupus erythematosus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Temporomandibular joint syndrome	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Tendon disorder	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tendon pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tendonitis	11	0.2	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Tenosynovitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tenosynovitis stenosans	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Torticollis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Trigger finger	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	63	0.9	(0.7, 1.2)	60	0.9	(0.7, 1.1)
Acrochordon	0	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, 0.1)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenocarcinoma of colon	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenocarcinoma pancreas	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenoma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adrenal gland cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
B-cell lymphoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Basal cell carcinoma	3	0.0	(0.0, 0.1)	10	0.1	(0.1, 0.3)
Benign breast neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Benign hydatidiform mole	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Benign pancreatic neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Benign uterine neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary cancer metastatic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bladder cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Borderline serous tumour of ovary	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cancer	2	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Breast cancer in situ	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Carcinoid tumour of the stomach	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chondroma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colon adenoma	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Fibroadenoma of breast	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gallbladder cancer stage II	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastric cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glomus tumour	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haemangioma of skin	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Infected naevus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Invasive ductal breast carcinoma	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Leydig cell tumour of the testis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lipoma	4	0.1	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Lobular breast carcinoma in situ	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lung adenocarcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphoproliferative disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Malignant melanoma	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Malignant melanoma of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Meningioma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Meningioma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to liver	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Non-Hodgkin's lymphoma recurrent	0	0.0	(0.0, 0.1)	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, 0.1)
Oropharyngeal cancer recurrent	0	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, 0.1)
Pancreatic carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papillary serous endometrial carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papillary thyroid cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Penile neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Penile squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Plasma cell myeloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Polycythaemia vera	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Prostate cancer	5	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Prostate cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Seborrhoeic keratosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin papilloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Squamous cell carcinoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Squamous cell carcinoma of head and neck	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Squamous cell carcinoma of skin	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Teratoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thyroid cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transitional cell carcinoma	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Uterine cancer	0	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)
NERVOUS SYSTEM DISORDERS	1312	19.0	(18.0, 20.1)	512	7.5	(6.9, 8.2)
Ageusia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Amnesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Amyotrophic lateral sclerosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aphasia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Balance disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Burning sensation	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Carpal tunnel syndrome	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Cerebellar infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebral atrophy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebral capillary telangiectasia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebral infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebrovascular accident	4	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cervical radiculopathy	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Cervicogenic headache	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dementia Alzheimer's type	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depressed level of consciousness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diabetic neuropathy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Disturbance in attention	4	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dizziness	67	1.0	(0.8, 1.2)	48	0.7	(0.5, 0.9)
Dizziness postural	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dysgeusia	8	0.1	(0.1, 0.2)	4	0.1	(0.0, 0.2)
Dyskinesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Facial paralysis	4	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial paresis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Generalised tonic-clonic seizure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haemorrhagic stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Head discomfort	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Headache	1093	15.9	(14.9, 16.8)	347	5.1	(4.6, 5.7)
Hemiparaesthesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hemiplegic migraine	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyperaesthesia	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypersomnia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoaesthesia	3	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Hypogeusia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyposmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Idiopathic intracranial hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intraventricular haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ischaemic stroke	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lethargy	22	0.3	(0.2, 0.5)	6	0.1	(0.0, 0.2)
Mental impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Migraine	23	0.3	(0.2, 0.5)	10	0.1	(0.1, 0.3)
Migraine with aura	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Migraine without aura	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Morton's neuralgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Motor dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Muscle spasticity	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myoclonus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nerve compression	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Neuralgia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neuritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neuropathy peripheral	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Nystagmus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paraesthesia	20	0.3	(0.2, 0.4)	20	0.3	(0.2, 0.5)
Paraparesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Parosmia	5	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Periodic limb movement disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peripheral nerve lesion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Piriformis syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post herpetic neuralgia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Presyncope	7	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Radiculopathy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Restless legs syndrome	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sciatic nerve neuropathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sciatica	13	0.2	(0.1, 0.3)	11	0.2	(0.1, 0.3)
Seizure	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinus headache	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Somnolence	7	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Subarachnoid haemorrhage	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Syncope	12	0.2	(0.1, 0.3)	12	0.2	(0.1, 0.3)
Taste disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tension headache	9	0.1	(0.1, 0.2)	8	0.1	(0.1, 0.2)
Thoracic radiculopathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Toxic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transient global amnesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transient ischaemic attack	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Tremor	8	0.1	(0.1, 0.2)	5	0.1	(0.0, 0.2)
Trigeminal neuralgia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
VIth nerve paralysis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Abortion incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abortion spontaneous	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
PRODUCT ISSUES	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Device breakage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Device connection issue	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
PSYCHIATRIC DISORDERS	94	1.4	(1.1, 1.7)	100	1.5	(1.2, 1.8)
Abnormal dreams	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adjustment disorder with depressed mood	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Anxiety	19	0.3	(0.2, 0.4)	30	0.4	(0.3, 0.6)
Anxiety disorder	3	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Attention deficit hyperactivity disorder	5	0.1	(0.0, 0.2)	8	0.1	(0.1, 0.2)
Bipolar disorder	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bruxism	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Confusional state	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cyclothymic disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depressed mood	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depression	19	0.3	(0.2, 0.4)	24	0.4	(0.2, 0.5)
Depression suicidal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Disorientation	5	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastrointestinal somatic symptom disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Generalised anxiety disorder	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Insomnia	22	0.3	(0.2, 0.5)	13	0.2	(0.1, 0.3)
Irritability	4	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Libido decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Major depression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mental disorder	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mental fatigue	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mental status changes	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mood swings	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nightmare	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Panic attack	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Panic disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Panic reaction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Paranoia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post-traumatic stress disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Restlessness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sleep disorder	4	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Stress	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Substance abuse	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Suicidal ideation	0	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Suicide attempt	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	50	0.7	(0.5, 1.0)	45	0.7	(0.5, 0.9)
Acute kidney injury	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Bladder spasm	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chronic kidney disease	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Costovertebral angle tenderness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dysuria	8	0.1	(0.1, 0.2)	5	0.1	(0.0, 0.2)
Haematuria	5	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Hydronephrosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypertonic bladder	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Micturition urgency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nephrolithiasis	14	0.2	(0.1, 0.3)	13	0.2	(0.1, 0.3)
Nocturia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Obstructive nephropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oedematous kidney	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Perinephric oedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pollakiuria	4	0.1	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Polyuria	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Renal atrophy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Renal colic	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Renal cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Renal cyst haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Renal failure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subcapsular renal haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ureterolithiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urethral discharge	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urethral stenosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urinary bladder polyp	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urinary retention	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Urinary tract obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urine odour abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vesical fistula	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	40	0.6	(0.4, 0.8)	49	0.7	(0.5, 1.0)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Adenomyosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Adnexal torsion	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Amenorrhoea	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Benign prostatic hyperplasia	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Breast calcifications	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Breast cyst	0	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Breast hyperplasia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Breast mass	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Breast pain	4	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cervical dysplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cervical polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dysmenorrhoea	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Ejaculation disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Endometriosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Erectile dysfunction	0	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Genital erythema	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haematospermia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haemorrhagic ovarian cyst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mammary duct ectasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Menometrorrhagia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Menorrhagia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Menstruation delayed	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Menstruation irregular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metrorrhagia	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Nipple pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ovarian cyst	4	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ovarian mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pelvic pain	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Penile vein thrombosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Polycystic ovaries	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Postmenopausal haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Premenstrual syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Prostatitis	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Prostatomegaly	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pruritus genital	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Rectocele	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Scrotal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Testicular pain	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Testicular torsion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Uterine haemorrhage	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Uterine prolapse	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vaginal haemorrhage	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vaginal prolapse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vulvovaginal pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	188	2.7	(2.4, 3.1)	170	2.5	(2.1, 2.9)
Acute respiratory failure	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Allergic respiratory disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Allergic sinusitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthma	14	0.2	(0.1, 0.3)	8	0.1	(0.1, 0.2)
Asthma exercise induced	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Asthmatic crisis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atelectasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bronchospasm	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	6	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cough	18	0.3	(0.2, 0.4)	13	0.2	(0.1, 0.3)
Dry throat	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dysphonia	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Dyspnoea	6	0.1	(0.0, 0.2)	9	0.1	(0.1, 0.3)
Dyspnoea exertional	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Emphysema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Epistaxis	6	0.1	(0.0, 0.2)	8	0.1	(0.1, 0.2)
Haemoptysis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hiccups	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Interstitial lung disease	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lung infiltration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal congestion	21	0.3	(0.2, 0.5)	26	0.4	(0.2, 0.6)
Nasal discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nasal polyps	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal septum deviation	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Nasal turbinate hypertrophy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal valve collapse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasopharyngeal polyp	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oropharyngeal discomfort	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Oropharyngeal pain	31	0.4	(0.3, 0.6)	29	0.4	(0.3, 0.6)
Paranasal sinus discomfort	3	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Pharyngeal lesion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pharyngeal swelling	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pleuritic pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonia aspiration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumothorax	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Productive cough	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pulmonary embolism	5	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Pulmonary hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pulmonary mass	0	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Pulmonary oedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pulmonary pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Reflux laryngitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory failure	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory tract congestion	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Rhinitis allergic	10	0.1	(0.1, 0.3)	13	0.2	(0.1, 0.3)
Rhinitis perennial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rhinorrhoea	17	0.2	(0.1, 0.4)	11	0.2	(0.1, 0.3)
Sinus congestion	5	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Sleep apnoea syndrome	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Sneezing	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Snoring	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sputum discoloured	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Throat irritation	6	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Tonsillar hypertrophy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Upper respiratory tract congestion	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper-airway cough syndrome	7	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Wheezing	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	224	3.2	(2.8, 3.7)	165	2.4	(2.1, 2.8)
Acne	4	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Acne cystic	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Actinic keratosis	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Alopecia	5	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Alopecia areata	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angioedema	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blister	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Cold sweat	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dermal cyst	5	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Dermatitis	5	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Dermatitis acneiform	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dermatitis allergic	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Dermatitis atopic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis bullous	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis contact	14	0.2	(0.1, 0.3)	19	0.3	(0.2, 0.4)
Dermatitis exfoliative	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diabetic foot	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug eruption	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Dry skin	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dyshidrotic eczema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ecchymosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eczema	6	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Erythema	8	0.1	(0.1, 0.2)	2	0.0	(0.0, 0.1)
Erythema nodosum	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fixed eruption	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hand dermatitis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hangnail	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hidradenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperhidrosis	25	0.4	(0.2, 0.5)	8	0.1	(0.1, 0.2)
Ingrowing nail	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Intertrigo	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lipodystrophy acquired	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Livedo reticularis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Macule	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mechanical urticaria	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Night sweats	14	0.2	(0.1, 0.3)	2	0.0	(0.0, 0.1)
Onycholysis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Onychomadesis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pain of skin	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peau d'orange	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Perioral dermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pityriasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pityriasis rosea	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Pruritus	21	0.3	(0.2, 0.5)	13	0.2	(0.1, 0.3)
Pruritus allergic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pseudofolliculitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Psoriasis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Purpura	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rash	54	0.8	(0.6, 1.0)	46	0.7	(0.5, 0.9)
Rash erythematous	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Rash maculo-papular	6	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Rash papular	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rash pruritic	8	0.1	(0.1, 0.2)	5	0.1	(0.0, 0.2)
Rosacea	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Seborrhoeic dermatitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Skin discolouration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin induration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin lesion	1	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Skin mass	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Stasis dermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Transient acantholytic dermatosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urticaria	16	0.2	(0.1, 0.4)	10	0.1	(0.1, 0.3)
Urticaria contact	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	4	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
High risk sexual behaviour	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Menopause	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Miscarriage of partner	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	31	0.4	(0.3, 0.6)	24	0.4	(0.2, 0.5)
Abortion induced	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Apicectomy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Botulinum toxin injection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiac pacemaker replacement	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardioversion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Carpal tunnel decompression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cataract operation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chondroplasty	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dental care	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Dental implantation	5	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Drug titration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Endodontic procedure	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facet joint block	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Finger amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lacrimal duct procedure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lens extraction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mammoplasty	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Medical device implantation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal polypectomy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Open reduction of fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Postoperative care	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Retinal operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rhinoplasty	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rotator cuff repair	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sclerotherapy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin neoplasm excision	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Toe amputation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Toe operation	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Tonsillectomy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tooth extraction	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Vasectomy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Wisdom teeth removal	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Wound drainage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
VASCULAR DISORDERS	97	1.4	(1.1, 1.7)	107	1.6	(1.3, 1.9)
Accelerated hypertension	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Aortic aneurysm	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic dilatation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Aortic rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic stenosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Arteriosclerosis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blood pressure inadequately controlled	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deep vein thrombosis	4	0.1	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Diastolic hypertension	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Flushing	11	0.2	(0.1, 0.3)	1	0.0	(0.0, 0.1)
Haematoma	4	0.1	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Hot flush	7	0.1	(0.0, 0.2)	8	0.1	(0.1, 0.2)
Hypertension	53	0.8	(0.6, 1.0)	63	0.9	(0.7, 1.2)
Hypertensive crisis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertensive emergency	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertensive urgency	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypotension	5	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Intermittent claudication	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphoedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymphorrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Orthostatic hypotension	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Pallor	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peripheral artery stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Phlebitis superficial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Phlebolith	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Raynaud's phenomenon	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subgaleal haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Systolic hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Varicose vein	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Venous thrombosis limb	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.127. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: MedDRA (v23.1) 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.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_unb_race_p3_saf

14.128. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=2046, TE[b]=7.9)			Placebo (N[a]=2061, TE[b]=7.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	421	53.5	(48.5, 58.9)	275	35.3	(31.2, 39.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	12	1.5	(0.8, 2.7)	4	0.5	(0.1, 1.3)
Anaemia	2	0.3	(0.0, 0.9)	2	0.3	(0.0, 0.9)
Blood loss anaemia	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Iron deficiency anaemia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Lymph node pain	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Lymphadenopathy	8	1.0	(0.4, 2.0)	0	0.0	(0.0, 0.5)
Microcytic anaemia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Neutropenia	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Thrombocytopenia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
CARDIAC DISORDERS	3	0.4	(0.1, 1.1)	6	0.8	(0.3, 1.7)
Acute left ventricular failure	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Atrial fibrillation	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Atrioventricular block complete	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Bradycardia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Cardiac arrest	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Cardiac failure acute	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Cardiac failure congestive	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Coronary artery disease	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Myocardial infarction	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Myocardial ischaemia	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Palpitations	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Sinus bradycardia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2	0.3	(0.0, 0.9)	0	0.0	(0.0, 0.5)
Gastrointestinal arteriovenous malformation	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Protein S deficiency	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
EAR AND LABYRINTH DISORDERS	3	0.4	(0.1, 1.1)	5	0.6	(0.2, 1.5)
Ear pain	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Ear pruritus	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Tinnitus	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Vertigo	3	0.4	(0.1, 1.1)	2	0.3	(0.0, 0.9)

14.128. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=2046, TE[b]=7.9)			Placebo (N[a]=2061, TE[b]=7.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
EYE DISORDERS	4	0.5	(0.1, 1.3)	6	0.8	(0.3, 1.7)
Amaurosis fugax	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Asthenopia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Cataract	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Conjunctival haemorrhage	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Conjunctivitis allergic	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Eye irritation	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Eye pain	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Glaucoma	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Ocular hyperaemia	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Photophobia	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Uveitis	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Vision blurred	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
GASTROINTESTINAL DISORDERS	46	5.8	(4.3, 7.8)	40	5.1	(3.7, 7.0)
Abdominal pain	1	0.1	(0.0, 0.7)	4	0.5	(0.1, 1.3)
Abdominal pain upper	2	0.3	(0.0, 0.9)	0	0.0	(0.0, 0.5)
Cheilitis	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Constipation	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Dental caries	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Diarrhoea	21	2.7	(1.7, 4.1)	11	1.4	(0.7, 2.5)
Dry mouth	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Dyspepsia	2	0.3	(0.0, 0.9)	1	0.1	(0.0, 0.7)
Femoral hernia	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Flatulence	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Gastric antral vascular ectasia	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Gastritis	1	0.1	(0.0, 0.7)	2	0.3	(0.0, 0.9)
Gastrointestinal disorder	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Gastrointestinal haemorrhage	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Gastrointestinal mucosa hyperaemia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Gastrooesophageal reflux disease	0	0.0	(0.0, 0.5)	2	0.3	(0.0, 0.9)
Haematochezia	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Haemorrhoids	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Hypoaesthesia oral	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Ileus	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Inguinal hernia	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)

14.128. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=2046, TE[b]=7.9)			Placebo (N[a]=2061, TE[b]=7.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Large intestine polyp	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Nausea	10	1.3	(0.6, 2.3)	9	1.2	(0.5, 2.2)
Obstructive pancreatitis	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Odynophagia	2	0.3	(0.0, 0.9)	0	0.0	(0.0, 0.5)
Rectal haemorrhage	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Retching	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Salivary gland calculus	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Tooth impacted	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Toothache	2	0.3	(0.0, 0.9)	0	0.0	(0.0, 0.5)
Volvulus	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Vomiting	5	0.6	(0.2, 1.5)	5	0.6	(0.2, 1.5)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	257	32.7	(28.8, 36.9)	93	11.9	(9.6, 14.6)
Asthenia	6	0.8	(0.3, 1.7)	1	0.1	(0.0, 0.7)
Chest discomfort	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Chest pain	0	0.0	(0.0, 0.5)	3	0.4	(0.1, 1.1)
Chills	65	8.3	(6.4, 10.5)	14	1.8	(1.0, 3.0)
Fatigue	71	9.0	(7.0, 11.4)	29	3.7	(2.5, 5.3)
Influenza like illness	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Injection site erythema	4	0.5	(0.1, 1.3)	1	0.1	(0.0, 0.7)
Injection site injury	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Injection site oedema	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Injection site pain	149	18.9	(16.0, 22.2)	45	5.8	(4.2, 7.7)
Injection site pruritus	3	0.4	(0.1, 1.1)	0	0.0	(0.0, 0.5)
Injection site reaction	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Injection site swelling	9	1.1	(0.5, 2.2)	3	0.4	(0.1, 1.1)
Malaise	5	0.6	(0.2, 1.5)	1	0.1	(0.0, 0.7)
Non-cardiac chest pain	1	0.1	(0.0, 0.7)	2	0.3	(0.0, 0.9)
Pain	20	2.5	(1.6, 3.9)	3	0.4	(0.1, 1.1)
Peripheral swelling	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Pyrexia	77	9.8	(7.7, 12.2)	10	1.3	(0.6, 2.4)
Sensation of foreign body	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Swelling	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
HEPATOBILIARY DISORDERS	2	0.3	(0.0, 0.9)	0	0.0	(0.0, 0.5)
Bile duct stone	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)

14.128. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=2046, TE[b]=7.9)			Placebo (N[a]=2061, TE[b]=7.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hepatic steatosis	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
IMMUNE SYSTEM DISORDERS	3	0.4	(0.1, 1.1)	6	0.8	(0.3, 1.7)
Allergy to animal	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Drug hypersensitivity	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Food allergy	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Hypersensitivity	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Seasonal allergy	1	0.1	(0.0, 0.7)	3	0.4	(0.1, 1.1)
INFECTIONS AND INFESTATIONS	28	3.6	(2.4, 5.1)	30	3.8	(2.6, 5.5)
Abscess oral	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Acarodermatitis	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Appendicitis	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Bacterial vulvovaginitis	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Balanitis candida	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Bronchitis	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Cellulitis	1	0.1	(0.0, 0.7)	3	0.4	(0.1, 1.1)
Conjunctivitis	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Dermatitis infected	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Ear infection	2	0.3	(0.0, 0.9)	1	0.1	(0.0, 0.7)
Eye infection	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Folliculitis	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Fungal infection	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Fungal skin infection	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Gastroenteritis	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Gingivitis	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Gonorrhoea	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Hepatitis C	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Oral herpes	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Orchitis	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Otitis externa	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Otitis media	3	0.4	(0.1, 1.1)	1	0.1	(0.0, 0.7)
Pelvic inflammatory disease	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Peritonsillar abscess	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Pharyngitis streptococcal	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Pneumonia	1	0.1	(0.0, 0.7)	2	0.3	(0.0, 0.9)

14.128. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=2046, TE[b]=7.9)			Placebo (N[a]=2061, TE[b]=7.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pulmonary tuberculosis	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Rhinitis	2	0.3	(0.0, 0.9)	0	0.0	(0.0, 0.5)
Sinusitis	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Sinusitis bacterial	2	0.3	(0.0, 0.9)	0	0.0	(0.0, 0.5)
Skin bacterial infection	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Subcutaneous abscess	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Tinea versicolour	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Tooth infection	2	0.3	(0.0, 0.9)	1	0.1	(0.0, 0.7)
Trichomoniasis	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Urinary tract infection	6	0.8	(0.3, 1.7)	4	0.5	(0.1, 1.3)
Vaginal infection	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Varicella	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Vulvovaginal mycotic infection	0	0.0	(0.0, 0.5)	2	0.3	(0.0, 0.9)
Wound infection	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	19	2.4	(1.5, 3.8)	27	3.5	(2.3, 5.0)
Animal bite	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Ankle fracture	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Arthropod bite	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Concussion	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Exposure during pregnancy	6	0.8	(0.3, 1.7)	6	0.8	(0.3, 1.7)
Fall	0	0.0	(0.0, 0.5)	2	0.3	(0.0, 0.9)
Foot fracture	0	0.0	(0.0, 0.5)	2	0.3	(0.0, 0.9)
Head injury	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Ligament injury	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Ligament sprain	2	0.3	(0.0, 0.9)	2	0.3	(0.0, 0.9)
Limb injury	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Maternal exposure before pregnancy	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Maternal exposure during pregnancy	2	0.3	(0.0, 0.9)	0	0.0	(0.0, 0.5)
Meniscus injury	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Overdose	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Post procedural discomfort	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Rib fracture	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Road traffic accident	1	0.1	(0.0, 0.7)	3	0.4	(0.1, 1.1)
Skin laceration	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)

14.128. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=2046, TE[b]=7.9)			Placebo (N[a]=2061, TE[b]=7.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Spinal column injury	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Stress fracture	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Subdural haematoma	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Sunburn	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Tendon rupture	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Thermal burn	1	0.1	(0.0, 0.7)	2	0.3	(0.0, 0.9)
Toxicity to various agents	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Traumatic haemothorax	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Wound	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Wrist fracture	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
INVESTIGATIONS	5	0.6	(0.2, 1.5)	9	1.2	(0.5, 2.2)
Biopsy breast normal	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Blood cholesterol increased	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Blood creatinine decreased	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Blood glucose increased	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Blood iron decreased	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Blood potassium decreased	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Blood pressure increased	0	0.0	(0.0, 0.5)	3	0.4	(0.1, 1.1)
Body temperature increased	1	0.1	(0.0, 0.7)	2	0.3	(0.0, 0.9)
Cardiac stress test abnormal	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Haemoglobin decreased	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Red blood cell morphology abnormal	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
METABOLISM AND NUTRITION DISORDERS	15	1.9	(1.1, 3.1)	7	0.9	(0.4, 1.8)
Decreased appetite	3	0.4	(0.1, 1.1)	1	0.1	(0.0, 0.7)
Dehydration	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Diabetes mellitus	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Diabetic ketoacidosis	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Gout	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Hypercholesterolaemia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Hyperlipidaemia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Hypertriglyceridaemia	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Hypoglycaemia	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Hypokalaemia	2	0.3	(0.0, 0.9)	0	0.0	(0.0, 0.5)
Increased appetite	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)

14.128. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=2046, TE[b]=7.9)			Placebo (N[a]=2061, TE[b]=7.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Type 2 diabetes mellitus	2	0.3	(0.0, 0.9)	2	0.3	(0.0, 0.9)
Vitamin B12 deficiency	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Vitamin D deficiency	3	0.4	(0.1, 1.1)	0	0.0	(0.0, 0.5)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	91	11.6	(9.3, 14.2)	45	5.8	(4.2, 7.7)
Arthralgia	10	1.3	(0.6, 2.3)	12	1.5	(0.8, 2.7)
Axillary mass	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Back pain	9	1.1	(0.5, 2.2)	5	0.6	(0.2, 1.5)
Coccydynia	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Exostosis	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Fibromyalgia	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Intervertebral disc degeneration	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Joint range of motion decreased	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Muscle discomfort	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Muscle spasms	1	0.1	(0.0, 0.7)	2	0.3	(0.0, 0.9)
Muscular weakness	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Musculoskeletal stiffness	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Myalgia	57	7.2	(5.5, 9.4)	13	1.7	(0.9, 2.9)
Neck pain	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Osteoarthritis	2	0.3	(0.0, 0.9)	1	0.1	(0.0, 0.7)
Pain in extremity	10	1.3	(0.6, 2.3)	8	1.0	(0.4, 2.0)
Rotator cuff syndrome	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Synovitis	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Tendon disorder	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Tendonitis	1	0.1	(0.0, 0.7)	3	0.4	(0.1, 1.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	0.0	(0.0, 0.5)	4	0.5	(0.1, 1.3)
Lipoma	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Lung adenocarcinoma	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Uterine leiomyoma	0	0.0	(0.0, 0.5)	2	0.3	(0.0, 0.9)
NERVOUS SYSTEM DISORDERS	86	10.9	(8.7, 13.5)	51	6.5	(4.9, 8.6)
Burning sensation	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Dizziness	4	0.5	(0.1, 1.3)	8	1.0	(0.4, 2.0)
Dizziness postural	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Dysgeusia	2	0.3	(0.0, 0.9)	1	0.1	(0.0, 0.7)

14.128. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=2046, TE[b]=7.9)			Placebo (N[a]=2061, TE[b]=7.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Headache	72	9.2	(7.2, 11.5)	28	3.6	(2.4, 5.2)
Hypoaesthesia	0	0.0	(0.0, 0.5)	4	0.5	(0.1, 1.3)
Idiopathic intracranial hypertension	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Migraine	2	0.3	(0.0, 0.9)	2	0.3	(0.0, 0.9)
Paraesthesia	2	0.3	(0.0, 0.9)	2	0.3	(0.0, 0.9)
Parosmia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Restless legs syndrome	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Seizure	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Somnolence	1	0.1	(0.0, 0.7)	3	0.4	(0.1, 1.1)
Spinal cord compression	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Syncope	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Tension headache	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	0.0	(0.0, 0.5)	2	0.3	(0.0, 0.9)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Retained products of conception	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
PSYCHIATRIC DISORDERS	8	1.0	(0.4, 2.0)	4	0.5	(0.1, 1.3)
Anxiety	3	0.4	(0.1, 1.1)	1	0.1	(0.0, 0.7)
Anxiety disorder	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Bipolar disorder	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Depressed mood	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Depression	2	0.3	(0.0, 0.9)	1	0.1	(0.0, 0.7)
Dysphemia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Libido increased	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Suicide attempt	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
RENAL AND URINARY DISORDERS	2	0.3	(0.0, 0.9)	1	0.1	(0.0, 0.7)
Nephrolithiasis	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Pollakiuria	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Renal colic	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	5	0.6	(0.2, 1.5)	3	0.4	(0.1, 1.1)
Benign prostatic hyperplasia	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Dysfunctional uterine bleeding	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Endometriosis	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)

14.128. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=2046, TE[b]=7.9)			Placebo (N[a]=2061, TE[b]=7.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Erectile dysfunction	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Prostatomegaly	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Vaginal discharge	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Vaginal haemorrhage	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	18	2.3	(1.4, 3.6)	16	2.1	(1.2, 3.3)
Asthma	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Bronchospasm	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Cough	2	0.3	(0.0, 0.9)	2	0.3	(0.0, 0.9)
Haemoptysis	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Hypoxia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Nasal congestion	7	0.9	(0.4, 1.8)	5	0.6	(0.2, 1.5)
Oropharyngeal pain	2	0.3	(0.0, 0.9)	2	0.3	(0.0, 0.9)
Paranasal sinus hypersecretion	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Pharyngeal swelling	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Pneumonia aspiration	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Pneumothorax	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Productive cough	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Pulmonary embolism	3	0.4	(0.1, 1.1)	1	0.1	(0.0, 0.7)
Respiratory tract congestion	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Rhinitis allergic	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Rhinorrhoea	2	0.3	(0.0, 0.9)	1	0.1	(0.0, 0.7)
Sinus congestion	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Throat irritation	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Wheezing	2	0.3	(0.0, 0.9)	0	0.0	(0.0, 0.5)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	9	1.1	(0.5, 2.2)	12	1.5	(0.8, 2.7)
Alopecia areata	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Dermatitis allergic	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Dermatitis contact	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Eczema	1	0.1	(0.0, 0.7)	2	0.3	(0.0, 0.9)
Hyperhidrosis	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Night sweats	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Pruritus	3	0.4	(0.1, 1.1)	3	0.4	(0.1, 1.1)
Rash	2	0.3	(0.0, 0.9)	3	0.4	(0.1, 1.1)

14.128. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=2046, TE[b]=7.9)			Placebo (N[a]=2061, TE[b]=7.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Rash maculo-papular	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Urticaria	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Urticaria papular	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
SOCIAL CIRCUMSTANCES	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
High risk sexual behaviour	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
SURGICAL AND MEDICAL PROCEDURES	1	0.1	(0.0, 0.7)	2	0.3	(0.0, 0.9)
Dental implantation	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Inguinal hernia repair	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Tooth extraction	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
VASCULAR DISORDERS	12	1.5	(0.8, 2.7)	8	1.0	(0.4, 2.0)
Deep vein thrombosis	3	0.4	(0.1, 1.1)	1	0.1	(0.0, 0.7)
Essential hypertension	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Flushing	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Hot flush	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Hypertension	7	0.9	(0.4, 1.8)	4	0.5	(0.1, 1.3)
Hypertensive urgency	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Peripheral arterial occlusive disease	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)

Note: MedDRA (v23.1) 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.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 unb race p3 saf

14.129. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1868, TE[b]=6.6)			Placebo (N[a]=1833, TE[b]=6.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	798	120.1	(111.9, 128.8)	308	48.6	(43.3, 54.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	8	1.2	(0.5, 2.4)	0	0.0	(0.0, 0.6)
Hypochromic anaemia	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Iron deficiency anaemia	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Lymphadenopathy	6	0.9	(0.3, 2.0)	0	0.0	(0.0, 0.6)
CARDIAC DISORDERS	4	0.6	(0.2, 1.5)	2	0.3	(0.0, 1.1)
Acute myocardial infarction	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Angina pectoris	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Atrial fibrillation	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Cardio-respiratory arrest	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Coronary artery disease	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Palpitations	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Heart disease congenital	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Type V hyperlipidaemia	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
EAR AND LABYRINTH DISORDERS	7	1.1	(0.4, 2.2)	0	0.0	(0.0, 0.6)
Cerumen impaction	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Ear pain	2	0.3	(0.0, 1.1)	0	0.0	(0.0, 0.6)
Vertigo	3	0.5	(0.1, 1.3)	0	0.0	(0.0, 0.6)
Vertigo positional	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
EYE DISORDERS	5	0.8	(0.2, 1.8)	4	0.6	(0.2, 1.6)
Blepharospasm	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Conjunctival oedema	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Conjunctivitis allergic	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Corneal irritation	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Diabetic retinopathy	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Eye irritation	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Eye pain	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Lacrimation increased	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Ocular hyperaemia	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Vitreous floaters	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)

14.129. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1868, TE[b]=6.6)			Placebo (N[a]=1833, TE[b]=6.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
GASTROINTESTINAL DISORDERS	81	12.2	(9.7, 15.2)	51	8.0	(6.0, 10.6)
Abdominal discomfort	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Abdominal distension	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Abdominal pain	3	0.5	(0.1, 1.3)	0	0.0	(0.0, 0.6)
Abdominal pain lower	0	0.0	(0.0, 0.6)	2	0.3	(0.0, 1.1)
Abdominal pain upper	6	0.9	(0.3, 2.0)	3	0.5	(0.1, 1.4)
Abnormal faeces	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Aphthous ulcer	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Constipation	3	0.5	(0.1, 1.3)	0	0.0	(0.0, 0.6)
Dental caries	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Diarrhoea	31	4.7	(3.2, 6.6)	20	3.2	(1.9, 4.9)
Dyspepsia	3	0.5	(0.1, 1.3)	1	0.2	(0.0, 0.9)
Dysphagia	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Eructation	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Faeces soft	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Flatulence	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Frequent bowel movements	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Gastrointestinal disorder	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Gastrooesophageal reflux disease	2	0.3	(0.0, 1.1)	2	0.3	(0.0, 1.1)
Gingival bleeding	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Gingival discomfort	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Intra-abdominal fluid collection	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Loose tooth	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Nausea	31	4.7	(3.2, 6.6)	10	1.6	(0.8, 2.9)
Noninfective gingivitis	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Odynophagia	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Oesophageal ulcer	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Oesophageal varices haemorrhage	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Pancreatic failure	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Precancerous lesion of digestive tract	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Toothache	1	0.2	(0.0, 0.8)	5	0.8	(0.3, 1.8)
Umbilical hernia	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Vomiting	9	1.4	(0.6, 2.6)	6	0.9	(0.3, 2.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	624	93.9	(86.7, 101.6)	146	23.0	(19.4, 27.1)

14.129. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1868, TE[b]=6.6)			Placebo (N[a]=1833, TE[b]=6.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Application site reaction	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Asthenia	9	1.4	(0.6, 2.6)	1	0.2	(0.0, 0.9)
Axillary pain	3	0.5	(0.1, 1.3)	0	0.0	(0.0, 0.6)
Chest discomfort	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Chest pain	0	0.0	(0.0, 0.6)	2	0.3	(0.0, 1.1)
Chills	159	23.9	(20.4, 28.0)	15	2.4	(1.3, 3.9)
Fatigue	221	33.3	(29.0, 38.0)	59	9.3	(7.1, 12.0)
Feeling hot	3	0.5	(0.1, 1.3)	0	0.0	(0.0, 0.6)
Influenza like illness	2	0.3	(0.0, 1.1)	1	0.2	(0.0, 0.9)
Injection site discolouration	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Injection site discomfort	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Injection site erythema	23	3.5	(2.2, 5.2)	1	0.2	(0.0, 0.9)
Injection site haematoma	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Injection site induration	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Injection site macule	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Injection site oedema	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Injection site pain	399	60.1	(54.3, 66.3)	63	9.9	(7.6, 12.7)
Injection site papule	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Injection site pruritus	3	0.5	(0.1, 1.3)	0	0.0	(0.0, 0.6)
Injection site rash	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Injection site reaction	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Injection site swelling	20	3.0	(1.8, 4.6)	5	0.8	(0.3, 1.8)
Malaise	13	2.0	(1.0, 3.3)	1	0.2	(0.0, 0.9)
Non-cardiac chest pain	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Pain	77	11.6	(9.1, 14.5)	8	1.3	(0.5, 2.5)
Peripheral swelling	2	0.3	(0.0, 1.1)	0	0.0	(0.0, 0.6)
Pyrexia	220	33.1	(28.9, 37.8)	10	1.6	(0.8, 2.9)
Shoulder injury related to vaccine administration	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Swelling face	0	0.0	(0.0, 0.6)	2	0.3	(0.0, 1.1)
Vaccination site pain	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
HEPATOBILIARY DISORDERS	2	0.3	(0.0, 1.1)	1	0.2	(0.0, 0.9)
Cholecystitis acute	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Cholelithiasis	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Hepatic steatosis	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)

14.129. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1868, TE[b]=6.6)			Placebo (N[a]=1833, TE[b]=6.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
IMMUNE SYSTEM DISORDERS	1	0.2	(0.0, 0.8)	3	0.5	(0.1, 1.4)
Drug hypersensitivity	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Food allergy	0	0.0	(0.0, 0.6)	2	0.3	(0.0, 1.1)
Seasonal allergy	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
INFECTIONS AND INFESTATIONS	42	6.3	(4.6, 8.5)	26	4.1	(2.7, 6.0)
Abscess jaw	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Anal abscess	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Appendicitis	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Appendicitis perforated	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Bacterial rhinitis	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Campylobacter infection	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Cellulitis	4	0.6	(0.2, 1.5)	0	0.0	(0.0, 0.6)
Chronic sinusitis	2	0.3	(0.0, 1.1)	0	0.0	(0.0, 0.6)
Conjunctivitis	3	0.5	(0.1, 1.3)	0	0.0	(0.0, 0.6)
Cystitis	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Dental fistula	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Ear infection	1	0.2	(0.0, 0.8)	2	0.3	(0.0, 1.1)
Escherichia urinary tract infection	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Folliculitis	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Gastroenteritis	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Gastroenteritis viral	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Gingival abscess	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Gingivitis	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Helicobacter infection	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Herpes simplex	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Herpes zoster	2	0.3	(0.0, 1.1)	1	0.2	(0.0, 0.9)
Herpes zoster cutaneous disseminated	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Hordeolum	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Infectious mononucleosis	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Influenza	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Injection site abscess	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Mastoiditis	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Meningitis bacterial	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Nail infection	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Onychomycosis	2	0.3	(0.0, 1.1)	0	0.0	(0.0, 0.6)

14.129. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1868, TE[b]=6.6)			Placebo (N[a]=1833, TE[b]=6.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Oral candidiasis	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Oral herpes	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Otitis externa	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Otitis media	2	0.3	(0.0, 1.1)	0	0.0	(0.0, 0.6)
Otitis media acute	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Parasitic gastroenteritis	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Pyelonephritis acute	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Respiratory tract infection viral	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Rhinitis	0	0.0	(0.0, 0.6)	2	0.3	(0.0, 1.1)
Sinusitis	2	0.3	(0.0, 1.1)	0	0.0	(0.0, 0.6)
Subcutaneous abscess	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Syphilis	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Tinea cruris	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Tinea infection	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Tinea versicolour	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Tonsillitis	0	0.0	(0.0, 0.6)	2	0.3	(0.0, 1.1)
Tooth infection	1	0.2	(0.0, 0.8)	2	0.3	(0.0, 1.1)
Upper respiratory tract infection	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Urinary tract infection	4	0.6	(0.2, 1.5)	2	0.3	(0.0, 1.1)
Vaginal infection	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Vulvovaginal candidiasis	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	24	3.6	(2.3, 5.4)	32	5.0	(3.5, 7.1)
Administration related reaction	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Anaemia postoperative	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Animal bite	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Arthropod sting	0	0.0	(0.0, 0.6)	2	0.3	(0.0, 1.1)
Back injury	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Bone contusion	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Burns second degree	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Concussion	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Contusion	1	0.2	(0.0, 0.8)	3	0.5	(0.1, 1.4)
Epicondylitis	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Exposure during pregnancy	2	0.3	(0.0, 1.1)	4	0.6	(0.2, 1.6)
Exposure to communicable disease	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)

14.129. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1868, TE[b]=6.6)			Placebo (N[a]=1833, TE[b]=6.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Facial bones fracture	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Fall	6	0.9	(0.3, 2.0)	4	0.6	(0.2, 1.6)
Foot fracture	0	0.0	(0.0, 0.6)	2	0.3	(0.0, 1.1)
Hand fracture	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Joint dislocation	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Joint injury	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Ligament sprain	2	0.3	(0.0, 1.1)	3	0.5	(0.1, 1.4)
Limb injury	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Maternal exposure during pregnancy	0	0.0	(0.0, 0.6)	3	0.5	(0.1, 1.4)
Muscle strain	0	0.0	(0.0, 0.6)	3	0.5	(0.1, 1.4)
Road traffic accident	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Skin laceration	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Spinal compression fracture	2	0.3	(0.0, 1.1)	0	0.0	(0.0, 0.6)
Stab wound	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Tendon rupture	0	0.0	(0.0, 0.6)	2	0.3	(0.0, 1.1)
Tooth fracture	2	0.3	(0.0, 1.1)	0	0.0	(0.0, 0.6)
Tooth injury	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Vaccination complication	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Wrist fracture	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
INVESTIGATIONS	20	3.0	(1.8, 4.6)	1	0.2	(0.0, 0.9)
Blood cholesterol increased	2	0.3	(0.0, 1.1)	0	0.0	(0.0, 0.6)
Blood glucose increased	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Blood pressure increased	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Blood thyroid stimulating hormone increased	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Body temperature increased	15	2.3	(1.3, 3.7)	1	0.2	(0.0, 0.9)
Low density lipoprotein increased	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
SARS-CoV-2 antibody test positive	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
METABOLISM AND NUTRITION DISORDERS	10	1.5	(0.7, 2.8)	3	0.5	(0.1, 1.4)
Decreased appetite	5	0.8	(0.2, 1.8)	0	0.0	(0.0, 0.6)
Dehydration	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Dyslipidaemia	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Hyperlipidaemia	0	0.0	(0.0, 0.6)	2	0.3	(0.0, 1.1)
Insulin resistance	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Obesity	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)

14.129. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1868, TE[b]=6.6)			Placebo (N[a]=1833, TE[b]=6.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Type 2 diabetes mellitus	3	0.5	(0.1, 1.3)	0	0.0	(0.0, 0.6)
Vitamin D deficiency	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	220	33.1	(28.9, 37.8)	49	7.7	(5.7, 10.2)
Arthralgia	29	4.4	(2.9, 6.3)	11	1.7	(0.9, 3.1)
Arthritis	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Back pain	11	1.7	(0.8, 3.0)	5	0.8	(0.3, 1.8)
Bursitis	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Coccydynia	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Flank pain	1	0.2	(0.0, 0.8)	2	0.3	(0.0, 1.1)
Intervertebral disc degeneration	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Intervertebral disc protrusion	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Joint instability	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Joint range of motion decreased	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Joint stiffness	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Muscle spasms	2	0.3	(0.0, 1.1)	2	0.3	(0.0, 1.1)
Musculoskeletal chest pain	3	0.5	(0.1, 1.3)	1	0.2	(0.0, 0.9)
Musculoskeletal pain	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Myalgia	166	25.0	(21.3, 29.1)	20	3.2	(1.9, 4.9)
Neck pain	5	0.8	(0.2, 1.8)	0	0.0	(0.0, 0.6)
Osteopenia	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Pain in extremity	16	2.4	(1.4, 3.9)	6	0.9	(0.3, 2.1)
Psoriatic arthropathy	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Rotator cuff syndrome	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Spinal osteoarthritis	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Temporomandibular joint syndrome	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Tenosynovitis stenosans	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	4	0.6	(0.2, 1.5)	5	0.8	(0.3, 1.8)
Basal cell carcinoma	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Bladder cancer	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Breast cancer stage I	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Fibroadenoma of breast	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Lipoma	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Malignant melanoma	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)

14.129. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1868, TE[b]=6.6)			Placebo (N[a]=1833, TE[b]=6.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Ovarian germ cell teratoma benign	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Tonsil cancer	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Uterine leiomyoma	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
NERVOUS SYSTEM DISORDERS	204	30.7	(26.6, 35.2)	72	11.4	(8.9, 14.3)
Dizziness	10	1.5	(0.7, 2.8)	8	1.3	(0.5, 2.5)
Drug withdrawal headache	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Dysgeusia	2	0.3	(0.0, 1.1)	3	0.5	(0.1, 1.4)
Dystonia	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Guillain-Barre syndrome	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Headache	183	27.5	(23.7, 31.8)	54	8.5	(6.4, 11.1)
Hyperaesthesia	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Hypoaesthesia	2	0.3	(0.0, 1.1)	0	0.0	(0.0, 0.6)
Lethargy	3	0.5	(0.1, 1.3)	0	0.0	(0.0, 0.6)
Migraine	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Paraesthesia	1	0.2	(0.0, 0.8)	2	0.3	(0.0, 1.1)
Parkinsonism	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Peripheral sensory neuropathy	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Presyncope	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Somnolence	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Subarachnoid haemorrhage	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Syncope	2	0.3	(0.0, 1.1)	0	0.0	(0.0, 0.6)
Taste disorder	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Tension headache	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Tremor	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
PSYCHIATRIC DISORDERS	10	1.5	(0.7, 2.8)	4	0.6	(0.2, 1.6)
Alcohol abuse	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Alcohol withdrawal syndrome	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Anxiety	5	0.8	(0.2, 1.8)	0	0.0	(0.0, 0.6)
Depressed mood	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Depression	2	0.3	(0.0, 1.1)	1	0.2	(0.0, 0.9)
Insomnia	3	0.5	(0.1, 1.3)	0	0.0	(0.0, 0.6)
Listless	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Schizophrenia	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
RENAL AND URINARY DISORDERS	0	0.0	(0.0, 0.6)	2	0.3	(0.0, 1.1)

14.129. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1868, TE[b]=6.6)			Placebo (N[a]=1833, TE[b]=6.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Haematuria	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Nephrolithiasis	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	5	0.8	(0.2, 1.8)	6	0.9	(0.3, 2.1)
Amenorrhoea	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Benign prostatic hyperplasia	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Breast hyperplasia	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Breast mass	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Dysmenorrhoea	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Menstruation irregular	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Ovarian cyst	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Pelvic pain	0	0.0	(0.0, 0.6)	2	0.3	(0.0, 1.1)
Uterine inflammation	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	18	2.7	(1.6, 4.3)	9	1.4	(0.6, 2.7)
Cough	3	0.5	(0.1, 1.3)	0	0.0	(0.0, 0.6)
Dyspnoea	0	0.0	(0.0, 0.6)	2	0.3	(0.0, 1.1)
Dyspnoea exertional	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Epistaxis	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Nasal congestion	2	0.3	(0.0, 1.1)	2	0.3	(0.0, 1.1)
Nasal obstruction	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Oropharyngeal pain	3	0.5	(0.1, 1.3)	0	0.0	(0.0, 0.6)
Paranasal sinus discomfort	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Pleurisy	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Productive cough	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Pulmonary embolism	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Rhinalgia	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Rhinitis allergic	2	0.3	(0.0, 1.1)	0	0.0	(0.0, 0.6)
Rhinorrhoea	2	0.3	(0.0, 1.1)	1	0.2	(0.0, 0.9)
Sinus disorder	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Throat irritation	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Upper respiratory tract congestion	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Upper-airway cough syndrome	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	21	3.2	(2.0, 4.8)	17	2.7	(1.6, 4.3)

14.129. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1868, TE[b]=6.6)			Placebo (N[a]=1833, TE[b]=6.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Alopecia	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Cold sweat	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Dermatitis	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Dermatitis allergic	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Dermatitis contact	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Ecchymosis	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Erythema	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Hyperhidrosis	5	0.8	(0.2, 1.8)	1	0.2	(0.0, 0.9)
Night sweats	2	0.3	(0.0, 1.1)	0	0.0	(0.0, 0.6)
Pruritus	0	0.0	(0.0, 0.6)	4	0.6	(0.2, 1.6)
Pruritus allergic	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Rash	6	0.9	(0.3, 2.0)	3	0.5	(0.1, 1.4)
Rash maculo-papular	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Rash pruritic	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Seborrhoeic dermatitis	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Skin irritation	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Skin lesion	2	0.3	(0.0, 1.1)	1	0.2	(0.0, 0.9)
Urticaria	1	0.2	(0.0, 0.8)	4	0.6	(0.2, 1.6)
SURGICAL AND MEDICAL PROCEDURES	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Gingival operation	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
VASCULAR DISORDERS	3	0.5	(0.1, 1.3)	3	0.5	(0.1, 1.4)
Aortic aneurysm	0	0.0	(0.0, 0.6)	2	0.3	(0.0, 1.1)
Hypertension	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Hypotension	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Thrombophlebitis superficial	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)

14.129. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1868, TE[b]=6.6)			Placebo (N[a]=1833, TE[b]=6.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: MedDRA (v23.1) 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.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_unb_race_p3_saf

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	3279	76.0	(73.4, 78.6)	1668	40.1	(38.2, 42.1)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	49	1.1	(0.8, 1.5)	13	0.3	(0.2, 0.5)
Anaemia	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Blood loss anaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Coagulopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypochromic anaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Iron deficiency anaemia	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Leukocytosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Leukopenia	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lymph node pain	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Lymphadenopathy	36	0.8	(0.6, 1.2)	5	0.1	(0.0, 0.3)
Lymphadenopathy mediastinal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neutropenia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Splenomegaly	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thrombocytopenia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Thrombocytosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
CARDIAC DISORDERS	52	1.2	(0.9, 1.6)	48	1.2	(0.9, 1.5)
Acute coronary syndrome	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Acute left ventricular failure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Acute myocardial infarction	6	0.1	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Angina pectoris	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Angina unstable	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Aortic valve incompetence	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Arrhythmia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Arrhythmia supraventricular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arteriosclerosis coronary artery	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arteriospasm coronary	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Atrial fibrillation	9	0.2	(0.1, 0.4)	11	0.3	(0.1, 0.5)
Atrial flutter	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Atrioventricular block complete	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrioventricular block first degree	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bradycardia	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Bundle branch block left	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bundle branch block right	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiac arrest	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.2)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiomegaly	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Coronary artery disease	4	0.1	(0.0, 0.2)	6	0.1	(0.1, 0.3)
Coronary artery occlusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertensive heart disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Left atrial enlargement	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Left ventricular dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Left ventricular hypertrophy	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Mitral valve incompetence	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Mitral valve prolapse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myocardial infarction	4	0.1	(0.0, 0.2)	7	0.2	(0.1, 0.3)
Palpitations	2	0.0	(0.0, 0.2)	8	0.2	(0.1, 0.4)
Pericarditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sinus bradycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tachyarrhythmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tachycardia	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Tricuspid valve incompetence	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ventricular extrasystoles	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ventricular tachycardia	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Congenital bladder neck obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Congenital ureteropelvic junction obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Protein S deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	33	0.8	(0.5, 1.1)	33	0.8	(0.5, 1.1)
Allergic otitis media	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerumen impaction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deafness	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Deafness neurosensory	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Deafness unilateral	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear discomfort	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Ear pain	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.3)
Ear pruritus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eustachian tube dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Meniere's disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Otorrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tinnitus	5	0.1	(0.0, 0.3)	9	0.2	(0.1, 0.4)
Tympanic membrane perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vertigo	17	0.4	(0.2, 0.6)	10	0.2	(0.1, 0.4)
Vertigo positional	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
ENDOCRINE DISORDERS	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Autoimmune thyroiditis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypogonadism	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypothyroidism	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Thyroid mass	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
EYE DISORDERS	25	0.6	(0.4, 0.9)	34	0.8	(0.6, 1.1)
Amaurosis fugax	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Asthenopia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Astigmatism	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blepharitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blepharospasm	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cataract	5	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.2)
Chalazion	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Conjunctival haemorrhage	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Conjunctival oedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Conjunctivitis allergic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diabetic retinopathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diplopia	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dry age-related macular degeneration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dry eye	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Episcleritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eye haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye irritation	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Eye pain	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Eye pruritus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eyelid haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Glaucoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypermetropia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Keratitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lacrimation increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Macular oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ocular discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ocular hyperaemia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Photophobia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Retinal artery occlusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal detachment	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Swelling of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ulcerative keratitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vision blurred	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Visual acuity reduced	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Visual impairment	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vitreous detachment	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Vitreous floaters	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	320	7.4	(6.6, 8.3)	249	6.0	(5.3, 6.8)
Abdominal adhesions	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abdominal discomfort	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Abdominal distension	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Abdominal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abdominal pain	6	0.1	(0.1, 0.3)	11	0.3	(0.1, 0.5)
Abdominal pain lower	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abdominal pain upper	8	0.2	(0.1, 0.4)	7	0.2	(0.1, 0.3)
Abdominal rigidity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anal pruritus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angular cheilitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Aphthous ulcer	6	0.1	(0.1, 0.3)	1	0.0	(0.0, 0.1)
Coeliac disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colitis ulcerative	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Constipation	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Crohn's disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dental caries	7	0.2	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Diarrhoea	125	2.9	(2.4, 3.5)	89	2.1	(1.7, 2.6)
Diverticular perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulum	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulum intestinal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diverticulum intestinal haemorrhagic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dry mouth	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Dyspepsia	8	0.2	(0.1, 0.4)	6	0.1	(0.1, 0.3)
Dysphagia	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Epiploic appendagitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eructation	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Faeces soft	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Femoral hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Flatulence	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Food poisoning	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastric polyps	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastritis	2	0.0	(0.0, 0.2)	7	0.2	(0.1, 0.3)
Gastrointestinal disorder	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastrointestinal sounds abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrooesophageal reflux disease	9	0.2	(0.1, 0.4)	9	0.2	(0.1, 0.4)
Gingival bleeding	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gingival discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gingival pain	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gingival swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haematemesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haematochezia	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Haemorrhoids	3	0.1	(0.0, 0.2)	7	0.2	(0.1, 0.3)
Hiatus hernia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoaesthesia oral	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Incarcerated inguinal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Inguinal hernia	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.3)
Internal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intestinal obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Intestinal strangulation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intra-abdominal fluid collection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Irritable bowel syndrome	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Large intestine polyp	2	0.0	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Lip swelling	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Loose tooth	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mouth ulceration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nausea	91	2.1	(1.7, 2.6)	43	1.0	(0.7, 1.4)
Noninfective gingivitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Odynophagia	7	0.2	(0.1, 0.3)	1	0.0	(0.0, 0.1)
Oesophageal ulcer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oesophageal varices haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oesophagitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Oral mucosa haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Palatal disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis acute	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Paraesthesia oral	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Peptic ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Proctalgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectal haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectal polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Retching	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retroperitoneal haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Salivary gland mucocoele	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Small intestinal obstruction	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Stomatitis	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Swollen tongue	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Teething	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tongue discolouration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tongue discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tongue oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tooth impacted	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Toothache	11	0.3	(0.1, 0.5)	15	0.4	(0.2, 0.6)
Umbilical hernia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Varices oesophageal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vomiting	20	0.5	(0.3, 0.7)	15	0.4	(0.2, 0.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2229	51.6	(49.5, 53.8)	465	11.2	(10.2, 12.2)
Application site rash	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Asthenia	46	1.1	(0.8, 1.4)	12	0.3	(0.1, 0.5)
Axillary pain	5	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.1)
Chest discomfort	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Chest pain	10	0.2	(0.1, 0.4)	8	0.2	(0.1, 0.4)
Chills	638	14.8	(13.7, 16.0)	58	1.4	(1.1, 1.8)
Cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug withdrawal syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Face oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fatigue	719	16.7	(15.5, 17.9)	167	4.0	(3.4, 4.7)
Feeling abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Feeling cold	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Feeling hot	5	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.1)
Gait disturbance	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Illness	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Induration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Inflammation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Influenza like illness	14	0.3	(0.2, 0.5)	2	0.0	(0.0, 0.2)
Injection site bruising	2	0.0	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Injection site discolouration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site discomfort	5	0.1	(0.0, 0.3)	2	0.0	(0.0, 0.2)
Injection site erythema	48	1.1	(0.8, 1.5)	10	0.2	(0.1, 0.4)
Injection site haematoma	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Injection site haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site induration	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site macule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site oedema	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site pain	1351	31.3	(29.7, 33.0)	186	4.5	(3.9, 5.2)
Injection site paraesthesia	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site plaque	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site pruritus	9	0.2	(0.1, 0.4)	3	0.1	(0.0, 0.2)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site rash	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site reaction	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Injection site swelling	44	1.0	(0.7, 1.4)	10	0.2	(0.1, 0.4)
Injection site urticaria	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site warmth	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Malaise	70	1.6	(1.3, 2.0)	12	0.3	(0.1, 0.5)
Mucosal disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nodule	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Non-cardiac chest pain	3	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Oedema peripheral	6	0.1	(0.1, 0.3)	3	0.1	(0.0, 0.2)
Pain	271	6.3	(5.6, 7.1)	22	0.5	(0.3, 0.8)
Peripheral swelling	5	0.1	(0.0, 0.3)	5	0.1	(0.0, 0.3)
Pyrexia	689	16.0	(14.8, 17.2)	37	0.9	(0.6, 1.2)
Sensation of foreign body	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sluggishness	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Swelling	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Swelling face	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Vaccination site pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vessel puncture site bruise	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vessel puncture site haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vessel puncture site induration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	12	0.3	(0.1, 0.5)	7	0.2	(0.1, 0.3)
Bile duct stone	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary colic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary dyskinesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholecystitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholecystitis acute	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Cholelithiasis	8	0.2	(0.1, 0.4)	2	0.0	(0.0, 0.2)
Cirrhosis alcoholic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hepatic cirrhosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatic cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	9	0.2	(0.1, 0.4)	15	0.4	(0.2, 0.6)
Allergy to animal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Allergy to arthropod bite	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Allergy to arthropod sting	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anaphylactic shock	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug hypersensitivity	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Food allergy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypersensitivity	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Seasonal allergy	2	0.0	(0.0, 0.2)	8	0.2	(0.1, 0.4)
INFECTIONS AND INFESTATIONS	172	4.0	(3.4, 4.6)	196	4.7	(4.1, 5.4)
Abdominal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess intestinal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abscess jaw	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess limb	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Acarodermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Acute sinusitis	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Anal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anal fistula infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Appendicitis	7	0.2	(0.1, 0.3)	5	0.1	(0.0, 0.3)
Appendicitis perforated	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arthritis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bacterial blepharitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bacterial infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bacterial sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Balanitis candida	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bone abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bronchitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.1)	8	0.2	(0.1, 0.4)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cellulitis	11	0.3	(0.1, 0.5)	11	0.3	(0.1, 0.5)
Chlamydial infection	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Chronic sinusitis	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Conjunctivitis	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Cystitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Device related infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Diverticulitis	5	0.1	(0.0, 0.3)	5	0.1	(0.0, 0.3)
Ear infection	7	0.2	(0.1, 0.3)	8	0.2	(0.1, 0.4)
Emphysematous cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Erysipelas	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Escherichia sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Escherichia urinary tract infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Extradural abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye infection bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Folliculitis	6	0.1	(0.1, 0.3)	0	0.0	(0.0, 0.1)
Fungal skin infection	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Furuncle	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Gangrene	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastroenteritis	3	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Gastrointestinal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Genital herpes	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Genitourinary chlamydia infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gingivitis	5	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.1)
Gonorrhoea	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Helicobacter gastritis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Helicobacter infection	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Hepatitis A	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Herpes simplex	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Herpes zoster	10	0.2	(0.1, 0.4)	6	0.1	(0.1, 0.3)
Herpes zoster cutaneous disseminated	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hordeolum	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Impetigo	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Infected bite	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Infected dermal cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Influenza	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Laryngitis	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Localised infection	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Lyme disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mastoiditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Meningitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasopharyngitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Onychomycosis	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Ophthalmic herpes zoster	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral candidiasis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral fungal infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral herpes	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Oral infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Orchitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Osteomyelitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Otitis externa	4	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Otitis media	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Otitis media acute	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Otitis media bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Paronychia	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Parotitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Penile infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Periodontitis	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peritonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peritonsillar abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pharyngitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Pharyngitis streptococcal	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Pharyngotonsillitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pilonidal cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumonia	2	0.0	(0.0, 0.2)	6	0.1	(0.1, 0.3)
Postoperative wound infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Primary syphilis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pustule	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pyelonephritis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pyelonephritis acute	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Respiratory tract infection viral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rhinitis	4	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Sepsis	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Shigella sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Sialoadenitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinusitis	6	0.1	(0.1, 0.3)	9	0.2	(0.1, 0.4)
Sinusitis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin bacterial infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin infection	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Soft tissue infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Staphylococcal infection	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Staphylococcal sepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subacute endocarditis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subcutaneous abscess	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Syphilis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tinea cruris	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tinea versicolour	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tonsillitis	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Tooth abscess	7	0.2	(0.1, 0.3)	2	0.0	(0.0, 0.2)
Tooth infection	13	0.3	(0.2, 0.5)	18	0.4	(0.3, 0.7)
Trichomoniasis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper respiratory tract infection	5	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.2)
Urinary tract infection	10	0.2	(0.1, 0.4)	15	0.4	(0.2, 0.6)
Urosepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Viral upper respiratory tract infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Wound infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	133	3.1	(2.6, 3.7)	176	4.2	(3.6, 4.9)
Administration related reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Alcohol poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Animal bite	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Ankle fracture	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Arthropod bite	3	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Arthropod sting	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Back injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bone contusion	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Bone fissure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Brain contusion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Burn oral cavity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Burns first degree	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Burns second degree	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cervical vertebral fracture	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Chest injury	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Chillblains	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clavicle fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colon injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Concussion	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Contusion	9	0.2	(0.1, 0.4)	12	0.3	(0.1, 0.5)
Corneal abrasion	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Craniocerebral injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Delayed recovery from anaesthesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dental restoration failure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Epicondylitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Exposure during pregnancy	7	0.2	(0.1, 0.3)	8	0.2	(0.1, 0.4)
Exposure to communicable disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eyelid injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Facial bones fracture	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Fall	29	0.7	(0.5, 1.0)	31	0.7	(0.5, 1.1)
Fibula fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foot fracture	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Forearm fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foreign body aspiration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foreign body in eye	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fractured sacrum	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hand fracture	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Head injury	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Heat stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hip fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Humerus fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Jaw fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Joint dislocation	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.2)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Joint injury	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.3)
Ligament injury	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Ligament rupture	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Ligament sprain	7	0.2	(0.1, 0.3)	10	0.2	(0.1, 0.4)
Limb injury	6	0.1	(0.1, 0.3)	7	0.2	(0.1, 0.3)
Limb traumatic amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lip injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lower limb fracture	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Meniscus injury	4	0.1	(0.0, 0.2)	7	0.2	(0.1, 0.3)
Mouth injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle contusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Muscle injury	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Muscle rupture	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Muscle strain	7	0.2	(0.1, 0.3)	9	0.2	(0.1, 0.4)
Overdose	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Patella fracture	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pelvic fracture	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Penis injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pharyngeal perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Post procedural discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post procedural haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Post procedural haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Postoperative ileus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Procedural hypotension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Procedural pain	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Radius fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Respiratory fume inhalation disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rib fracture	2	0.0	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Road traffic accident	12	0.3	(0.1, 0.5)	12	0.3	(0.1, 0.5)
Scapula fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Scar	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin abrasion	5	0.1	(0.0, 0.3)	8	0.2	(0.1, 0.4)
Skin injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin laceration	7	0.2	(0.1, 0.3)	17	0.4	(0.2, 0.7)
Spinal compression fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Spinal cord injury cervical	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Spinal fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Stab wound	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Stoma site rash	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Subdural haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sunburn	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tendon injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tendon rupture	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Thermal burn	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Tibia fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tooth fracture	5	0.1	(0.0, 0.3)	7	0.2	(0.1, 0.3)
Toxicity to various agents	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Wound	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Wrist fracture	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
INVESTIGATIONS	80	1.9	(1.5, 2.3)	28	0.7	(0.4, 1.0)
Alanine aminotransferase increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Autoantibody positive	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood cholesterol increased	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Blood creatinine increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood glucose abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood glucose fluctuation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood glucose increased	6	0.1	(0.1, 0.3)	0	0.0	(0.0, 0.1)
Blood potassium decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood pressure diastolic increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood pressure increased	2	0.0	(0.0, 0.2)	7	0.2	(0.1, 0.3)
Blood pressure systolic increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood testosterone decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Body temperature decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Body temperature increased	53	1.2	(0.9, 1.6)	6	0.1	(0.1, 0.3)
Fractional exhaled nitric oxide increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Heart rate increased	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Hepatic enzyme increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatitis C antibody positive	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Herpes simplex test positive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
High density lipoprotein increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Liver function test increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Low density lipoprotein increased	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Lymphocyte count decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Monocyte count increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Platelet count decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Prostatic specific antigen increased	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Respiratory rate increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
SARS-CoV-2 antibody test positive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Troponin increased	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Weight decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	60	1.4	(1.1, 1.8)	59	1.4	(1.1, 1.8)
Decreased appetite	13	0.3	(0.2, 0.5)	4	0.1	(0.0, 0.2)
Dehydration	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Diabetes mellitus	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Diabetic ketoacidosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dyslipidaemia	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Folate deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glucose tolerance impaired	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Gout	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Hypercholesterolaemia	4	0.1	(0.0, 0.2)	7	0.2	(0.1, 0.3)
Hyperglycaemia	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Hyperkalaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperlipidaemia	3	0.1	(0.0, 0.2)	6	0.1	(0.1, 0.3)
Hypernatraemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypertriglyceridaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperuricaemia	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Hypocalcaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypocholesterolaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypoglycaemia	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Hypokalaemia	6	0.1	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Hypomagnesaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyponatraemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hypovolaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Insulin resistance	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Iron deficiency	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lactic acidosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Obesity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Polydipsia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Type 2 diabetes mellitus	7	0.2	(0.1, 0.3)	10	0.2	(0.1, 0.4)
Vitamin B12 deficiency	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vitamin D deficiency	5	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	874	20.3	(18.9, 21.6)	292	7.0	(6.2, 7.9)
Arthralgia	136	3.2	(2.6, 3.7)	61	1.5	(1.1, 1.9)
Arthritis	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Arthropathy	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Axillary mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Back pain	57	1.3	(1.0, 1.7)	47	1.1	(0.8, 1.5)
Bone disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bone pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bone swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bursitis	6	0.1	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Coccydynia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Costochondritis	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Exostosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Flank pain	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Groin pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intervertebral disc degeneration	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Intervertebral disc disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	5	0.1	(0.0, 0.3)	6	0.1	(0.1, 0.3)
Joint effusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Joint instability	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Joint stiffness	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Joint swelling	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Limb discomfort	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Mobility decreased	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Muscle contracture	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Muscle fatigue	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Muscle spasms	15	0.3	(0.2, 0.6)	8	0.2	(0.1, 0.4)
Muscle tightness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Muscle twitching	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Muscular weakness	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Musculoskeletal chest pain	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.2)
Musculoskeletal discomfort	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Musculoskeletal pain	2	0.0	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Musculoskeletal stiffness	6	0.1	(0.1, 0.3)	3	0.1	(0.0, 0.2)
Myalgia	571	13.2	(12.2, 14.4)	78	1.9	(1.5, 2.3)
Neck pain	14	0.3	(0.2, 0.5)	12	0.3	(0.1, 0.5)
Osteitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteoarthritis	5	0.1	(0.0, 0.3)	12	0.3	(0.1, 0.5)
Osteochondrosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteopenia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Osteoporosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pain in extremity	90	2.1	(1.7, 2.6)	27	0.6	(0.4, 0.9)
Pain in jaw	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Periarthritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Plantar fasciitis	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Psoriatic arthropathy	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Rhabdomyolysis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rheumatoid arthritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rotator cuff syndrome	2	0.0	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Scoliosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Spinal disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal osteoarthritis	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Spinal stenosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Synovial cyst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Synovitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Temporomandibular joint syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tendon disorder	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Tendon pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tendonitis	7	0.2	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Tenosynovitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Tenosynovitis stenosans	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Torticollis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Trigger finger	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	33	0.8	(0.5, 1.1)	29	0.7	(0.5, 1.0)
Adenocarcinoma of colon	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenocarcinoma pancreas	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Basal cell carcinoma	2	0.0	(0.0, 0.2)	6	0.1	(0.1, 0.3)
Benign breast neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Benign hydatidiform mole	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary cancer metastatic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bladder cancer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Breast cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Carcinoid tumour of the stomach	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colon adenoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Leydig cell tumour of the testis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lipoma	4	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Malignant melanoma	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Malignant melanoma of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to liver	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Non-Hodgkin's lymphoma recurrent	0	0.0	(0.0, 0.1)	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, 0.1)
Oropharyngeal cancer recurrent	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatic carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Penile neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Penile squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Polycythaemia vera	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Prostate cancer	5	0.1	(0.0, 0.3)	2	0.0	(0.0, 0.2)
Prostate cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Squamous cell carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Squamous cell carcinoma of head and neck	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Squamous cell carcinoma of skin	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Thyroid cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tonsil cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transitional cell carcinoma	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	695	16.1	(14.9, 17.3)	277	6.7	(5.9, 7.5)
Ageusia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Amnesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Amyotrophic lateral sclerosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aphasia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Balance disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Burning sensation	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Carpal tunnel syndrome	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Cerebrovascular accident	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cervical radiculopathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diabetic neuropathy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Disturbance in attention	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dizziness	39	0.9	(0.6, 1.2)	36	0.9	(0.6, 1.2)
Dizziness postural	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Drug withdrawal headache	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dysgeusia	3	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Dyskinesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Facial paralysis	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Guillain-Barre syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Head discomfort	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Headache	568	13.2	(12.1, 14.3)	175	4.2	(3.6, 4.9)
Hemiparaesthesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyperaesthesia	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypoaesthesia	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Hypogeusia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyposmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intraventricular haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ischaemic stroke	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Lethargy	14	0.3	(0.2, 0.5)	4	0.1	(0.0, 0.2)
Mental impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Migraine	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.2)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Muscle spasticity	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nerve compression	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Neuralgia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neuritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neuropathy peripheral	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Nystagmus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Optic neuritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paraesthesia	17	0.4	(0.2, 0.6)	12	0.3	(0.1, 0.5)
Paraparesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Parkinsonism	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Parosmia	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Periodic limb movement disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peripheral nerve lesion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peripheral sensory neuropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post herpetic neuralgia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Presyncope	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Radiculopathy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Restless legs syndrome	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Sciatica	5	0.1	(0.0, 0.3)	5	0.1	(0.0, 0.3)
Seizure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sinus headache	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Somnolence	6	0.1	(0.1, 0.3)	5	0.1	(0.0, 0.3)
Subarachnoid haemorrhage	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Syncope	8	0.2	(0.1, 0.4)	9	0.2	(0.1, 0.4)
Taste disorder	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Tension headache	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Thoracic radiculopathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Transient global amnesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transient ischaemic attack	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tremor	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Trigeminal neuralgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
VIth nerve paralysis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PRODUCT ISSUES	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Device breakage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
PSYCHIATRIC DISORDERS	51	1.2	(0.9, 1.6)	45	1.1	(0.8, 1.4)
Abnormal dreams	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Alcohol withdrawal syndrome	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Anxiety	10	0.2	(0.1, 0.4)	10	0.2	(0.1, 0.4)
Anxiety disorder	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Attention deficit hyperactivity disorder	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Bipolar disorder	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Cyclothymic disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depression	7	0.2	(0.1, 0.3)	13	0.3	(0.2, 0.5)
Disorientation	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dysphemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Insomnia	15	0.3	(0.2, 0.6)	7	0.2	(0.1, 0.3)
Irritability	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Libido decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Libido increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Listless	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Major depression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mental disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mental status changes	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mood swings	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nightmare	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Panic attack	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Panic disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Paranoia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post-traumatic stress disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Schizophrenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sleep disorder	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Substance abuse	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Suicidal ideation	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Suicide attempt	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	31	0.7	(0.5, 1.0)	31	0.7	(0.5, 1.1)
Acute kidney injury	5	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.2)
Bladder spasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chronic kidney disease	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Costovertebral angle tenderness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dysuria	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Haematuria	3	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Hydronephrosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Micturition urgency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nephrolithiasis	7	0.2	(0.1, 0.3)	11	0.3	(0.1, 0.5)
Nocturia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oedematous kidney	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Perinephric oedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pollakiuria	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Renal colic	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Renal cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Renal cyst haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subcapsular renal haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ureterolithiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urethral discharge	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urethral stenosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urinary retention	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Urine odour abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	15	0.3	(0.2, 0.6)	17	0.4	(0.2, 0.7)
Benign prostatic hyperplasia	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Ejaculation disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Erectile dysfunction	1	0.0	(0.0, 0.1)	6	0.1	(0.1, 0.3)
Genital erythema	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Haematospermia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Penile vein thrombosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Prostatitis	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Prostatomegaly	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Pruritus genital	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Scrotal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Testicular pain	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Testicular torsion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	112	2.6	(2.1, 3.1)	88	2.1	(1.7, 2.6)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Acute respiratory failure	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Allergic respiratory disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Allergic sinusitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthma	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.2)
Atelectasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bronchospasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cough	11	0.3	(0.1, 0.5)	8	0.2	(0.1, 0.4)
Dry throat	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dysphonia	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Dyspnoea	3	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Dyspnoea exertional	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Epistaxis	4	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Haemoptysis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hiccups	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypoxia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Interstitial lung disease	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Nasal congestion	24	0.6	(0.4, 0.8)	17	0.4	(0.2, 0.7)
Nasal discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nasal polyps	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal septum deviation	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal valve collapse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasopharyngeal polyp	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oropharyngeal discomfort	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Oropharyngeal pain	13	0.3	(0.2, 0.5)	14	0.3	(0.2, 0.6)
Paranasal sinus discomfort	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Paranasal sinus hypersecretion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pharyngeal lesion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pharyngeal swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonia aspiration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumothorax	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Productive cough	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Pulmonary embolism	7	0.2	(0.1, 0.3)	5	0.1	(0.0, 0.3)
Pulmonary hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pulmonary mass	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pulmonary oedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pulmonary pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Reflux laryngitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory failure	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory tract congestion	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Rhinitis allergic	6	0.1	(0.1, 0.3)	9	0.2	(0.1, 0.4)
Rhinitis perennial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rhinorrhoea	10	0.2	(0.1, 0.4)	4	0.1	(0.0, 0.2)
Sinus congestion	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Sleep apnoea syndrome	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sneezing	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Snoring	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sputum discoloured	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Throat irritation	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Upper respiratory tract congestion	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Upper-airway cough syndrome	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Wheezing	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	108	2.5	(2.1, 3.0)	80	1.9	(1.5, 2.4)
Acne	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Actinic keratosis	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Alopecia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Alopecia areata	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angioedema	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cold sweat	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dermal cyst	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Dermatitis	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dermatitis allergic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis atopic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis bullous	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis contact	8	0.2	(0.1, 0.4)	7	0.2	(0.1, 0.3)
Dermatitis exfoliative	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diabetic foot	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug eruption	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dry skin	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ecchymosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eczema	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Erythema	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hand dermatitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Hyperhidrosis	15	0.3	(0.2, 0.6)	7	0.2	(0.1, 0.3)
Ingrowing nail	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intertrigo	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Livedo reticularis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Macule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Night sweats	13	0.3	(0.2, 0.5)	0	0.0	(0.0, 0.1)
Pain of skin	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Papule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peau d'orange	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pityriasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pityriasis rosea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pruritus	11	0.3	(0.1, 0.5)	8	0.2	(0.1, 0.4)
Pruritus allergic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Psoriasis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Purpura	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rash	26	0.6	(0.4, 0.9)	18	0.4	(0.3, 0.7)
Rash erythematous	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Rash maculo-papular	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Rash pruritic	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.3)
Rosacea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Seborrhoeic dermatitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Skin induration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin lesion	2	0.0	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Skin mass	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transient acantholytic dermatosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urticaria	3	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.3)
SOCIAL CIRCUMSTANCES	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
High risk sexual behaviour	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Miscarriage of partner	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
SURGICAL AND MEDICAL PROCEDURES	14	0.3	(0.2, 0.5)	11	0.3	(0.1, 0.5)
Cardiac pacemaker replacement	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardioversion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Carpal tunnel decompression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cataract operation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chondroplasty	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dental care	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dental implantation	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Endodontic procedure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Inguinal hernia repair	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lacrimal duct procedure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Medical device implantation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal polypectomy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin neoplasm excision	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Toe operation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tonsillectomy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tooth extraction	4	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Vasectomy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Wisdom teeth removal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Wound drainage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
VASCULAR DISORDERS	56	1.3	(1.0, 1.7)	67	1.6	(1.2, 2.0)
Accelerated hypertension	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Aortic aneurysm	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Aortic dilatation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Aortic rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic stenosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Arteriosclerosis	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Blood pressure inadequately controlled	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deep vein thrombosis	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Flushing	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Haematoma	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Hot flush	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Hypertension	33	0.8	(0.5, 1.1)	42	1.0	(0.7, 1.4)
Hypertensive crisis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.130. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hypertensive emergency	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertensive urgency	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Hypotension	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Lymphorrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Orthostatic hypotension	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Pallor	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peripheral arterial occlusive disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peripheral artery stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Raynaud's phenomenon	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 unb sex p3 saf

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	3668	91.0	(88.1, 94.0)	1900	46.8	(44.7, 49.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	69	1.7	(1.3, 2.2)	19	0.5	(0.3, 0.7)
Anaemia	5	0.1	(0.0, 0.3)	7	0.2	(0.1, 0.4)
Blood loss anaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Iron deficiency anaemia	5	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Leukocytosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Leukopenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymph node pain	5	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Lymphadenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphadenopathy	51	1.3	(0.9, 1.7)	3	0.1	(0.0, 0.2)
Lymphadenopathy mediastinal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphocytosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphopenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Microcytic anaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Monoclonal B-cell lymphocytosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neutropenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Thrombocytosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
CARDIAC DISORDERS	35	0.9	(0.6, 1.2)	30	0.7	(0.5, 1.1)
Acute coronary syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angina pectoris	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Angina unstable	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arrhythmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arteriospasm coronary	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrial fibrillation	4	0.1	(0.0, 0.3)	6	0.1	(0.1, 0.3)
Bradycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac arrest	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cardiac disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiac failure acute	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiovascular disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Coronary artery disease	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Coronary artery dissection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mitral valve prolapse	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Myocardial infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myocardial ischaemia	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Myocarditis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Palpitations	5	0.1	(0.0, 0.3)	8	0.2	(0.1, 0.4)
Pericardial effusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Postural orthostatic tachycardia syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinus tachycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Supraventricular tachycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tachycardia	11	0.3	(0.1, 0.5)	5	0.1	(0.0, 0.3)
Ventricular arrhythmia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ventricular extrasystoles	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Arnold-Chiari malformation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Congenital cystic kidney disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Developmental hip dysplasia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal arteriovenous malformation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Heart disease congenital	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Type V hyperlipidaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	43	1.1	(0.8, 1.4)	28	0.7	(0.5, 1.0)
Cerumen impaction	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Deafness unilateral	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ear discomfort	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear disorder	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Ear pain	12	0.3	(0.2, 0.5)	6	0.1	(0.1, 0.3)
Eustachian tube dysfunction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyperacusis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypoacusis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Meniere's disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sudden hearing loss	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tinnitus	4	0.1	(0.0, 0.3)	2	0.0	(0.0, 0.2)
Vertigo	14	0.3	(0.2, 0.6)	16	0.4	(0.2, 0.6)
Vertigo positional	6	0.1	(0.1, 0.3)	1	0.0	(0.0, 0.1)
ENDOCRINE DISORDERS	13	0.3	(0.2, 0.6)	7	0.2	(0.1, 0.4)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Autoimmune thyroiditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Goitre	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperprolactinaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperthyroidism	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypothyroidism	7	0.2	(0.1, 0.4)	5	0.1	(0.0, 0.3)
Oestrogen deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Thyroid cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thyroid mass	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
EYE DISORDERS	45	1.1	(0.8, 1.5)	31	0.8	(0.5, 1.1)
Angle closure glaucoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthenopia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blepharitis	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Blepharospasm	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cataract	2	0.0	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Chalazion	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Choroidal neovascularisation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Conjunctival haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Conjunctival hyperaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Conjunctivitis allergic	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Corneal irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dacryostenosis acquired	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dry eye	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Eye allergy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye inflammation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye irritation	5	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.1)
Eye pain	6	0.1	(0.1, 0.3)	3	0.1	(0.0, 0.2)
Eye pruritus	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Eye swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eyelid oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eyelid pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eyelids pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glaucoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Iritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Keratitis	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Lacrimation increased	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Macular oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ocular hyperaemia	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Photophobia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal artery occlusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Retinal detachment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal tear	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Scleral discolouration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ulcerative keratitis	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Uveitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vision blurred	4	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.1)
Visual impairment	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vitreous detachment	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Vitreous floaters	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	428	10.6	(9.6, 11.7)	262	6.5	(5.7, 7.3)
Abdominal discomfort	6	0.1	(0.1, 0.3)	2	0.0	(0.0, 0.2)
Abdominal distension	4	0.1	(0.0, 0.3)	2	0.0	(0.0, 0.2)
Abdominal hernia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Abdominal pain	17	0.4	(0.2, 0.7)	11	0.3	(0.1, 0.5)
Abdominal pain lower	2	0.0	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Abdominal pain upper	19	0.5	(0.3, 0.7)	8	0.2	(0.1, 0.4)
Abnormal faeces	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Acute abdomen	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aphthous ulcer	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Appendix disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cheilitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Chronic gastritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coeliac artery aneurysm	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colitis	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Colitis ischaemic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colitis microscopic	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Constipation	6	0.1	(0.1, 0.3)	10	0.2	(0.1, 0.5)
Dental caries	3	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Diarrhoea	130	3.2	(2.7, 3.8)	100	2.5	(2.0, 3.0)
Diverticulum	4	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Diverticulum intestinal	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Dry mouth	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Duodenal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Duodenal ulcer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dyspepsia	7	0.2	(0.1, 0.4)	8	0.2	(0.1, 0.4)
Dysphagia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Enterocolitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Faeces soft	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Flatulence	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Food poisoning	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Frequent bowel movements	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastric antral vascular ectasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastric ulcer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastric ulcer haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastritis	3	0.1	(0.0, 0.2)	7	0.2	(0.1, 0.4)
Gastritis erosive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal mucosa hyperaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastrooesophageal reflux disease	6	0.1	(0.1, 0.3)	14	0.3	(0.2, 0.6)
Gingival discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Glossitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glossodynia	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Haematochezia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haemorrhoidal haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haemorrhoids	2	0.0	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Hiatus hernia	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Hypoaesthesia oral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoaesthesia teeth	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ileus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Impaired gastric emptying	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Intestinal perforation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Irritable bowel syndrome	5	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.1)
Large intestine perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Large intestine polyp	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Lip oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lip swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mouth ulceration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nausea	186	4.6	(4.0, 5.3)	45	1.1	(0.8, 1.5)
Noninfective gingivitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Obstructive pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Odynophagia	6	0.1	(0.1, 0.3)	7	0.2	(0.1, 0.4)
Oesophageal food impaction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oesophageal spasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oral discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oral lichenoid reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oral pain	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pancreatic cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatic failure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis acute	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Paraesthesia oral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Parotid duct obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Precancerous lesion of digestive tract	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Proctalgia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rectal haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Retching	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Salivary gland calculus	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Small intestinal obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Stomatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Swollen tongue	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tongue pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tongue ulceration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tooth disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tooth impacted	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Toothache	15	0.4	(0.2, 0.6)	13	0.3	(0.2, 0.5)
Umbilical hernia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Volvulus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vomiting	48	1.2	(0.9, 1.6)	20	0.5	(0.3, 0.8)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2519	62.5	(60.1, 65.0)	545	13.4	(12.3, 14.6)
Adverse drug reaction	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Application site erythema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Application site pain	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Application site pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Application site reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthenia	31	0.8	(0.5, 1.1)	13	0.3	(0.2, 0.5)
Axillary pain	9	0.2	(0.1, 0.4)	2	0.0	(0.0, 0.2)
Capsular contracture associated with breast implant	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chest discomfort	5	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.1)
Chest pain	7	0.2	(0.1, 0.4)	8	0.2	(0.1, 0.4)
Chills	730	18.1	(16.8, 19.5)	63	1.6	(1.2, 2.0)
Chronic fatigue syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cyst	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Drug withdrawal syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Effusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Exercise tolerance decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Face oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Facial pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fatigue	747	18.5	(17.2, 19.9)	212	5.2	(4.5, 6.0)
Feeling abnormal	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Feeling cold	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Feeling hot	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Influenza like illness	10	0.2	(0.1, 0.5)	2	0.0	(0.0, 0.2)
Injection site bruising	11	0.3	(0.1, 0.5)	13	0.3	(0.2, 0.5)
Injection site dermatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site discolouration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site discomfort	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site erythema	137	3.4	(2.9, 4.0)	19	0.5	(0.3, 0.7)
Injection site haematoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site haemorrhage	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site hyperaesthesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site induration	8	0.2	(0.1, 0.4)	4	0.1	(0.0, 0.3)
Injection site injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site mass	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Injection site nodule	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site oedema	10	0.2	(0.1, 0.5)	0	0.0	(0.0, 0.1)
Injection site pain	1566	38.9	(37.0, 40.8)	213	5.2	(4.6, 6.0)
Injection site papule	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site paraesthesia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Injection site pruritus	29	0.7	(0.5, 1.0)	3	0.1	(0.0, 0.2)
Injection site rash	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site reaction	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site swelling	96	2.4	(1.9, 2.9)	13	0.3	(0.2, 0.5)
Injection site warmth	13	0.3	(0.2, 0.6)	4	0.1	(0.0, 0.3)
Injury associated with device	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Malaise	60	1.5	(1.1, 1.9)	10	0.2	(0.1, 0.5)
Mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Medical device pain	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Medical device site granuloma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nodule	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Non-cardiac chest pain	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Oedema peripheral	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Pain	357	8.9	(8.0, 9.8)	40	1.0	(0.7, 1.3)
Peripheral swelling	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Pyrexia	831	20.6	(19.2, 22.1)	41	1.0	(0.7, 1.4)
Sensation of foreign body	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Shoulder injury related to vaccine administration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sudden cardiac death	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Swelling face	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Temperature intolerance	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Therapeutic response unexpected	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Thirst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaccination site induration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vaccination site pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaccination site swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vascular stent occlusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vessel puncture site bruise	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vessel puncture site haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	12	0.3	(0.2, 0.5)	9	0.2	(0.1, 0.4)
Bile duct stone	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary colic	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Biliary dyskinesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cholecystitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholecystitis acute	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cholecystitis chronic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholelithiasis	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Gallbladder disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hepatic cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatic steatosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Hepatocellular injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nonalcoholic fatty liver disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	14	0.3	(0.2, 0.6)	19	0.5	(0.3, 0.7)
Allergy to arthropod bite	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug hypersensitivity	4	0.1	(0.0, 0.3)	5	0.1	(0.0, 0.3)
Food allergy	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Hypersensitivity	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Jarisch-Herxheimer reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Milk allergy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Seasonal allergy	6	0.1	(0.1, 0.3)	8	0.2	(0.1, 0.4)
INFECTIONS AND INFESTATIONS	245	6.1	(5.3, 6.9)	303	7.5	(6.6, 8.4)
Abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess limb	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Abscess neck	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abscess oral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Acarodermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Acute sinusitis	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Anal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Appendicitis	7	0.2	(0.1, 0.4)	4	0.1	(0.0, 0.3)
Appendicitis perforated	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bacterial rhinitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bacterial vaginosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Bacterial vulvovaginitis	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Bartholin's abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bartholinitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blister infected	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Brain abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bronchitis	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.3)
COVID-19 pneumonia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Campylobacter infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Carbuncle	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Catheter site infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cellulitis	4	0.1	(0.0, 0.3)	9	0.2	(0.1, 0.4)
Cellulitis orbital	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chronic sinusitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clostridium difficile infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Complicated appendicitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Conjunctivitis	8	0.2	(0.1, 0.4)	7	0.2	(0.1, 0.4)
Conjunctivitis bacterial	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Coxsackie viral infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cystitis	8	0.2	(0.1, 0.4)	11	0.3	(0.1, 0.5)
Dental fistula	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis infected	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Device related infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diabetic foot infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulitis	5	0.1	(0.0, 0.3)	6	0.1	(0.1, 0.3)
Ear infection	4	0.1	(0.0, 0.3)	9	0.2	(0.1, 0.4)
Empyema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Escherichia urinary tract infection	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Eye infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Folliculitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fungal infection	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Fungal skin infection	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Furuncle	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Gastroenteritis	3	0.1	(0.0, 0.2)	7	0.2	(0.1, 0.4)
Gastroenteritis viral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Genital herpes	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Genital herpes simplex	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gingival abscess	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Gingivitis	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Gonorrhoea	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Groin abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Helicobacter infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatitis C	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Herpes ophthalmic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Herpes simplex	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Herpes virus infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Herpes zoster	8	0.2	(0.1, 0.4)	10	0.2	(0.1, 0.5)
Herpes zoster oticus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hordeolum	7	0.2	(0.1, 0.4)	7	0.2	(0.1, 0.4)
Impetigo	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Infected bite	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Infected dermal cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Infectious mononucleosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Influenza	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Kidney infection	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Labyrinthitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Localised infection	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Lyme disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mastitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nail infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasopharyngitis	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Onychomycosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ophthalmic herpes zoster	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oral candidiasis	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Oral herpes	5	0.1	(0.0, 0.3)	5	0.1	(0.0, 0.3)
Otitis externa	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Otitis media	7	0.2	(0.1, 0.4)	6	0.1	(0.1, 0.3)
Otitis media acute	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Papilloma viral infection	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Parasitic gastroenteritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paronychia	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Parotitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Pelvic inflammatory disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Periodontitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Peritonitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritonsillar abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pharyngitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pharyngitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pharyngitis streptococcal	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonia	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Post procedural infection	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Postoperative wound infection	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Pulmonary tuberculosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Puncture site infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pyelonephritis	5	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.1)
Rash pustular	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Renal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory tract infection viral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rhinitis	2	0.0	(0.0, 0.2)	6	0.1	(0.1, 0.3)
Sepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Septic shock	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sialoadenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sinusitis	14	0.3	(0.2, 0.6)	22	0.5	(0.3, 0.8)
Sinusitis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin bacterial infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin infection	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Tinea infection	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Tinea versicolour	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tonsillitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Tonsillitis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tooth abscess	5	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Tooth infection	13	0.3	(0.2, 0.6)	15	0.4	(0.2, 0.6)
Trichomoniasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Upper respiratory tract infection	5	0.1	(0.0, 0.3)	5	0.1	(0.0, 0.3)
Ureaplasma infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urinary tract infection	64	1.6	(1.2, 2.0)	67	1.7	(1.3, 2.1)
Vaginal infection	0	0.0	(0.0, 0.1)	7	0.2	(0.1, 0.4)
Varicella	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Viral infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vulval abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vulvovaginal candidiasis	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.2)
Vulvovaginal mycotic infection	6	0.1	(0.1, 0.3)	10	0.2	(0.1, 0.5)
Vulvovaginitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	161	4.0	(3.4, 4.7)	202	5.0	(4.3, 5.7)
Administration related reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anaemia postoperative	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Animal bite	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Ankle fracture	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Arthropod bite	9	0.2	(0.1, 0.4)	2	0.0	(0.0, 0.2)
Arthropod sting	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Back injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bone fissure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Burns second degree	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cartilage injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cervical vertebral fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chest injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Concussion	4	0.1	(0.0, 0.3)	2	0.0	(0.0, 0.2)
Contusion	5	0.1	(0.0, 0.3)	10	0.2	(0.1, 0.5)
Corneal abrasion	4	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Craniocerebral injury	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Ear canal abrasion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Epicondylitis	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Exposure during pregnancy	23	0.6	(0.4, 0.9)	34	0.8	(0.6, 1.2)
Eye contusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial bones fracture	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Fall	33	0.8	(0.6, 1.2)	45	1.1	(0.8, 1.5)
Femur fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Fibula fracture	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Flail chest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foot fracture	7	0.2	(0.1, 0.4)	8	0.2	(0.1, 0.4)
Forearm fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foreign body	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hand fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Head injury	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Hip fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Humerus fracture	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Joint dislocation	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Joint injury	5	0.1	(0.0, 0.3)	6	0.1	(0.1, 0.3)
Ligament rupture	0	0.0	(0.0, 0.1)	7	0.2	(0.1, 0.4)
Ligament sprain	14	0.3	(0.2, 0.6)	17	0.4	(0.2, 0.7)
Limb fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Limb injury	2	0.0	(0.0, 0.2)	9	0.2	(0.1, 0.4)
Lower limb fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lumbar vertebral fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Maternal exposure before pregnancy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Maternal exposure during breast feeding	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Maternal exposure during pregnancy	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.2)
Meniscus injury	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Multiple injuries	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle rupture	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Muscle strain	11	0.3	(0.1, 0.5)	8	0.2	(0.1, 0.4)
Patella fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Post concussion syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post procedural swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post-traumatic pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Procedural dizziness	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Procedural haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Procedural pain	5	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.1)
Radius fracture	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Rib fracture	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Road traffic accident	4	0.1	(0.0, 0.3)	8	0.2	(0.1, 0.4)
Skin abrasion	3	0.1	(0.0, 0.2)	7	0.2	(0.1, 0.4)
Skin laceration	11	0.3	(0.1, 0.5)	7	0.2	(0.1, 0.4)
Skull fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Soft tissue injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal column injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal compression fracture	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Spinal fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Stress fracture	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.3)
Subdural haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tendon injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tendon rupture	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Thermal burn	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Tibia fracture	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Tooth fracture	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.2)
Tooth injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Traumatic haemothorax	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ulna fracture	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Upper limb fracture	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Vaccination complication	5	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Venom poisoning	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vulvovaginal injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Wound	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Wrist fracture	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
INVESTIGATIONS	103	2.6	(2.1, 3.1)	23	0.6	(0.4, 0.9)
Alanine aminotransferase increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Aspartate aminotransferase increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biopsy breast normal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood chloride decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood cholesterol increased	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Blood creatinine decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Blood glucose abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood glucose increased	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Blood immunoglobulin E increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood iron decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood potassium decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood pressure abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood pressure increased	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.2)
Blood sodium decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood testosterone increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood thyroid stimulating hormone increased	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Blood triglycerides increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood urea increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Body temperature	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Body temperature increased	68	1.7	(1.3, 2.1)	7	0.2	(0.1, 0.4)
C-reactive protein	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiac stress test abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Electrocardiogram QT prolonged	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glomerular filtration rate decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haemoglobin decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Heart rate increased	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Heart rate irregular	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatic enzyme increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
High density lipoprotein increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intraocular pressure increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Low density lipoprotein increased	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Mammogram abnormal	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Mean cell haemoglobin decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mean cell volume decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mean cell volume increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Platelet count increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Red blood cell morphology abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SARS-CoV-2 antibody test positive	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Serum ferritin decreased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thyroid function test abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urine ketone body present	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Weight decreased	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Weight increased	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
White blood cell count increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
White blood cells urine positive	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	69	1.7	(1.3, 2.2)	58	1.4	(1.1, 1.8)
Decreased appetite	26	0.6	(0.4, 0.9)	5	0.1	(0.0, 0.3)
Dehydration	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Diabetic ketoacidosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dyslipidaemia	4	0.1	(0.0, 0.3)	5	0.1	(0.0, 0.3)
Fluid retention	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Food intolerance	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glucose tolerance impaired	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Gout	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypercholesterolaemia	3	0.1	(0.0, 0.2)	14	0.3	(0.2, 0.6)
Hyperglycaemia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Hyperkalaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperlipidaemia	6	0.1	(0.1, 0.3)	5	0.1	(0.0, 0.3)
Hypertriglyceridaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypocalcaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypocholesterolaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoglycaemia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Hypokalaemia	2	0.0	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Impaired fasting glucose	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Increased appetite	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Insulin resistance	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Iron deficiency	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Obesity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Polydipsia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Type 2 diabetes mellitus	7	0.2	(0.1, 0.4)	3	0.1	(0.0, 0.2)
Vitamin B12 deficiency	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Vitamin D deficiency	7	0.2	(0.1, 0.4)	6	0.1	(0.1, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	985	24.4	(22.9, 26.0)	330	8.1	(7.3, 9.1)
Arthralgia	145	3.6	(3.0, 4.2)	61	1.5	(1.1, 1.9)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Arthritis	4	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Arthritis reactive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arthropathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Axillary mass	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Back pain	47	1.2	(0.9, 1.6)	52	1.3	(1.0, 1.7)
Bone pain	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Bursitis	5	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.1)
Coccydynia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Costochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dupuytren's contracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Exostosis	5	0.1	(0.0, 0.3)	2	0.0	(0.0, 0.2)
Fibromyalgia	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Flank pain	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Groin pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc compression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intervertebral disc degeneration	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Intervertebral disc protrusion	5	0.1	(0.0, 0.3)	5	0.1	(0.0, 0.3)
Joint effusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Joint range of motion decreased	5	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Joint stiffness	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Joint swelling	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Limb discomfort	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Metatarsalgia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Muscle contracture	3	0.1	(0.0, 0.2)	6	0.1	(0.1, 0.3)
Muscle discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle fatigue	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Muscle spasms	14	0.3	(0.2, 0.6)	8	0.2	(0.1, 0.4)
Muscle twitching	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscular weakness	9	0.2	(0.1, 0.4)	1	0.0	(0.0, 0.1)
Musculoskeletal chest pain	6	0.1	(0.1, 0.3)	4	0.1	(0.0, 0.3)
Musculoskeletal discomfort	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Musculoskeletal stiffness	6	0.1	(0.1, 0.3)	3	0.1	(0.0, 0.2)
Myalgia	674	16.7	(15.5, 18.0)	92	2.3	(1.8, 2.8)
Myalgia intercostal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neck pain	20	0.5	(0.3, 0.8)	24	0.6	(0.4, 0.9)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Osteitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Osteoarthritis	10	0.2	(0.1, 0.5)	11	0.3	(0.1, 0.5)
Osteochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Osteopenia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Osteoporosis	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.3)
Pain in extremity	99	2.5	(2.0, 3.0)	25	0.6	(0.4, 0.9)
Pain in jaw	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Patellofemoral pain syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Periarthritis	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Plantar fasciitis	3	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Polyarthritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Psoriatic arthropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rheumatoid arthritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rotator cuff syndrome	3	0.1	(0.0, 0.2)	8	0.2	(0.1, 0.4)
Sinus tarsi syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal osteoarthritis	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Spondylitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spondylolisthesis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Synovial cyst	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Synovitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Systemic lupus erythematosus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Temporomandibular joint syndrome	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Tendon disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tendonitis	5	0.1	(0.0, 0.3)	6	0.1	(0.1, 0.3)
Tenosynovitis stenosans	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Torticollis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Trigger finger	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	34	0.8	(0.6, 1.2)	40	1.0	(0.7, 1.3)
Acrochordon	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Acute myeloid leukaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenocarcinoma pancreas	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenoma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adrenal gland cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
B-cell lymphoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Basal cell carcinoma	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.3)
Benign pancreatic neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Benign uterine neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Borderline serous tumour of ovary	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cancer	1	0.0	(0.0, 0.1)	7	0.2	(0.1, 0.4)
Breast cancer in situ	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cancer stage I	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chondroma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colon adenoma	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Fibroadenoma of breast	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Gallbladder cancer stage II	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastric cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Glomus tumour	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haemangioma of skin	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Infected naevus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Invasive ductal breast carcinoma	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Lipoma	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Lobular breast carcinoma in situ	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lung adenocarcinoma	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Lymphoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphoproliferative disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Malignant melanoma	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Meningioma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Meningioma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Oropharyngeal squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ovarian germ cell teratoma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Papillary serous endometrial carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papillary thyroid cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Plasma cell myeloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Seborrhoeic keratosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin papilloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Teratoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Transitional cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Uterine cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uterine leiomyoma	2	0.0	(0.0, 0.2)	4	0.1	(0.0, 0.3)
NERVOUS SYSTEM DISORDERS	907	22.5	(21.1, 24.0)	358	8.8	(7.9, 9.8)
Aphasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Burning sensation	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Carpal tunnel syndrome	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Cerebellar infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebral atrophy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebral capillary telangiectasia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebral infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebrovascular accident	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cervical radiculopathy	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cervicogenic headache	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dementia Alzheimer's type	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depressed level of consciousness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Disturbance in attention	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dizziness	42	1.0	(0.8, 1.4)	28	0.7	(0.5, 1.0)
Dizziness postural	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dysgeusia	9	0.2	(0.1, 0.4)	3	0.1	(0.0, 0.2)
Dystonia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial paresis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Generalised tonic-clonic seizure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haemorrhagic stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Head discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Headache	780	19.4	(18.0, 20.8)	254	6.3	(5.5, 7.1)
Hemiplegic migraine	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyperaesthesia	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypersomnia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoaesthesia	3	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Idiopathic intracranial hypertension	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ischaemic stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lethargy	11	0.3	(0.1, 0.5)	2	0.0	(0.0, 0.2)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Migraine	21	0.5	(0.3, 0.8)	10	0.2	(0.1, 0.5)
Migraine with aura	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Migraine without aura	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Morton's neuralgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Motor dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Myoclonus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nerve compression	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Neuropathy peripheral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Optic neuritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paraesthesia	6	0.1	(0.1, 0.3)	12	0.3	(0.2, 0.5)
Parosmia	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Piriformis syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post herpetic neuralgia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Presyncope	4	0.1	(0.0, 0.3)	2	0.0	(0.0, 0.2)
Radiculopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Restless legs syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sciatic nerve neuropathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sciatica	8	0.2	(0.1, 0.4)	6	0.1	(0.1, 0.3)
Seizure	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinus headache	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Somnolence	3	0.1	(0.0, 0.2)	6	0.1	(0.1, 0.3)
Spinal cord compression	0	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	(0.0, 0.1)
Syncope	6	0.1	(0.1, 0.3)	4	0.1	(0.0, 0.3)
Tension headache	7	0.2	(0.1, 0.4)	7	0.2	(0.1, 0.4)
Toxic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transient ischaemic attack	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Tremor	7	0.2	(0.1, 0.4)	4	0.1	(0.0, 0.3)
Trigeminal neuralgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.0	(0.0, 0.2)	6	0.1	(0.1, 0.3)
Abortion incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abortion spontaneous	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Retained products of conception	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PRODUCT ISSUES	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Device connection issue	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	61	1.5	(1.2, 1.9)	63	1.6	(1.2, 2.0)
Abnormal dreams	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Adjustment disorder with depressed mood	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Alcohol abuse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Anxiety	17	0.4	(0.2, 0.7)	21	0.5	(0.3, 0.8)
Anxiety disorder	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Attention deficit hyperactivity disorder	4	0.1	(0.0, 0.3)	5	0.1	(0.0, 0.3)
Bruxism	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Confusional state	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depressed mood	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Depression	16	0.4	(0.2, 0.6)	13	0.3	(0.2, 0.5)
Depression suicidal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Disorientation	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastrointestinal somatic symptom disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Generalised anxiety disorder	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Insomnia	10	0.2	(0.1, 0.5)	6	0.1	(0.1, 0.3)
Irritability	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Mental disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mental fatigue	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mental status changes	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nightmare	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Panic attack	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Panic reaction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Restlessness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sleep disorder	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Stress	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Suicidal ideation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Suicide attempt	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	21	0.5	(0.3, 0.8)	17	0.4	(0.2, 0.7)
Acute kidney injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bladder spasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dysuria	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.2)
Haematuria	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Hydronephrosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Hypertonic bladder	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nephrolithiasis	7	0.2	(0.1, 0.4)	4	0.1	(0.0, 0.3)
Obstructive nephropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pollakiuria	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Polyuria	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Renal atrophy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Renal colic	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Renal failure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urinary bladder polyp	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urinary retention	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urinary tract obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vesical fistula	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	35	0.9	(0.6, 1.2)	41	1.0	(0.7, 1.4)
Adenomyosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Adnexal torsion	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Amenorrhoea	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Breast calcifications	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Breast cyst	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Breast hyperplasia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Breast mass	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Breast pain	4	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Cervical dysplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cervical polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dysfunctional uterine bleeding	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dysmenorrhoea	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.2)
Endometriosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haemorrhagic ovarian cyst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mammary duct ectasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Menometrorrhagia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Menorrhagia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Menstruation delayed	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Menstruation irregular	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Metrorrhagia	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Nipple pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ovarian cyst	5	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.1)
Ovarian mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pelvic pain	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Polycystic ovaries	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Postmenopausal haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Premenstrual syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectocele	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uterine haemorrhage	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Uterine inflammation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uterine prolapse	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vaginal discharge	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaginal haemorrhage	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Vaginal prolapse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vulvovaginal pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	112	2.8	(2.3, 3.3)	107	2.6	(2.2, 3.2)
Acute respiratory failure	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Allergic sinusitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthma	10	0.2	(0.1, 0.5)	6	0.1	(0.1, 0.3)
Asthma exercise induced	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Asthmatic crisis	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Bronchospasm	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Chronic obstructive pulmonary disease	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cough	12	0.3	(0.2, 0.5)	7	0.2	(0.1, 0.4)
Dry throat	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dysphonia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Dyspnoea	3	0.1	(0.0, 0.2)	6	0.1	(0.1, 0.3)
Dyspnoea exertional	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Emphysema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Epistaxis	2	0.0	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Haemoptysis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lung infiltration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Nasal congestion	6	0.1	(0.1, 0.3)	16	0.4	(0.2, 0.6)
Nasal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nasal polyps	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Nasal septum deviation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nasal turbinate hypertrophy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oropharyngeal discomfort	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oropharyngeal pain	23	0.6	(0.4, 0.9)	17	0.4	(0.2, 0.7)
Paranasal sinus discomfort	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Pharyngeal swelling	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Pleurisy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pleuritic pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumothorax	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Productive cough	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pulmonary embolism	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Pulmonary mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory tract congestion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rhinalgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rhinitis allergic	7	0.2	(0.1, 0.4)	5	0.1	(0.0, 0.3)
Rhinorrhoea	11	0.3	(0.1, 0.5)	9	0.2	(0.1, 0.4)
Sinus congestion	3	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Sinus disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sleep apnoea syndrome	5	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.1)
Sneezing	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Throat irritation	4	0.1	(0.0, 0.3)	6	0.1	(0.1, 0.3)
Tonsillar hypertrophy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Upper respiratory tract congestion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper-airway cough syndrome	5	0.1	(0.0, 0.3)	5	0.1	(0.0, 0.3)
Wheezing	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	146	3.6	(3.1, 4.3)	114	2.8	(2.3, 3.4)
Acne	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Acne cystic	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Actinic keratosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Alopecia	5	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Alopecia areata	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Angioedema	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blister	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Cold sweat	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dermal cyst	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dermatitis	3	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Dermatitis acneiform	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dermatitis allergic	3	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Dermatitis contact	6	0.1	(0.1, 0.3)	14	0.3	(0.2, 0.6)
Diabetic foot	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Drug eruption	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dyshidrotic eczema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ecchymosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Eczema	6	0.1	(0.1, 0.3)	2	0.0	(0.0, 0.2)
Erythema	8	0.2	(0.1, 0.4)	1	0.0	(0.0, 0.1)
Erythema nodosum	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fixed eruption	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hand dermatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hangnail	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hidradenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperhidrosis	16	0.4	(0.2, 0.6)	2	0.0	(0.0, 0.2)
Ingrowing nail	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lipodystrophy acquired	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Macule	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mechanical urticaria	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Night sweats	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.2)
Onycholysis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Onychomadesis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pain of skin	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papule	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Perioral dermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pityriasis rosea	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Pruritus	13	0.3	(0.2, 0.6)	12	0.3	(0.2, 0.5)
Pruritus allergic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pseudofolliculitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Psoriasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rash	36	0.9	(0.6, 1.2)	34	0.8	(0.6, 1.2)
Rash erythematous	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Rash maculo-papular	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Rash papular	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Rash pruritic	7	0.2	(0.1, 0.4)	1	0.0	(0.0, 0.1)
Rosacea	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Seborrhoeic dermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin discolouration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin lesion	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Stasis dermatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urticaria	15	0.4	(0.2, 0.6)	10	0.2	(0.1, 0.5)
Urticaria contact	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urticaria papular	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
High risk sexual behaviour	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Menopause	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	19	0.5	(0.3, 0.7)	15	0.4	(0.2, 0.6)
Abortion induced	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Apicectomy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Botulinum toxin injection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dental care	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dental implantation	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Drug titration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Endodontic procedure	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facet joint block	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Finger amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gingival operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lens extraction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mammoplasty	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Open reduction of fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Postoperative care	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Retinal operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Rhinoplasty	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rotator cuff repair	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sclerotherapy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Toe amputation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Toe operation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tooth extraction	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Wisdom teeth removal	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
VASCULAR DISORDERS	56	1.4	(1.0, 1.8)	51	1.3	(0.9, 1.7)
Aortic aneurysm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arteriosclerosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deep vein thrombosis	3	0.1	(0.0, 0.2)	6	0.1	(0.1, 0.3)
Diastolic hypertension	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Essential hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Flushing	7	0.2	(0.1, 0.4)	1	0.0	(0.0, 0.1)
Haematoma	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Hot flush	4	0.1	(0.0, 0.3)	6	0.1	(0.1, 0.3)
Hypertension	28	0.7	(0.5, 1.0)	26	0.6	(0.4, 0.9)
Hypertensive crisis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypotension	4	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.1)
Intermittent claudication	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphoedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Orthostatic hypotension	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Phlebitis superficial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Phlebolith	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subgaleal haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Systolic hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Thrombophlebitis superficial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Varicose vein	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Venous thrombosis limb	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.131. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 unb sex p3 saf

14.132. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=100, TE[b]=0.3)			Placebo (N[a]=100, TE[b]=0.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	29	95.8	(64.2, 137.6)	15	52.0	(29.1, 85.8)
EYE DISORDERS	0	0.0	(0.0, 12.2)	3	10.4	(2.1, 30.4)
Meibomianitis	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
Retinal haemorrhage	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
Vitreous detachment	0	0.0	(0.0, 12.2)	2	6.9	(0.8, 25.1)
GASTROINTESTINAL DISORDERS	3	9.9	(2.0, 29.0)	4	13.9	(3.8, 35.5)
Diarrhoea	0	0.0	(0.0, 12.2)	2	6.9	(0.8, 25.1)
Dyspepsia	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
Gastritis	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
Gastrooesophageal reflux disease	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
Mouth ulceration	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
Nausea	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
Stomatitis	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
Vomiting	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	20	66.1	(40.4, 102.0)	2	6.9	(0.8, 25.1)
Chills	6	19.8	(7.3, 43.1)	1	3.5	(0.1, 19.3)
Fatigue	7	23.1	(9.3, 47.6)	1	3.5	(0.1, 19.3)
Injection site erythema	2	6.6	(0.8, 23.9)	0	0.0	(0.0, 12.8)
Injection site pain	11	36.3	(18.1, 65.0)	0	0.0	(0.0, 12.8)
Injection site swelling	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
Malaise	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
Oedema peripheral	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
Pyrexia	7	23.1	(9.3, 47.6)	0	0.0	(0.0, 12.8)
INFECTIONS AND INFESTATIONS	3	9.9	(2.0, 29.0)	3	10.4	(2.1, 30.4)
Abscess limb	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
COVID-19 pneumonia	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
Conjunctivitis	1	3.3	(0.1, 18.4)	1	3.5	(0.1, 19.3)
Folliculitis	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
Pneumonia	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2	6.6	(0.8, 23.9)	1	3.5	(0.1, 19.3)

14.132. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=100, TE[b]=0.3)			Placebo (N[a]=100, TE[b]=0.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Exposure during pregnancy	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
Foot fracture	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
Road traffic accident	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
INVESTIGATIONS	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
Transaminases increased	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
METABOLISM AND NUTRITION DISORDERS	0	0.0	(0.0, 12.2)	2	6.9	(0.8, 25.1)
Diabetes mellitus	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
Hyperkalaemia	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	6	19.8	(7.3, 43.1)	3	10.4	(2.1, 30.4)
Arthralgia	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
Back pain	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
Myalgia	6	19.8	(7.3, 43.1)	2	6.9	(0.8, 25.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
Breast cancer	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
NERVOUS SYSTEM DISORDERS	5	16.5	(5.4, 38.5)	0	0.0	(0.0, 12.8)
Dizziness	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
Headache	3	9.9	(2.0, 29.0)	0	0.0	(0.0, 12.8)
Hypoaesthesia	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
PSYCHIATRIC DISORDERS	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
Insomnia	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
Rhinorrhoea	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
Urticaria	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)

14.132. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=100, TE[b]=0.3)			Placebo (N[a]=100, TE[b]=0.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])

Abbreviation: HIV = human immunodeficiency virus.
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_hiv_exp_p3_saf

14.133. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	5246	62.9	(61.2, 64.6)	1313	16.0	(15.1, 16.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	68	0.8	(0.6, 1.0)	5	0.1	(0.0, 0.1)
Leukopenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymph node pain	6	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Lymphadenopathy	62	0.7	(0.6, 1.0)	4	0.0	(0.0, 0.1)
Lymphopenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Neutropenia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
CARDIAC DISORDERS	13	0.2	(0.1, 0.3)	4	0.0	(0.0, 0.1)
Palpitations	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Sinus tachycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Supraventricular tachycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tachycardia	10	0.1	(0.1, 0.2)	1	0.0	(0.0, 0.1)
Ventricular arrhythmia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	15	0.2	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Deafness unilateral	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ear discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ear pain	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Otorrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tinnitus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tympanic membrane perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vertigo	8	0.1	(0.0, 0.2)	4	0.0	(0.0, 0.1)
Vertigo positional	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EYE DISORDERS	17	0.2	(0.1, 0.3)	8	0.1	(0.0, 0.2)
Asthenopia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Conjunctival oedema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dry eye	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eye irritation	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Eye pain	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lacrimation increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ocular hyperaemia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Photophobia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.133. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Swelling of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vision blurred	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	481	5.8	(5.3, 6.3)	215	2.6	(2.3, 3.0)
Abdominal discomfort	5	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abdominal distension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abdominal pain	5	0.1	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Abdominal pain upper	11	0.1	(0.1, 0.2)	3	0.0	(0.0, 0.1)
Aphthous ulcer	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cheilitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diarrhoea	209	2.5	(2.2, 2.9)	136	1.7	(1.4, 2.0)
Dry mouth	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Dyspepsia	6	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Dysphagia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eructation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Faeces soft	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Flatulence	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Gastrointestinal disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gingival bleeding	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gingival discomfort	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gingival pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gingival swelling	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Glossodynia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haemorrhoids	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypoaesthesia oral	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypoaesthesia teeth	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Irritable bowel syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lip swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Loose tooth	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nausea	248	3.0	(2.6, 3.4)	58	0.7	(0.5, 0.9)
Noninfective gingivitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Odynophagia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Paraesthesia oral	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Retching	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Swollen tongue	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.133. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Tongue discomfort	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tongue pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tongue ulceration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Toothache	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vomiting	55	0.7	(0.5, 0.9)	15	0.2	(0.1, 0.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4651	55.7	(54.1, 57.4)	884	10.8	(10.1, 11.5)
Adverse drug reaction	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Application site erythema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Application site pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Application site pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Application site rash	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Application site reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Asthenia	69	0.8	(0.6, 1.0)	11	0.1	(0.1, 0.2)
Axillary pain	9	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Chest discomfort	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chest pain	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chills	1361	16.3	(15.5, 17.2)	111	1.4	(1.1, 1.6)
Exercise tolerance decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fatigue	1435	17.2	(16.3, 18.1)	351	4.3	(3.8, 4.7)
Feeling abnormal	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Feeling cold	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Feeling hot	8	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Gait disturbance	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Illness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Induration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Influenza like illness	23	0.3	(0.2, 0.4)	3	0.0	(0.0, 0.1)
Injection site bruising	12	0.1	(0.1, 0.3)	17	0.2	(0.1, 0.3)
Injection site dermatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site discolouration	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site discomfort	6	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Injection site erythema	185	2.2	(1.9, 2.6)	26	0.3	(0.2, 0.5)
Injection site haematoma	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Injection site haemorrhage	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Injection site hyperaesthesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.133. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site induration	10	0.1	(0.1, 0.2)	4	0.0	(0.0, 0.1)
Injection site injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Injection site irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site macule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site mass	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site nodule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site oedema	12	0.1	(0.1, 0.3)	0	0.0	(0.0, 0.0)
Injection site pain	2914	34.9	(33.7, 36.2)	392	4.8	(4.3, 5.3)
Injection site papule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site paraesthesia	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Injection site plaque	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Injection site pruritus	38	0.5	(0.3, 0.6)	6	0.1	(0.0, 0.2)
Injection site rash	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site reaction	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site swelling	139	1.7	(1.4, 2.0)	22	0.3	(0.2, 0.4)
Injection site urticaria	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site warmth	14	0.2	(0.1, 0.3)	5	0.1	(0.0, 0.1)
Malaise	129	1.5	(1.3, 1.8)	17	0.2	(0.1, 0.3)
Medical device pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Nodule	0	0.0	(0.0, 0.0)	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)
Pain	623	7.5	(6.9, 8.1)	52	0.6	(0.5, 0.8)
Peripheral swelling	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pyrexia	1510	18.1	(17.2, 19.0)	66	0.8	(0.6, 1.0)
Sensation of foreign body	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sluggishness	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Swelling	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Swelling face	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Thirst	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vaccination site pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vessel puncture site bruise	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)

14.133. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Drug hypersensitivity	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	8	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Conjunctivitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cystitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Gastrointestinal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Herpes zoster	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Influenza	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oral candidiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oral herpes	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Otitis media	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Otitis media acute	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pharyngitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pustule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Rhinitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	15	0.2	(0.1, 0.3)	2	0.0	(0.0, 0.1)
Administration related reaction	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Contusion	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Exposure during pregnancy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Fall	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Procedural pain	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Upper limb fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vaccination complication	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
INVESTIGATIONS	127	1.5	(1.3, 1.8)	13	0.2	(0.1, 0.3)
Blood glucose abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood glucose increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood pressure diastolic increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood pressure increased	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood pressure systolic increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Body temperature	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Body temperature increased	115	1.4	(1.1, 1.7)	9	0.1	(0.1, 0.2)
Heart rate increased	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Heart rate irregular	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.133. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Intraocular pressure increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Respiratory rate increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
SARS-CoV-2 antibody test positive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Weight decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	38	0.5	(0.3, 0.6)	9	0.1	(0.1, 0.2)
Decreased appetite	35	0.4	(0.3, 0.6)	8	0.1	(0.0, 0.2)
Gout	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Increased appetite	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Polydipsia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1527	18.3	(17.4, 19.2)	208	2.5	(2.2, 2.9)
Arthralgia	204	2.4	(2.1, 2.8)	38	0.5	(0.3, 0.6)
Arthritis reactive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Axillary mass	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Back pain	23	0.3	(0.2, 0.4)	8	0.1	(0.0, 0.2)
Bone pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bursitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Costochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Flank pain	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Groin pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Joint effusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Joint range of motion decreased	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Joint stiffness	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Joint swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Limb discomfort	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mobility decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Muscle discomfort	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Muscle fatigue	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle spasms	8	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Muscle tightness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Muscle twitching	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Muscular weakness	7	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.0)
Musculoskeletal chest pain	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Musculoskeletal discomfort	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.133. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Musculoskeletal pain	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Musculoskeletal stiffness	10	0.1	(0.1, 0.2)	3	0.0	(0.0, 0.1)
Myalgia	1217	14.6	(13.8, 15.4)	144	1.8	(1.5, 2.1)
Neck pain	9	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Osteoarthritis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pain in extremity	158	1.9	(1.6, 2.2)	14	0.2	(0.1, 0.3)
Pain in jaw	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Periarthritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Psoriatic arthropathy	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Tendonitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	1379	16.5	(15.7, 17.4)	376	4.6	(4.1, 5.1)
Ageusia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Aphasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Burning sensation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Disturbance in attention	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dizziness	53	0.6	(0.5, 0.8)	29	0.4	(0.2, 0.5)
Dizziness postural	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dysgeusia	10	0.1	(0.1, 0.2)	7	0.1	(0.0, 0.2)
Dyskinesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Facial paralysis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Head discomfort	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Headache	1269	15.2	(14.4, 16.1)	319	3.9	(3.5, 4.3)
Hyperaesthesia	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypersomnia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypoaesthesia	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hypogeusia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hyposmia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lethargy	24	0.3	(0.2, 0.4)	5	0.1	(0.0, 0.1)
Mental impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Migraine	9	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Migraine with aura	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Migraine without aura	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Nerve compression	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nystagmus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Paraesthesia	11	0.1	(0.1, 0.2)	10	0.1	(0.1, 0.2)

14.133. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Parosmia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peripheral sensory neuropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post herpetic neuralgia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Presyncope	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Sinus headache	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Somnolence	9	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Syncope	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Taste disorder	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tension headache	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tremor	5	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	30	0.4	(0.2, 0.5)	6	0.1	(0.0, 0.2)
Abnormal dreams	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anxiety	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Depression	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Disorientation	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Insomnia	17	0.2	(0.1, 0.3)	2	0.0	(0.0, 0.1)
Irritability	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mental fatigue	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nightmare	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Paranoia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Restlessness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sleep disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bladder spasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Micturition urgency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Nocturia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pollakiuria	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Erectile dysfunction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Menorrhagia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Menstruation irregular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pelvic pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Premenstrual syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.133. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Scrotal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	62	0.7	(0.6, 1.0)	39	0.5	(0.3, 0.6)
Asthma	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cough	7	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Dry throat	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dyspnoea	0	0.0	(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)
Epistaxis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Nasal congestion	15	0.2	(0.1, 0.3)	8	0.1	(0.0, 0.2)
Nasal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oropharyngeal discomfort	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oropharyngeal pain	16	0.2	(0.1, 0.3)	9	0.1	(0.1, 0.2)
Paranasal sinus discomfort	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pharyngeal swelling	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Pleurisy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Productive cough	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rhinorrhoea	8	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Sinus congestion	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Sneezing	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Throat irritation	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper respiratory tract congestion	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper-airway cough syndrome	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	106	1.3	(1.0, 1.5)	44	0.5	(0.4, 0.7)
Alopecia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Alopecia areata	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Angioedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cold sweat	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dermatitis allergic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dermatitis contact	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Drug eruption	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ecchymosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eczema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Erythema	6	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.0)

14.133. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Fixed eruption	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperhidrosis	27	0.3	(0.2, 0.5)	7	0.1	(0.0, 0.2)
Macule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Night sweats	17	0.2	(0.1, 0.3)	1	0.0	(0.0, 0.1)
Pain of skin	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Papule	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pityriasis rosea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pruritus	7	0.1	(0.0, 0.2)	10	0.1	(0.1, 0.2)
Pruritus allergic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Psoriasis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rash	24	0.3	(0.2, 0.4)	12	0.1	(0.1, 0.3)
Rash erythematous	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Rash maculo-papular	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Rash papular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Rash pruritic	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin discolouration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin induration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Skin lesion	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urticaria	8	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
VASCULAR DISORDERS	17	0.2	(0.1, 0.3)	10	0.1	(0.1, 0.2)
Flushing	10	0.1	(0.1, 0.2)	2	0.0	(0.0, 0.1)
Hot flush	4	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Hypertension	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypotension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_rel_exp_p3_saf

14.134. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	3484	70.0	(67.7, 72.4)	884	18.0	(16.8, 19.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	56	1.1	(0.9, 1.5)	2	0.0	(0.0, 0.1)
Lymph node pain	5	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lymphadenopathy	52	1.0	(0.8, 1.4)	2	0.0	(0.0, 0.1)
Neutropenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
CARDIAC DISORDERS	9	0.2	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Palpitations	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Sinus tachycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Supraventricular tachycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tachycardia	7	0.1	(0.1, 0.3)	1	0.0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	7	0.1	(0.1, 0.3)	6	0.1	(0.0, 0.3)
Deafness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ear discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ear pain	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Otorrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tympanic membrane perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vertigo	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Vertigo positional	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EYE DISORDERS	12	0.2	(0.1, 0.4)	5	0.1	(0.0, 0.2)
Asthenopia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Conjunctival oedema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dry eye	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye irritation	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Eye pain	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Lacrimation increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ocular hyperaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Photophobia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Swelling of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	323	6.5	(5.8, 7.2)	140	2.9	(2.4, 3.4)
Abdominal discomfort	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Abdominal distension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.134. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Abdominal pain	3	0.1	(0.0, 0.2)	7	0.1	(0.1, 0.3)
Abdominal pain upper	8	0.2	(0.1, 0.3)	2	0.0	(0.0, 0.1)
Aphthous ulcer	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Diarrhoea	135	2.7	(2.3, 3.2)	87	1.8	(1.4, 2.2)
Dry mouth	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Dyspepsia	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dysphagia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eructation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Faeces soft	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Flatulence	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Gastrointestinal disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gingival bleeding	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gingival pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gingival swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoaesthesia oral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoaesthesia teeth	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Irritable bowel syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lip swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Loose tooth	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nausea	168	3.4	(2.9, 3.9)	41	0.8	(0.6, 1.1)
Noninfective gingivitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Odynophagia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paraesthesia oral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retching	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tongue discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Toothache	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vomiting	45	0.9	(0.7, 1.2)	9	0.2	(0.1, 0.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3118	62.7	(60.5, 64.9)	609	12.4	(11.4, 13.4)
Adverse drug reaction	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Application site erythema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Application site pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Application site rash	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Application site reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthenia	42	0.8	(0.6, 1.1)	7	0.1	(0.1, 0.3)

14.134. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Axillary pain	5	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Chest discomfort	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chest pain	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chills	966	19.4	(18.2, 20.7)	71	1.4	(1.1, 1.8)
Exercise tolerance decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fatigue	991	19.9	(18.7, 21.2)	254	5.2	(4.6, 5.9)
Feeling abnormal	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Feeling cold	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Feeling hot	6	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.1)
Illness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Influenza like illness	15	0.3	(0.2, 0.5)	2	0.0	(0.0, 0.1)
Injection site bruising	8	0.2	(0.1, 0.3)	11	0.2	(0.1, 0.4)
Injection site dermatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site discolouration	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site discomfort	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site erythema	119	2.4	(2.0, 2.9)	18	0.4	(0.2, 0.6)
Injection site haematoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site hyperaesthesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site induration	5	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Injection site injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site macule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site mass	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site nodule	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site oedema	10	0.2	(0.1, 0.4)	0	0.0	(0.0, 0.1)
Injection site pain	1927	38.7	(37.0, 40.5)	281	5.7	(5.1, 6.4)
Injection site papule	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site paraesthesia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site pruritus	23	0.5	(0.3, 0.7)	5	0.1	(0.0, 0.2)
Injection site rash	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site reaction	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Injection site swelling	86	1.7	(1.4, 2.1)	11	0.2	(0.1, 0.4)
Injection site warmth	8	0.2	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Malaise	85	1.7	(1.4, 2.1)	7	0.1	(0.1, 0.3)

14.134. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Medical device pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nodule	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Non-cardiac chest pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pain	429	8.6	(7.8, 9.5)	36	0.7	(0.5, 1.0)
Peripheral swelling	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pyrexia	1114	22.4	(21.1, 23.7)	50	1.0	(0.8, 1.3)
Sensation of foreign body	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Shoulder injury related to vaccine administration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Swelling face	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Thirst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaccination site pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vessel puncture site bruise	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Drug hypersensitivity	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	6	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.2)
Conjunctivitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cystitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Gastrointestinal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oral candidiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Otitis media	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Otitis media acute	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pharyngitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pustule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rhinitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	11	0.2	(0.1, 0.4)	2	0.0	(0.0, 0.1)
Administration related reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Contusion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Exposure during pregnancy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Fall	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Procedural pain	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Upper limb fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vaccination complication	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.134. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
INVESTIGATIONS	87	1.7	(1.4, 2.2)	11	0.2	(0.1, 0.4)
Blood glucose abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blood pressure diastolic increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood pressure increased	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Body temperature	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Body temperature increased	79	1.6	(1.3, 2.0)	8	0.2	(0.1, 0.3)
Heart rate increased	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Heart rate irregular	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SARS-CoV-2 antibody test positive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Weight decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	26	0.5	(0.3, 0.8)	6	0.1	(0.0, 0.3)
Decreased appetite	24	0.5	(0.3, 0.7)	6	0.1	(0.0, 0.3)
Gout	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Polydipsia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1053	21.2	(19.9, 22.5)	129	2.6	(2.2, 3.1)
Arthralgia	142	2.9	(2.4, 3.4)	23	0.5	(0.3, 0.7)
Axillary mass	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Back pain	18	0.4	(0.2, 0.6)	4	0.1	(0.0, 0.2)
Bone pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Costochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Flank pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Groin pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Joint range of motion decreased	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Joint stiffness	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Joint swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Limb discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle fatigue	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Muscle spasms	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Muscle tightness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Muscle twitching	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Muscular weakness	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Musculoskeletal chest pain	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.134. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Musculoskeletal discomfort	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Musculoskeletal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Musculoskeletal stiffness	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myalgia	858	17.2	(16.1, 18.4)	96	2.0	(1.6, 2.4)
Neck pain	7	0.1	(0.1, 0.3)	1	0.0	(0.0, 0.1)
Pain in extremity	84	1.7	(1.3, 2.1)	4	0.1	(0.0, 0.2)
Pain in jaw	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Periarthritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Psoriatic arthropathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tendonitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	948	19.1	(17.9, 20.3)	262	5.3	(4.7, 6.0)
Ageusia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aphasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Burning sensation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Disturbance in attention	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dizziness	32	0.6	(0.4, 0.9)	19	0.4	(0.2, 0.6)
Dysgeusia	8	0.2	(0.1, 0.3)	2	0.0	(0.0, 0.1)
Facial paralysis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Head discomfort	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Headache	879	17.7	(16.5, 18.9)	221	4.5	(3.9, 5.1)
Hyperaesthesia	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypoaesthesia	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Hypogeusia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyposmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lethargy	7	0.1	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Mental impairment	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Migraine	8	0.2	(0.1, 0.3)	2	0.0	(0.0, 0.1)
Migraine with aura	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Migraine without aura	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nerve compression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Paraesthesia	10	0.2	(0.1, 0.4)	7	0.1	(0.1, 0.3)
Parosmia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peripheral sensory neuropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Presyncope	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Sinus headache	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.134. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Somnolence	5	0.1	(0.0, 0.2)	8	0.2	(0.1, 0.3)
Syncope	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Taste disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tension headache	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Tremor	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	16	0.3	(0.2, 0.5)	4	0.1	(0.0, 0.2)
Abnormal dreams	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anxiety	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Depression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Disorientation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Insomnia	10	0.2	(0.1, 0.4)	1	0.0	(0.0, 0.1)
Irritability	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Mental fatigue	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pollakiuria	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Menorrhagia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Menstruation irregular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Premenstrual syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Scrotal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	38	0.8	(0.5, 1.0)	27	0.5	(0.4, 0.8)
Asthma	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cough	5	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Dry throat	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dyspnoea	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Dyspnoea exertional	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal congestion	9	0.2	(0.1, 0.3)	8	0.2	(0.1, 0.3)
Nasal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oropharyngeal discomfort	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oropharyngeal pain	11	0.2	(0.1, 0.4)	6	0.1	(0.0, 0.3)
Paranasal sinus discomfort	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pharyngeal swelling	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.134. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Productive cough	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rhinorrhoea	5	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Sinus congestion	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Throat irritation	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper respiratory tract congestion	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper-airway cough syndrome	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	63	1.3	(1.0, 1.6)	28	0.6	(0.4, 0.8)
Alopecia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Alopecia areata	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Angioedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cold sweat	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dermatitis allergic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis contact	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug eruption	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Erythema	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Fixed eruption	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperhidrosis	15	0.3	(0.2, 0.5)	5	0.1	(0.0, 0.2)
Night sweats	9	0.2	(0.1, 0.3)	0	0.0	(0.0, 0.1)
Papule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pityriasis rosea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pruritus	3	0.1	(0.0, 0.2)	7	0.1	(0.1, 0.3)
Pruritus allergic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Psoriasis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rash	17	0.3	(0.2, 0.5)	6	0.1	(0.0, 0.3)
Rash erythematous	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Rash papular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Rash pruritic	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin lesion	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urticaria	6	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.2)
VASCULAR DISORDERS	10	0.2	(0.1, 0.4)	7	0.1	(0.1, 0.3)
Flushing	5	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hot flush	3	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Hypertension	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypotension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.134. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_rel_age_p3_saf

14.135. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	1762	52.3	(49.9, 54.8)	429	13.0	(11.8, 14.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	12	0.4	(0.2, 0.6)	3	0.1	(0.0, 0.3)
Leukopenia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lymph node pain	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Lymphadenopathy	10	0.3	(0.1, 0.5)	2	0.1	(0.0, 0.2)
Lymphopenia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Neutropenia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
CARDIAC DISORDERS	4	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Tachycardia	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Ventricular arrhythmia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	8	0.2	(0.1, 0.5)	1	0.0	(0.0, 0.2)
Deafness unilateral	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Tinnitus	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Vertigo	5	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Vertigo positional	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
EYE DISORDERS	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Eye irritation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Eye pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lacrimation increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ocular hyperaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Vision blurred	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	158	4.7	(4.0, 5.5)	75	2.3	(1.8, 2.8)
Abdominal discomfort	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Abdominal pain	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Abdominal pain upper	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Aphthous ulcer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cheilitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Diarrhoea	74	2.2	(1.7, 2.8)	49	1.5	(1.1, 2.0)
Dry mouth	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Dyspepsia	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Faeces soft	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Gingival discomfort	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

14.135. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Glossodynia	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Haemorrhoids	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Hypoaesthesia oral	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Nausea	80	2.4	(1.9, 3.0)	17	0.5	(0.3, 0.8)
Odynophagia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Oral discomfort	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Paraesthesia oral	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Retching	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Swollen tongue	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Tongue pruritus	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Tongue ulceration	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Toothache	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Vomiting	10	0.3	(0.1, 0.5)	6	0.2	(0.1, 0.4)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1533	45.5	(43.2, 47.8)	275	8.3	(7.4, 9.4)
Application site pruritus	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Asthenia	27	0.8	(0.5, 1.2)	4	0.1	(0.0, 0.3)
Axillary pain	4	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Chills	395	11.7	(10.6, 12.9)	40	1.2	(0.9, 1.6)
Fatigue	444	13.2	(12.0, 14.5)	97	2.9	(2.4, 3.6)
Feeling hot	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gait disturbance	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Induration	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Influenza like illness	8	0.2	(0.1, 0.5)	1	0.0	(0.0, 0.2)
Injection site bruising	4	0.1	(0.0, 0.3)	6	0.2	(0.1, 0.4)
Injection site discolouration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Injection site discomfort	4	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Injection site erythema	66	2.0	(1.5, 2.5)	8	0.2	(0.1, 0.5)
Injection site haematoma	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Injection site haemorrhage	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Injection site induration	5	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Injection site irritation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site mass	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Injection site nodule	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site oedema	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.135. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site pain	987	29.3	(27.5, 31.2)	111	3.4	(2.8, 4.0)
Injection site paraesthesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Injection site plaque	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Injection site pruritus	15	0.4	(0.2, 0.7)	1	0.0	(0.0, 0.2)
Injection site rash	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Injection site reaction	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site swelling	53	1.6	(1.2, 2.1)	11	0.3	(0.2, 0.6)
Injection site urticaria	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site warmth	6	0.2	(0.1, 0.4)	1	0.0	(0.0, 0.2)
Malaise	44	1.3	(0.9, 1.8)	10	0.3	(0.1, 0.6)
Nodule	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Non-cardiac chest pain	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pain	194	5.8	(5.0, 6.6)	16	0.5	(0.3, 0.8)
Pyrexia	396	11.7	(10.6, 13.0)	16	0.5	(0.3, 0.8)
Sluggishness	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Drug hypersensitivity	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	2	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Herpes zoster	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Influenza	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Injection site abscess	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Oral herpes	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Administration related reaction	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Contusion	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Vaccination complication	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
INVESTIGATIONS	40	1.2	(0.8, 1.6)	2	0.1	(0.0, 0.2)
Blood glucose increased	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Blood pressure systolic increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Body temperature increased	36	1.1	(0.7, 1.5)	1	0.0	(0.0, 0.2)
Intraocular pressure increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Respiratory rate increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.135. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
METABOLISM AND NUTRITION DISORDERS	12	0.4	(0.2, 0.6)	3	0.1	(0.0, 0.3)
Decreased appetite	11	0.3	(0.2, 0.6)	2	0.1	(0.0, 0.2)
Increased appetite	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Polydipsia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	474	14.1	(12.8, 15.4)	79	2.4	(1.9, 3.0)
Arthralgia	62	1.8	(1.4, 2.4)	15	0.5	(0.3, 0.7)
Arthritis reactive	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Back pain	5	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Bursitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Flank pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Joint effusion	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Joint range of motion decreased	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Joint stiffness	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Limb discomfort	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Mobility decreased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Muscle fatigue	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Muscle spasms	4	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Muscle twitching	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Muscular weakness	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Musculoskeletal chest pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Musculoskeletal discomfort	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Musculoskeletal pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Musculoskeletal stiffness	8	0.2	(0.1, 0.5)	2	0.1	(0.0, 0.2)
Myalgia	359	10.7	(9.6, 11.8)	48	1.5	(1.1, 1.9)
Neck pain	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Osteoarthritis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pain in extremity	74	2.2	(1.7, 2.8)	10	0.3	(0.1, 0.6)
Psoriatic arthropathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	431	12.8	(11.6, 14.1)	114	3.4	(2.8, 4.1)
Disturbance in attention	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dizziness	21	0.6	(0.4, 1.0)	10	0.3	(0.1, 0.6)
Dizziness postural	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dysgeusia	2	0.1	(0.0, 0.2)	5	0.2	(0.0, 0.4)

14.135. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dyskinesia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Headache	390	11.6	(10.5, 12.8)	98	3.0	(2.4, 3.6)
Hypersomnia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypoaesthesia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lethargy	17	0.5	(0.3, 0.8)	1	0.0	(0.0, 0.2)
Mental impairment	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Migraine	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Migraine without aura	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Nystagmus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Paraesthesia	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Parosmia	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Post herpetic neuralgia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Presyncope	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Sinus headache	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Somnolence	4	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Syncope	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Taste disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Tremor	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
PSYCHIATRIC DISORDERS	14	0.4	(0.2, 0.7)	2	0.1	(0.0, 0.2)
Abnormal dreams	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Depression	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Disorientation	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Insomnia	7	0.2	(0.1, 0.4)	1	0.0	(0.0, 0.2)
Irritability	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Nightmare	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Paranoia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Restlessness	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Sleep disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Bladder spasm	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Micturition urgency	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Nocturia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.135. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Erectile dysfunction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pelvic pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	24	0.7	(0.5, 1.1)	12	0.4	(0.2, 0.6)
Asthma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cough	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Dyspnoea exertional	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Epistaxis	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Nasal congestion	6	0.2	(0.1, 0.4)	0	0.0	(0.0, 0.1)
Oropharyngeal pain	5	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Paranasal sinus discomfort	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Pharyngeal swelling	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pleurisy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Rhinorrhoea	3	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Sneezing	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Throat irritation	4	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Upper respiratory tract congestion	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Upper-airway cough syndrome	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	43	1.3	(0.9, 1.7)	16	0.5	(0.3, 0.8)
Cold sweat	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ecchymosis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Eczema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Erythema	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Hyperhidrosis	12	0.4	(0.2, 0.6)	2	0.1	(0.0, 0.2)
Macule	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Night sweats	8	0.2	(0.1, 0.5)	1	0.0	(0.0, 0.2)
Pain of skin	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Papule	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pruritus	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Rash	7	0.2	(0.1, 0.4)	6	0.2	(0.1, 0.4)
Rash erythematous	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Rash maculo-papular	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Rash pruritic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Skin discolouration	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.135. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Skin induration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Urticaria	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
VASCULAR DISORDERS	7	0.2	(0.1, 0.4)	3	0.1	(0.0, 0.3)
Flushing	5	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Hot flush	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hypotension	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_rel_age_p3_saf

14.136. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	356	4.3	(3.8, 4.7)	256	3.1	(2.7, 3.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	10	0.1	(0.1, 0.2)	5	0.1	(0.0, 0.1)
Anaemia	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blood loss anaemia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Iron deficiency anaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Leukocytosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lymph node pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphadenopathy	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphocytosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Microcytic anaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Neutropenia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thrombocytopenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Thrombocytosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
CARDIAC DISORDERS	12	0.1	(0.1, 0.3)	19	0.2	(0.1, 0.4)
Acute coronary syndrome	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Acute left ventricular failure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Acute myocardial infarction	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angina pectoris	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Angina unstable	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Arteriospasm coronary	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Atrial fibrillation	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Atrial flutter	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bradycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac failure acute	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coronary artery disease	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Mitral valve incompetence	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Myocardial infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Supraventricular tachycardia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tachyarrhythmia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tachycardia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Ventricular arrhythmia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.136. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Congenital ureteropelvic junction obstruction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastrointestinal arteriovenous malformation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	8	0.1	(0.0, 0.2)	4	0.0	(0.0, 0.1)
Deafness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tinnitus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vertigo	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Vertigo positional	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EYE DISORDERS	5	0.1	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Cataract	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Diplopia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Macular oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Retinal detachment	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Retinal tear	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Visual impairment	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	32	0.4	(0.3, 0.5)	26	0.3	(0.2, 0.5)
Abdominal adhesions	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abdominal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abdominal pain	5	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abdominal pain lower	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abdominal pain upper	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Colitis ischaemic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Colitis ulcerative	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Constipation	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diarrhoea	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Dyspepsia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Enterocolitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Flatulence	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Food poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastric antral vascular ectasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.136. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Gastrointestinal haemorrhage	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastrooesophageal reflux disease	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haematochezia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hiatus hernia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ileus	0	0.0	(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, 0.0)
Incarcerated inguinal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Internal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intestinal obstruction	0	0.0	(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, 0.0)
Intestinal strangulation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Large intestine perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nausea	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Obstructive pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oesophageal food impaction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oesophageal ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pancreatitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis acute	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retroperitoneal haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Small intestinal obstruction	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Varices oesophageal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vomiting	0	0.0	(0.0, 0.0)	4	0.0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	101	1.2	(1.0, 1.5)	7	0.1	(0.0, 0.2)
Asthenia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Chest pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chills	18	0.2	(0.1, 0.3)	0	0.0	(0.0, 0.0)
Fatigue	24	0.3	(0.2, 0.4)	2	0.0	(0.0, 0.1)
Influenza like illness	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Injection site erythema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site pain	19	0.2	(0.1, 0.4)	0	0.0	(0.0, 0.0)
Injection site swelling	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Malaise	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Non-cardiac chest pain	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.136. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pain	9	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.0)
Peripheral swelling	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pyrexia	38	0.5	(0.3, 0.6)	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, 0.0)
HEPATOBILIARY DISORDERS	12	0.1	(0.1, 0.3)	5	0.1	(0.0, 0.1)
Bile duct stone	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary colic	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cholecystitis acute	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Cholelithiasis	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cirrhosis alcoholic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hepatocellular injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Drug hypersensitivity	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	33	0.4	(0.3, 0.6)	40	0.5	(0.3, 0.7)
Abdominal abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abscess jaw	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abscess limb	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Appendicitis	11	0.1	(0.1, 0.2)	4	0.0	(0.0, 0.1)
Appendicitis perforated	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arthritis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bacterial sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bronchitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.0)	5	0.1	(0.0, 0.1)
Cellulitis	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Complicated appendicitis	0	0.0	(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, 0.0)
Diabetic foot infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diverticulitis	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Empyema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gangrene	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Infected bite	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Localised infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.136. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Meningitis bacterial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Osteomyelitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Otitis externa	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Paronychia	0	0.0	(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, 0.0)
Peritonitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritonsillar abscess	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pharyngitis streptococcal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pneumonia	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Post procedural infection	0	0.0	(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, 0.0)
Pyelonephritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sepsis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinusitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Staphylococcal sepsis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subcutaneous abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tooth infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper respiratory tract infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Urinary tract infection	4	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Urosepsis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Viral infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	26	0.3	(0.2, 0.5)	31	0.4	(0.3, 0.5)
Ankle fracture	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Cervical vertebral fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Colon injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Craniocerebral injury	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Exposure during pregnancy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial bones fracture	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fall	5	0.1	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Femur fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Fibula fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Flail chest	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Foot fracture	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)

14.136. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Forearm fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hand fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Head injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hip fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Humerus fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Jaw fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Joint dislocation	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ligament rupture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ligament sprain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Limb injury	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Lower limb fracture	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Lumbar vertebral fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Meniscus injury	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Multiple injuries	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Muscle strain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Overdose	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Patella fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pelvic fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post procedural haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Procedural haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rib fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Road traffic accident	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Skin laceration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Spinal column injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spinal cord injury cervical	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Subdural haematoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ulna fracture	0	0.0	(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, 0.0)
INVESTIGATIONS	4	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Autoantibody positive	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood glucose abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood glucose increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood pressure increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Body temperature increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.136. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Cardiac stress test abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hepatic enzyme increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Red blood cell morphology abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Weight decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	9	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Dehydration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diabetes mellitus inadequate control	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diabetic ketoacidosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Fluid retention	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperglycaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypoglycaemia	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypokalaemia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lactic acidosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Obesity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Type 2 diabetes mellitus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	48	0.6	(0.4, 0.8)	25	0.3	(0.2, 0.4)
Arthralgia	5	0.1	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Arthritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Back pain	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bone disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bursitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Costochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Flank pain	0	0.0	(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, 0.0)
Intervertebral disc degeneration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscle contracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Muscle spasms	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscular weakness	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Musculoskeletal chest pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Myalgia	21	0.3	(0.2, 0.4)	3	0.0	(0.0, 0.1)
Neck pain	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteoarthritis	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Pain in extremity	6	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.0)

14.136. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Spondylolisthesis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	23	0.3	(0.2, 0.4)	18	0.2	(0.1, 0.3)
Acute myeloid leukaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma of colon	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma pancreas	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Benign hydatidiform mole	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bladder cancer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Borderline serous tumour of ovary	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Breast cancer	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Breast cancer in situ	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Carcinoid tumour of the stomach	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastric cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Invasive ductal breast carcinoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lung adenocarcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Malignant melanoma	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Malignant melanoma of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to lymph nodes	0	0.0	(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, 0.0)
Oropharyngeal cancer recurrent	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oropharyngeal squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Papillary serous endometrial carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Papillary thyroid cancer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Penile neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Penile squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Prostate cancer	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Prostate cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Squamous cell carcinoma of head and neck	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Teratoma	0	0.0	(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, 0.0)
Transitional cell carcinoma	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Uterine leiomyoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	50	0.6	(0.4, 0.8)	35	0.4	(0.3, 0.6)

14.136. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Amnesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cerebral infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebrovascular accident	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cervicogenic headache	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dizziness	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Generalised tonic-clonic seizure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Guillain-Barre syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Headache	25	0.3	(0.2, 0.4)	12	0.1	(0.1, 0.3)
Hemiparaesthesia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypoaesthesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Idiopathic intracranial hypertension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ischaemic stroke	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Migraine	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Paraesthesia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Paraparesis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Peripheral nerve lesion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sciatica	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Seizure	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subarachnoid haemorrhage	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Syncope	3	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Tension headache	0	0.0	(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, 0.0)
Transient global amnesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Transient ischaemic attack	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	0.0	(0.0, 0.0)	5	0.1	(0.0, 0.1)
Abortion incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abortion spontaneous	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Retained products of conception	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	8	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Anxiety	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bipolar disorder	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)

14.136. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Depression	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depression suicidal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Disorientation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Major depression	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mental status changes	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Panic attack	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Panic reaction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Suicide attempt	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	8	0.1	(0.0, 0.2)	10	0.1	(0.1, 0.2)
Acute kidney injury	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hydronephrosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nephrolithiasis	4	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Renal colic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subcapsular renal haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	0.0	(0.0, 0.0)	5	0.1	(0.0, 0.1)
Adnexal torsion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Endometriosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Prostatitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rectocele	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Uterine haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vaginal prolapse	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	10	0.1	(0.1, 0.2)	9	0.1	(0.1, 0.2)
Acute respiratory failure	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Asthma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Asthmatic crisis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dyspnoea	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypoxia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pneumonia aspiration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pneumothorax	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pulmonary embolism	4	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Pulmonary mass	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.136. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Rhinorrhoea	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	6	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.0)
Acne cystic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hidradenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Night sweats	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Rash maculo-papular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urticaria	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Finger amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Inguinal hernia repair	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Retinal operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Toe operation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
VASCULAR DISORDERS	14	0.2	(0.1, 0.3)	13	0.2	(0.1, 0.3)
Accelerated hypertension	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Aortic aneurysm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Aortic stenosis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Deep vein thrombosis	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypertension	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertensive crisis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertensive emergency	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypertensive urgency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypotension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Orthostatic hypotension	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Peripheral artery stenosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.136. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sev exp p3 saf

14.137. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	48	0.6	(0.4, 0.8)	54	0.7	(0.5, 0.9)
CARDIAC DISORDERS	21	0.3	(0.2, 0.4)	13	0.2	(0.1, 0.3)
Acute myocardial infarction	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Aortic valve incompetence	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Arrhythmia supraventricular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Atrioventricular block complete	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac arrest	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Cardiac failure congestive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coronary artery disease	0	0.0	(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, 0.0)
Coronary artery occlusion	0	0.0	(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, 0.0)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Myocardial infarction	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Myocardial ischaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ventricular tachycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Heart disease congenital	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
EYE DISORDERS	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	4	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Abdominal pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diarrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diverticular perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diverticulum intestinal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Duodenal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastrointestinal mucosa hyperaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haemorrhoids	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intestinal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oesophageal varices haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.137. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Small intestinal obstruction	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Volvulus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Drug withdrawal syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Sudden cardiac death	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cholelithiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anaphylactic shock	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	8	0.1	(0.0, 0.2)	16	0.2	(0.1, 0.3)
Abscess intestinal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Appendicitis	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Brain abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.0)	6	0.1	(0.0, 0.2)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Complicated appendicitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diverticulitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Emphysematous cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pneumonia	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Septic shock	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Shigella sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Subacute endocarditis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Craniocerebral injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hip fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Overdose	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Road traffic accident	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.137. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Toxicity to various agents	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Traumatic haemothorax	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arthralgia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Osteoarthritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Adrenal gland cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary cancer metastatic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gallbladder cancer stage II	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Malignant melanoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Metastases to liver	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pancreatic carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Uterine cancer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	1	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Dementia Alzheimer's type	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haemorrhagic stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hemiplegic migraine	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spinal cord compression	0	0.0	(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, 0.0)
Syncope	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Transient ischaemic attack	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Suicidal ideation	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nephrolithiasis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Renal colic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Adnexal torsion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.137. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Acute respiratory failure	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Interstitial lung disease	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pneumothorax	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pulmonary embolism	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
VASCULAR DISORDERS	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Aortic rupture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Arteriosclerosis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Deep vein thrombosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 lif exp p3 saf

14.138. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	193	3.9	(3.4, 4.5)	124	2.5	(2.1, 3.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Leukocytosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymph node pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphadenopathy	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Microcytic anaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neutropenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Thrombocytosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
CARDIAC DISORDERS	3	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Acute coronary syndrome	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Acute left ventricular failure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Angina unstable	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arteriospasm coronary	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrial fibrillation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrial flutter	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bradycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tachycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Congenital ureteropelvic junction obstruction	0	0.0	(0.0, 0.1)	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)
Tinnitus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vertigo	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
EYE DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal tear	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Visual impairment	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	16	0.3	(0.2, 0.5)	11	0.2	(0.1, 0.4)
Abdominal pain	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Colitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colitis ulcerative	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diarrhoea	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Dyspepsia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Flatulence	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.138. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Food poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastrooesophageal reflux disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ileus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Impaired gastric emptying	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Incarcerated inguinal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Internal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intestinal perforation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nausea	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Obstructive pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oesophageal food impaction	0	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, 0.1)
Small intestinal obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vomiting	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	75	1.5	(1.2, 1.9)	4	0.1	(0.0, 0.2)
Asthenia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chills	12	0.2	(0.1, 0.4)	0	0.0	(0.0, 0.1)
Fatigue	16	0.3	(0.2, 0.5)	1	0.0	(0.0, 0.1)
Influenza like illness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site erythema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site pain	13	0.3	(0.1, 0.4)	0	0.0	(0.0, 0.1)
Injection site swelling	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pain	7	0.1	(0.1, 0.3)	0	0.0	(0.0, 0.1)
Pyrexia	34	0.7	(0.5, 1.0)	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, 0.1)
HEPATOBILIARY DISORDERS	5	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Bile duct stone	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary colic	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cholecystitis acute	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholelithiasis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatocellular injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Drug hypersensitivity	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.138. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
INFECTIONS AND INFESTATIONS	18	0.4	(0.2, 0.6)	19	0.4	(0.2, 0.6)
Abdominal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abscess jaw	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess limb	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Appendicitis	9	0.2	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Arthritis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Cellulitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diabetic foot infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gangrene	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Infected bite	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meningitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Otitis externa	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumonia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Postoperative wound infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pyelonephritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Upper respiratory tract infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urinary tract infection	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Urosepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Viral infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	12	0.2	(0.1, 0.4)	15	0.3	(0.2, 0.5)
Ankle fracture	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cervical vertebral fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colon injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Craniocerebral injury	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Exposure during pregnancy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial bones fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fall	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Fibula fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.138. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Flail chest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foot fracture	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Forearm fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hand fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hip fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Joint dislocation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ligament sprain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lower limb fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Multiple injuries	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Overdose	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Procedural haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Road traffic accident	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Spinal cord injury cervical	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ulna fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper limb fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INVESTIGATIONS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Red blood cell morphology abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Weight decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	5	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Dehydration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diabetic ketoacidosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoglycaemia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypokalaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Obesity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Type 2 diabetes mellitus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	31	0.6	(0.4, 0.9)	13	0.3	(0.1, 0.5)
Arthralgia	3	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Arthritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Back pain	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Costochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intervertebral disc degeneration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle contracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.138. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Muscle spasms	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscular weakness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Musculoskeletal chest pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Myalgia	18	0.4	(0.2, 0.6)	2	0.0	(0.0, 0.1)
Neck pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pain in extremity	4	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Spondylolisthesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	3	0.1	(0.0, 0.2)	8	0.2	(0.1, 0.3)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Benign hydatidiform mole	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cancer	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Invasive ductal breast carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Malignant melanoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papillary thyroid cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Teratoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Transitional cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Uterine leiomyoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	27	0.5	(0.4, 0.8)	21	0.4	(0.3, 0.7)
Cerebrovascular accident	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dizziness	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Generalised tonic-clonic seizure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Guillain-Barre syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Headache	15	0.3	(0.2, 0.5)	10	0.2	(0.1, 0.4)
Hemiparaesthesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Idiopathic intracranial hypertension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ischaemic stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Migraine	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paraesthesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Paraparesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peripheral nerve lesion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sciatica	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.138. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Seizure	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	(0.0, 0.1)
Syncope	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Abortion incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abortion spontaneous	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retained products of conception	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	5	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Anxiety	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Depression	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Depression suicidal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Major depression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Panic attack	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Panic reaction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Suicide attempt	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	3	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Nephrolithiasis	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Renal colic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subcapsular renal haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Adnexal torsion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Endometriosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Prostatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectocele	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uterine haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaginal prolapse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Asthmatic crisis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoxia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.138. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pneumonia aspiration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pulmonary embolism	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Rhinorrhoea	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Acne cystic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hidradenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urticaria	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Retinal operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
VASCULAR DISORDERS	7	0.1	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Accelerated hypertension	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deep vein thrombosis	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Hypertensive urgency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypotension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sev age p3 saf

14.139. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	163	4.8	(4.1, 5.6)	132	4.0	(3.3, 4.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	7	0.2	(0.1, 0.4)	3	0.1	(0.0, 0.3)
Anaemia	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Blood loss anaemia	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Iron deficiency anaemia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lymphadenopathy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lymphocytosis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Neutropenia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Thrombocytopenia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
CARDIAC DISORDERS	9	0.3	(0.1, 0.5)	14	0.4	(0.2, 0.7)
Acute coronary syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Acute myocardial infarction	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Angina pectoris	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Angina unstable	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Atrial fibrillation	1	0.0	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Cardiac failure acute	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cardiac failure congestive	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Coronary artery disease	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.3)
Mitral valve incompetence	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Myocardial infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Supraventricular tachycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Tachyarrhythmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Tachycardia	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Ventricular arrhythmia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastrointestinal arteriovenous malformation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	6	0.2	(0.1, 0.4)	3	0.1	(0.0, 0.3)
Deafness unilateral	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Vertigo	4	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Vertigo positional	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
EYE DISORDERS	4	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Cataract	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)

14.139. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Diplopia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Macular oedema	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Retinal detachment	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	16	0.5	(0.3, 0.8)	15	0.5	(0.3, 0.7)
Abdominal adhesions	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Abdominal hernia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Abdominal pain	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Abdominal pain lower	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Abdominal pain upper	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Colitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Colitis ischaemic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Constipation	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Diarrhoea	2	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Enterocolitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastric antral vascular ectasia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastritis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastrointestinal haemorrhage	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Gastrointestinal pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Haematochezia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hiatus hernia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Intestinal obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Intestinal strangulation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Large intestine perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Nausea	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Oesophageal ulcer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pancreatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pancreatitis acute	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Retroperitoneal haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Small intestinal obstruction	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Varices oesophageal	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Vomiting	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	26	0.8	(0.5, 1.1)	3	0.1	(0.0, 0.3)
Chest pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.139. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Chills	6	0.2	(0.1, 0.4)	0	0.0	(0.0, 0.1)
Fatigue	8	0.2	(0.1, 0.5)	1	0.0	(0.0, 0.2)
Injection site pain	6	0.2	(0.1, 0.4)	0	0.0	(0.0, 0.1)
Malaise	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Non-cardiac chest pain	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pain	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Peripheral swelling	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pyrexia	4	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	7	0.2	(0.1, 0.4)	2	0.1	(0.0, 0.2)
Biliary colic	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cholecystitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cholecystitis acute	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Cholelithiasis	5	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Cirrhosis alcoholic	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	15	0.4	(0.2, 0.7)	21	0.6	(0.4, 1.0)
Appendicitis	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Appendicitis perforated	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Bacterial sepsis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Bronchitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
COVID-19	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Cellulitis	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Complicated appendicitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Device related infection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Diverticulitis	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Empyema	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Localised infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Osteomyelitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Paronychia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Penile infection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Peritonitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Peritonsillar abscess	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pharyngitis streptococcal	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pneumonia	2	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Post procedural infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

14.139. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Sepsis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Sinusitis	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Staphylococcal sepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Subcutaneous abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Tooth infection	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Urinary tract infection	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	14	0.4	(0.2, 0.7)	16	0.5	(0.3, 0.8)
Ankle fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cervical vertebral fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Facial bones fracture	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Fall	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Femur fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Foot fracture	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Head injury	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Humerus fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Jaw fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Joint dislocation	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Ligament rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Limb injury	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Lower limb fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Lumbar vertebral fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Meniscus injury	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Muscle strain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Patella fracture	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pelvic fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Post procedural haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Rib fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Road traffic accident	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Skin laceration	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Spinal column injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Subdural haematoma	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
INVESTIGATIONS	3	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Autoantibody positive	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

14.139. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Blood glucose abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Blood glucose increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Blood pressure increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Body temperature increased	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cardiac stress test abnormal	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hepatic enzyme increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Diabetes mellitus inadequate control	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Fluid retention	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hyperglycaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Hypoglycaemia	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypokalaemia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lactic acidosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	17	0.5	(0.3, 0.8)	12	0.4	(0.2, 0.6)
Arthralgia	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Arthritis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Back pain	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Bone disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Bursitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Flank pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Intervertebral disc compression	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Intervertebral disc protrusion	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Muscle spasms	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Muscular weakness	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Myalgia	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Neck pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Osteoarthritis	2	0.1	(0.0, 0.2)	5	0.2	(0.0, 0.4)
Pain in extremity	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Spondylolisthesis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	20	0.6	(0.4, 0.9)	10	0.3	(0.1, 0.6)
Acute myeloid leukaemia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Adenocarcinoma of colon	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Adenocarcinoma pancreas	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.139. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Bladder cancer	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Borderline serous tumour of ovary	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Breast cancer	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Breast cancer in situ	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Carcinoid tumour of the stomach	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastric cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Invasive ductal breast carcinoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lung adenocarcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Malignant melanoma	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Malignant melanoma of eyelid	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Non-small cell lung cancer stage IV	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Oropharyngeal cancer recurrent	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Oropharyngeal squamous cell carcinoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Papillary serous endometrial carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Penile neoplasm	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Penile squamous cell carcinoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Prostate cancer	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Prostate cancer metastatic	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Squamous cell carcinoma of head and neck	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Thyroid cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Transitional cell carcinoma	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	23	0.7	(0.4, 1.0)	14	0.4	(0.2, 0.7)
Amnesia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cerebral infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cerebrovascular accident	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Cervicogenic headache	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Dizziness	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Headache	10	0.3	(0.1, 0.5)	2	0.1	(0.0, 0.2)
Hypoaesthesia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ischaemic stroke	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Subarachnoid haemorrhage	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Syncope	2	0.1	(0.0, 0.2)	5	0.2	(0.0, 0.4)
Tension headache	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Toxic encephalopathy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Transient global amnesia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.139. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Transient ischaemic attack	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Uraemic encephalopathy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	3	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Bipolar disorder	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Depression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Disorientation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Mental status changes	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Panic attack	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Suicide attempt	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	5	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Acute kidney injury	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Hydronephrosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Nephrolithiasis	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	7	0.2	(0.1, 0.4)	6	0.2	(0.1, 0.4)
Acute respiratory failure	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Asthma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dyspnoea	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pneumothorax	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pulmonary embolism	1	0.0	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Pulmonary mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Rhinorrhoea	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Night sweats	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pruritus	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Rash maculo-papular	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Finger amputation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Inguinal hernia repair	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Toe operation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
VASCULAR DISORDERS	7	0.2	(0.1, 0.4)	9	0.3	(0.1, 0.5)
Accelerated hypertension	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

14.139. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Aortic aneurysm	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Aortic stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Deep vein thrombosis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Haematoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypertension	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Hypertensive crisis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hypertensive emergency	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Orthostatic hypotension	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Peripheral artery stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sev age p3 saf

14.140. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	13	0.3	(0.1, 0.4)	20	0.4	(0.2, 0.6)
CARDIAC DISORDERS	6	0.1	(0.0, 0.3)	5	0.1	(0.0, 0.2)
Acute myocardial infarction	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arrhythmia supraventricular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiac failure congestive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myocardial infarction	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Myocardial ischaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
EYE DISORDERS	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abdominal pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticular perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haemorrhoids	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intestinal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oesophageal varices haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Appendicitis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Overdose	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Toxicity to various agents	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.140. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Hemiplegic migraine	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Syncope	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Transient ischaemic attack	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Suicidal ideation	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Renal colic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Adnexal torsion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pulmonary embolism	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 lif age p3 saf

14.141. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	35	1.0	(0.7, 1.4)	34	1.0	(0.7, 1.4)
CARDIAC DISORDERS	15	0.4	(0.2, 0.7)	8	0.2	(0.1, 0.5)
Acute myocardial infarction	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Aortic valve incompetence	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Atrioventricular block complete	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cardiac arrest	6	0.2	(0.1, 0.4)	2	0.1	(0.0, 0.2)
Coronary artery disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Coronary artery dissection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Coronary artery occlusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Hypertensive heart disease	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Myocardial infarction	3	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Ventricular tachycardia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Heart disease congenital	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	2	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Diarrhoea	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Diverticulum intestinal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Duodenal obstruction	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastrointestinal mucosa hyperaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Small intestinal obstruction	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Volvulus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Drug withdrawal syndrome	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Sudden cardiac death	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cholelithiasis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Anaphylactic shock	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	6	0.2	(0.1, 0.4)	12	0.4	(0.2, 0.6)
Abscess intestinal	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.141. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Appendicitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Brain abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
COVID-19	0	0.0	(0.0, 0.1)	5	0.2	(0.0, 0.4)
COVID-19 pneumonia	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Complicated appendicitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Diverticulitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Emphysematous cholecystitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pneumonia	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.3)
Sepsis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Septic shock	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Shigella sepsis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Subacute endocarditis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Craniocerebral injury	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hip fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Overdose	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Road traffic accident	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Traumatic haemothorax	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Arthralgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Osteoarthritis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.3)
Adrenal gland cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Biliary cancer metastatic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Gallbladder cancer stage II	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Malignant melanoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Metastases to liver	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pancreatic carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Uterine cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Dementia Alzheimer's type	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Haemorrhagic stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

14.141. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Spinal cord compression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Subarachnoid haemorrhage	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Nephrolithiasis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2	0.1	(0.0, 0.2)	5	0.2	(0.0, 0.4)
Acute respiratory failure	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Interstitial lung disease	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pneumothorax	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pulmonary embolism	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
VASCULAR DISORDERS	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Aortic rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Arteriosclerosis	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Deep vein thrombosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_lif_age_p3_saf

14.142. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	243	8.8	(7.7, 9.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	5	0.2	(0.1, 0.4)
Lymph node pain	1	0.0	(0.0, 0.2)
Lymphadenopathy	3	0.1	(0.0, 0.3)
Pancytopenia	1	0.0	(0.0, 0.2)
Splenic infarction	1	0.0	(0.0, 0.2)
Splenomegaly	1	0.0	(0.0, 0.2)
CARDIAC DISORDERS	14	0.5	(0.3, 0.8)
Atrial fibrillation	2	0.1	(0.0, 0.3)
Atrial flutter	1	0.0	(0.0, 0.2)
Cardiac failure congestive	1	0.0	(0.0, 0.2)
Cardiomegaly	1	0.0	(0.0, 0.2)
Coronary artery disease	3	0.1	(0.0, 0.3)
Coronary artery occlusion	1	0.0	(0.0, 0.2)
Myocardial infarction	4	0.1	(0.0, 0.4)
Tachycardia	1	0.0	(0.0, 0.2)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.2)
Benign familial pemphigus	1	0.0	(0.0, 0.2)
EAR AND LABYRINTH DISORDERS	2	0.1	(0.0, 0.3)
Vertigo	2	0.1	(0.0, 0.3)
ENDOCRINE DISORDERS	2	0.1	(0.0, 0.3)
Hyperthyroidism	1	0.0	(0.0, 0.2)
Pituitary cyst	1	0.0	(0.0, 0.2)
EYE DISORDERS	6	0.2	(0.1, 0.5)
Blepharitis	1	0.0	(0.0, 0.2)
Dry eye	1	0.0	(0.0, 0.2)
Glaucoma	2	0.1	(0.0, 0.3)
Macular oedema	1	0.0	(0.0, 0.2)
Retinal tear	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	17	0.6	(0.4, 1.0)
Abdominal pain upper	1	0.0	(0.0, 0.2)
Diverticulum	1	0.0	(0.0, 0.2)

14.142. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dyspepsia	1	0.0	(0.0, 0.2)
Eosinophilic oesophagitis	1	0.0	(0.0, 0.2)
Gastritis	1	0.0	(0.0, 0.2)
Gastritis alcoholic	1	0.0	(0.0, 0.2)
Gastritis erosive	1	0.0	(0.0, 0.2)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.2)
Gastrooesophageal reflux disease	3	0.1	(0.0, 0.3)
Haematemesis	1	0.0	(0.0, 0.2)
Hiatus hernia	2	0.1	(0.0, 0.3)
Irritable bowel syndrome	2	0.1	(0.0, 0.3)
Pancreatic calcification	1	0.0	(0.0, 0.2)
Rectal haemorrhage	2	0.1	(0.0, 0.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	19	0.7	(0.4, 1.1)
Chest pain	2	0.1	(0.0, 0.3)
Chills	3	0.1	(0.0, 0.3)
Fatigue	7	0.3	(0.1, 0.5)
Impaired healing	1	0.0	(0.0, 0.2)
Injection site pain	7	0.3	(0.1, 0.5)
Injection site swelling	1	0.0	(0.0, 0.2)
Non-cardiac chest pain	1	0.0	(0.0, 0.2)
Oedema peripheral	2	0.1	(0.0, 0.3)
Pain	2	0.1	(0.0, 0.3)
Pyrexia	2	0.1	(0.0, 0.3)
HEPATOBILIARY DISORDERS	8	0.3	(0.1, 0.6)
Acute hepatic failure	1	0.0	(0.0, 0.2)
Cholecystitis	1	0.0	(0.0, 0.2)
Cholecystitis acute	2	0.1	(0.0, 0.3)
Cholelithiasis	1	0.0	(0.0, 0.2)
Cholelithiasis obstructive	1	0.0	(0.0, 0.2)
Jaundice	1	0.0	(0.0, 0.2)
Portosplenomesenteric venous thrombosis	1	0.0	(0.0, 0.2)
Steatohepatitis	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	1	0.0	(0.0, 0.2)
Seasonal allergy	1	0.0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	39	1.4	(1.0, 1.9)
Appendicitis	1	0.0	(0.0, 0.2)
Bacteraemia	1	0.0	(0.0, 0.2)

14.142. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Bronchitis	1	0.0	(0.0, 0.2)
Clostridium difficile colitis	1	0.0	(0.0, 0.2)
Ear infection	1	0.0	(0.0, 0.2)
Endocarditis	1	0.0	(0.0, 0.2)
Endometritis	1	0.0	(0.0, 0.2)
Fungal skin infection	2	0.1	(0.0, 0.3)
Furuncle	1	0.0	(0.0, 0.2)
Gastritis viral	1	0.0	(0.0, 0.2)
Gastroenteritis	1	0.0	(0.0, 0.2)
Gonorrhoea	1	0.0	(0.0, 0.2)
Helicobacter gastritis	1	0.0	(0.0, 0.2)
Herpes zoster	1	0.0	(0.0, 0.2)
Herpes zoster oticus	1	0.0	(0.0, 0.2)
Meningitis bacterial	1	0.0	(0.0, 0.2)
Mumps	1	0.0	(0.0, 0.2)
Onychomycosis	1	0.0	(0.0, 0.2)
Pneumonia	1	0.0	(0.0, 0.2)
Post procedural infection	1	0.0	(0.0, 0.2)
Postoperative abscess	1	0.0	(0.0, 0.2)
Sepsis	1	0.0	(0.0, 0.2)
Sinusitis bacterial	1	0.0	(0.0, 0.2)
Subcutaneous abscess	1	0.0	(0.0, 0.2)
Tooth infection	3	0.1	(0.0, 0.3)
Urinary tract infection	10	0.4	(0.2, 0.7)
Viral infection	1	0.0	(0.0, 0.2)
Wound infection	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	40	1.4	(1.0, 2.0)
Animal bite	1	0.0	(0.0, 0.2)
Ankle fracture	2	0.1	(0.0, 0.3)
Bone contusion	1	0.0	(0.0, 0.2)
Burns second degree	1	0.0	(0.0, 0.2)
Burns third degree	1	0.0	(0.0, 0.2)
Chemical burns of eye	1	0.0	(0.0, 0.2)
Clavicle fracture	1	0.0	(0.0, 0.2)
Contusion	3	0.1	(0.0, 0.3)
Exposure during pregnancy	3	0.1	(0.0, 0.3)
Facial bones fracture	1	0.0	(0.0, 0.2)

14.142. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Fall	10	0.4	(0.2, 0.7)
Foot fracture	1	0.0	(0.0, 0.2)
Hip fracture	1	0.0	(0.0, 0.2)
Humerus fracture	3	0.1	(0.0, 0.3)
Injury	1	0.0	(0.0, 0.2)
Ligament rupture	1	0.0	(0.0, 0.2)
Ligament sprain	1	0.0	(0.0, 0.2)
Limb injury	1	0.0	(0.0, 0.2)
Muscle strain	2	0.1	(0.0, 0.3)
Procedural dizziness	1	0.0	(0.0, 0.2)
Procedural pain	4	0.1	(0.0, 0.4)
Radius fracture	1	0.0	(0.0, 0.2)
Rectal injury	1	0.0	(0.0, 0.2)
Rib fracture	2	0.1	(0.0, 0.3)
Road traffic accident	2	0.1	(0.0, 0.3)
Skin laceration	4	0.1	(0.0, 0.4)
Thermal burn	1	0.0	(0.0, 0.2)
Upper limb fracture	1	0.0	(0.0, 0.2)
Wrist fracture	2	0.1	(0.0, 0.3)
INVESTIGATIONS	5	0.2	(0.1, 0.4)
Blood cholesterol increased	1	0.0	(0.0, 0.2)
Blood pressure increased	1	0.0	(0.0, 0.2)
Body temperature increased	1	0.0	(0.0, 0.2)
Intraocular pressure increased	1	0.0	(0.0, 0.2)
SARS-CoV-2 antibody test positive	1	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	13	0.5	(0.2, 0.8)
Diabetes mellitus	1	0.0	(0.0, 0.2)
Glucose tolerance impaired	1	0.0	(0.0, 0.2)
Hypercholesterolaemia	2	0.1	(0.0, 0.3)
Hyperglycaemia	1	0.0	(0.0, 0.2)
Hyperlipidaemia	3	0.1	(0.0, 0.3)
Hypertriglyceridaemia	1	0.0	(0.0, 0.2)
Metabolic syndrome	1	0.0	(0.0, 0.2)
Type 2 diabetes mellitus	1	0.0	(0.0, 0.2)
Vitamin D deficiency	2	0.1	(0.0, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	27	1.0	(0.6, 1.4)
Arthralgia	4	0.1	(0.0, 0.4)

14.142. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Back pain	3	0.1	(0.0, 0.3)
Flank pain	1	0.0	(0.0, 0.2)
Intervertebral disc protrusion	3	0.1	(0.0, 0.3)
Muscle contracture	1	0.0	(0.0, 0.2)
Muscle spasms	1	0.0	(0.0, 0.2)
Musculoskeletal stiffness	1	0.0	(0.0, 0.2)
Myalgia	5	0.2	(0.1, 0.4)
Neck pain	1	0.0	(0.0, 0.2)
Osteoarthritis	3	0.1	(0.0, 0.3)
Pain in extremity	4	0.1	(0.0, 0.4)
Periarthritis	1	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	14	0.5	(0.3, 0.8)
Adenocarcinoma pancreas	1	0.0	(0.0, 0.2)
Basal cell carcinoma	2	0.1	(0.0, 0.3)
Brain cancer metastatic	1	0.0	(0.0, 0.2)
Breast cancer	1	0.0	(0.0, 0.2)
Fibroma	1	0.0	(0.0, 0.2)
Haemangioma of skin	1	0.0	(0.0, 0.2)
Hormone receptor positive breast cancer	1	0.0	(0.0, 0.2)
Lipoma	1	0.0	(0.0, 0.2)
Malignant melanoma	1	0.0	(0.0, 0.2)
Metastases to lung	1	0.0	(0.0, 0.2)
Pancreatic carcinoma metastatic	1	0.0	(0.0, 0.2)
Prostate cancer	1	0.0	(0.0, 0.2)
Skin papilloma	1	0.0	(0.0, 0.2)
Uterine cancer	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	18	0.6	(0.4, 1.0)
Carpal tunnel syndrome	1	0.0	(0.0, 0.2)
Cervical radiculopathy	1	0.0	(0.0, 0.2)
Dizziness	3	0.1	(0.0, 0.3)
Dysgeusia	1	0.0	(0.0, 0.2)
Facial paralysis	1	0.0	(0.0, 0.2)
Headache	7	0.3	(0.1, 0.5)
Intracranial aneurysm	1	0.0	(0.0, 0.2)
Restless legs syndrome	1	0.0	(0.0, 0.2)
Sciatica	1	0.0	(0.0, 0.2)

14.142. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Seizure	1	0.0	(0.0, 0.2)
Seizure like phenomena	1	0.0	(0.0, 0.2)
Tremor	1	0.0	(0.0, 0.2)
Vocal cord paralysis	1	0.0	(0.0, 0.2)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.1	(0.0, 0.3)
Abortion spontaneous	1	0.0	(0.0, 0.2)
Exposure during pregnancy	1	0.0	(0.0, 0.2)
PSYCHIATRIC DISORDERS	4	0.1	(0.0, 0.4)
Adjustment disorder	1	0.0	(0.0, 0.2)
Anxiety disorder	1	0.0	(0.0, 0.2)
Bipolar I disorder	1	0.0	(0.0, 0.2)
Insomnia	1	0.0	(0.0, 0.2)
RENAL AND URINARY DISORDERS	5	0.2	(0.1, 0.4)
Bladder irritation	1	0.0	(0.0, 0.2)
Nephrolithiasis	3	0.1	(0.0, 0.3)
Renal haematoma	1	0.0	(0.0, 0.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2	0.1	(0.0, 0.3)
Endometrial thickening	1	0.0	(0.0, 0.2)
Endometriosis	1	0.0	(0.0, 0.2)
Menorrhagia	1	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	11	0.4	(0.2, 0.7)
Asthma	1	0.0	(0.0, 0.2)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.2)
Dyspnoea	1	0.0	(0.0, 0.2)
Dyspnoea exertional	1	0.0	(0.0, 0.2)
Epistaxis	1	0.0	(0.0, 0.2)
Pulmonary embolism	1	0.0	(0.0, 0.2)
Respiratory tract congestion	2	0.1	(0.0, 0.3)
Rhinorrhoea	2	0.1	(0.0, 0.3)
Sleep apnoea syndrome	1	0.0	(0.0, 0.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	14	0.5	(0.3, 0.8)
Alopecia	1	0.0	(0.0, 0.2)
Angioedema	1	0.0	(0.0, 0.2)
Decubitus ulcer	1	0.0	(0.0, 0.2)
Dermatitis	1	0.0	(0.0, 0.2)
Dermatitis contact	1	0.0	(0.0, 0.2)

14.142. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hand dermatitis	1	0.0	(0.0, 0.2)
Necrobiosis lipoidica diabeticorum	1	0.0	(0.0, 0.2)
Onycholysis	1	0.0	(0.0, 0.2)
Rash	1	0.0	(0.0, 0.2)
Rash maculo-papular	1	0.0	(0.0, 0.2)
Urticaria	4	0.1	(0.0, 0.4)
SOCIAL CIRCUMSTANCES	2	0.1	(0.0, 0.3)
Job dissatisfaction	1	0.0	(0.0, 0.2)
Stress at work	1	0.0	(0.0, 0.2)
SURGICAL AND MEDICAL PROCEDURES	5	0.2	(0.1, 0.4)
Incisional drainage	1	0.0	(0.0, 0.2)
Meniscus operation	1	0.0	(0.0, 0.2)
Metabolic surgery	1	0.0	(0.0, 0.2)
Radioactive iodine therapy	1	0.0	(0.0, 0.2)
Tooth extraction	1	0.0	(0.0, 0.2)
VASCULAR DISORDERS	23	0.8	(0.5, 1.2)
Aortic aneurysm	2	0.1	(0.0, 0.3)
Arterial occlusive disease	1	0.0	(0.0, 0.2)
Deep vein thrombosis	2	0.1	(0.0, 0.3)
Hot flush	1	0.0	(0.0, 0.2)
Hypertension	17	0.6	(0.4, 1.0)
Peripheral vascular disorder	1	0.0	(0.0, 0.2)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from the unblinding date to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 all ex bnt p3 saf

14.143. Incidence Rates of at Least 1 Related Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	20	0.7	(0.4, 1.1)
CARDIAC DISORDERS	1	0.0	(0.0, 0.2)
Myocardial infarction	1	0.0	(0.0, 0.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	13	0.5	(0.2, 0.8)
Chills	3	0.1	(0.0, 0.3)
Fatigue	6	0.2	(0.1, 0.5)
Injection site pain	7	0.3	(0.1, 0.5)
Injection site swelling	1	0.0	(0.0, 0.2)
Pain	2	0.1	(0.0, 0.3)
Pyrexia	2	0.1	(0.0, 0.3)
INVESTIGATIONS	1	0.0	(0.0, 0.2)
Body temperature increased	1	0.0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4	0.1	(0.0, 0.4)
Back pain	1	0.0	(0.0, 0.2)
Myalgia	2	0.1	(0.0, 0.3)
Pain in extremity	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	6	0.2	(0.1, 0.5)
Dizziness	2	0.1	(0.0, 0.3)
Dysgeusia	1	0.0	(0.0, 0.2)
Headache	5	0.2	(0.1, 0.4)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1	0.0	(0.0, 0.2)
Menorrhagia	1	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1	0.0	(0.0, 0.2)
Respiratory tract congestion	1	0.0	(0.0, 0.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1	0.0	(0.0, 0.2)
Rash maculo-papular	1	0.0	(0.0, 0.2)

14.143. Incidence Rates of at Least 1 Related Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	**n[c]**	**IR (/100 PY)[d]**	**(95% CI[e])**

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from the unblinding date to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (14:24)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_rel_ex_bnt_p3_saf

14.144. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=6666)
Adverse Event	n[b] (%)
Any event	2013 (30.2)
Related[c]	1386 (20.8)
Severe	121 (1.8)
Life-threatening	9 (0.1)
Any serious adverse event	73 (1.1)
Related[c]	2 (0.0)
Severe	42 (0.6)
Life-threatening	9 (0.1)
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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (17:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s091 6m age pd2 p3

14.145. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=5340)
Adverse Event	n[b] (%)
Any event	1441 (27.0)
Related[c]	859 (16.1)
Severe	127 (2.4)
Life-threatening	14 (0.3)
Any serious adverse event	117 (2.2)
Related[c]	0
Severe	74 (1.4)
Life-threatening	14 (0.3)
Any adverse event leading to withdrawal	1 (0.0)
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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (17:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s091 6m age pd2 p3

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	2013 (30.2)	(29.1, 31.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	44 (0.7)	(0.5, 0.9)
Lymphadenopathy	36 (0.5)	(0.4, 0.7)
Anaemia	4 (0.1)	(0.0, 0.2)
Iron deficiency anaemia	1 (0.0)	(0.0, 0.1)
Lymph node pain	3 (0.0)	(0.0, 0.1)
Leukopenia	1 (0.0)	(0.0, 0.1)
Blood loss anaemia	0	(0.0, 0.1)
Coagulopathy	0	(0.0, 0.1)
Lymphadenopathy mediastinal	0	(0.0, 0.1)
Lymphocytosis	0	(0.0, 0.1)
Lymphopenia	0	(0.0, 0.1)
Neutropenia	0	(0.0, 0.1)
Pancytopenia	0	(0.0, 0.1)
Splenic infarction	0	(0.0, 0.1)
Splenomegaly	0	(0.0, 0.1)
CARDIAC DISORDERS	20 (0.3)	(0.2, 0.5)
Atrial fibrillation	1 (0.0)	(0.0, 0.1)
Tachycardia	7 (0.1)	(0.0, 0.2)
Palpitations	3 (0.0)	(0.0, 0.1)
Coronary artery disease	1 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)
Angina pectoris	0	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.1)
Cardiac failure congestive	0	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)
Arrhythmia	0	(0.0, 0.1)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.1)
Atrial flutter	0	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	(95% CI[c])
Atrioventricular block first degree	1 (0.0)	(0.0, 0.1)
Bradycardia	1 (0.0)	(0.0, 0.1)
Bundle branch block right	1 (0.0)	(0.0, 0.1)
Cardiac arrest	0	(0.0, 0.1)
Cardiac disorder	1 (0.0)	(0.0, 0.1)
Cardiomegaly	0	(0.0, 0.1)
Coronary artery occlusion	0	(0.0, 0.1)
Left ventricular dysfunction	0	(0.0, 0.1)
Mitral valve prolapse	0	(0.0, 0.1)
Pericarditis	0	(0.0, 0.1)
Sinus tachycardia	1 (0.0)	(0.0, 0.1)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.1)
Ventricular tachycardia	0	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2 (0.0)	(0.0, 0.1)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.1)
Gastrointestinal arteriovenous malformation	0	(0.0, 0.1)
Protein S deficiency	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	27 (0.4)	(0.3, 0.6)
Vertigo	11 (0.2)	(0.1, 0.3)
Ear pain	5 (0.1)	(0.0, 0.2)
Tinnitus	3 (0.0)	(0.0, 0.1)
Vertigo positional	1 (0.0)	(0.0, 0.1)
Cerumen impaction	2 (0.0)	(0.0, 0.1)
Deafness neurosensory	0	(0.0, 0.1)
Ear discomfort	2 (0.0)	(0.0, 0.1)
Deafness unilateral	1 (0.0)	(0.0, 0.1)
Hyperacusis	1 (0.0)	(0.0, 0.1)
Sudden hearing loss	1 (0.0)	(0.0, 0.1)
ENDOCRINE DISORDERS	7 (0.1)	(0.0, 0.2)
Hypothyroidism	4 (0.1)	(0.0, 0.2)
Hyperthyroidism	1 (0.0)	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Hypogonadism	1 (0.0)	(0.0, 0.1)
Thyroid mass	0	(0.0, 0.1)
Goitre	0	(0.0, 0.1)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.1)
Oestrogen deficiency	0	(0.0, 0.1)
Pituitary cyst	0	(0.0, 0.1)
EYE DISORDERS	23 (0.3)	(0.2, 0.5)
Cataract	0	(0.0, 0.1)
Vision blurred	3 (0.0)	(0.0, 0.1)
Chalazion	1 (0.0)	(0.0, 0.1)
Eye irritation	2 (0.0)	(0.0, 0.1)
Eye pain	1 (0.0)	(0.0, 0.1)
Macular oedema	0	(0.0, 0.1)
Vitreous detachment	0	(0.0, 0.1)
Blepharitis	2 (0.0)	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)
Dry eye	1 (0.0)	(0.0, 0.1)
Glaucoma	1 (0.0)	(0.0, 0.1)
Retinal tear	1 (0.0)	(0.0, 0.1)
Asthenopia	1 (0.0)	(0.0, 0.1)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.1)
Corneal irritation	1 (0.0)	(0.0, 0.1)
Episcleritis	1 (0.0)	(0.0, 0.1)
Eye pruritus	1 (0.0)	(0.0, 0.1)
Eyelid oedema	1 (0.0)	(0.0, 0.1)
Eyelid pain	1 (0.0)	(0.0, 0.1)
Eyelids pruritus	1 (0.0)	(0.0, 0.1)
Keratitis	0	(0.0, 0.1)
Ophthalmic vein thrombosis	0	(0.0, 0.1)
Photophobia	1 (0.0)	(0.0, 0.1)
Retinal artery occlusion	0	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Scleral discolouration	1 (0.0)	(0.0, 0.1)
Vitreous floaters	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	231 (3.5)	(3.0, 3.9)
Nausea	88 (1.3)	(1.1, 1.6)
Diarrhoea	69 (1.0)	(0.8, 1.3)
Vomiting	28 (0.4)	(0.3, 0.6)
Toothache	11 (0.2)	(0.1, 0.3)
Abdominal pain	9 (0.1)	(0.1, 0.3)
Gastrooesophageal reflux disease	7 (0.1)	(0.0, 0.2)
Dyspepsia	8 (0.1)	(0.1, 0.2)
Abdominal pain upper	6 (0.1)	(0.0, 0.2)
Odynophagia	6 (0.1)	(0.0, 0.2)
Constipation	3 (0.0)	(0.0, 0.1)
Dental caries	4 (0.1)	(0.0, 0.2)
Irritable bowel syndrome	3 (0.0)	(0.0, 0.1)
Abdominal distension	1 (0.0)	(0.0, 0.1)
Flatulence	3 (0.0)	(0.0, 0.1)
Gastritis	3 (0.0)	(0.0, 0.1)
Hiatus hernia	1 (0.0)	(0.0, 0.1)
Large intestine polyp	1 (0.0)	(0.0, 0.1)
Aphthous ulcer	1 (0.0)	(0.0, 0.1)
Diverticulum	1 (0.0)	(0.0, 0.1)
Food poisoning	2 (0.0)	(0.0, 0.1)
Haemorrhoids	2 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.1)
Gastritis erosive	1 (0.0)	(0.0, 0.1)
Gastrointestinal disorder	2 (0.0)	(0.0, 0.1)
Glossodynia	0	(0.0, 0.1)
Haematochezia	1 (0.0)	(0.0, 0.1)
Impaired gastric emptying	1 (0.0)	(0.0, 0.1)
Oral pain	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	0	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Abdominal discomfort	0	(0.0, 0.1)
Abdominal pain lower	0	(0.0, 0.1)
Abdominal rigidity	0	(0.0, 0.1)
Angular cheilitis	1 (0.0)	(0.0, 0.1)
Cheilitis	1 (0.0)	(0.0, 0.1)
Coeliac disease	1 (0.0)	(0.0, 0.1)
Colitis microscopic	0	(0.0, 0.1)
Colitis ulcerative	0	(0.0, 0.1)
Crohn's disease	1 (0.0)	(0.0, 0.1)
Diverticulum intestinal	0	(0.0, 0.1)
Dry mouth	0	(0.0, 0.1)
Dysphagia	0	(0.0, 0.1)
Epiploic appendagitis	0	(0.0, 0.1)
Eructation	0	(0.0, 0.1)
Faeces soft	1 (0.0)	(0.0, 0.1)
Femoral hernia	0	(0.0, 0.1)
Gastric antral vascular ectasia	0	(0.0, 0.1)
Gastric ulcer	0	(0.0, 0.1)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.1)
Gastrointestinal haemorrhage	0	(0.0, 0.1)
Gastrointestinal pain	0	(0.0, 0.1)
Gingival pain	1 (0.0)	(0.0, 0.1)
Glossitis	0	(0.0, 0.1)
Haematemesis	0	(0.0, 0.1)
Haemorrhoidal haemorrhage	0	(0.0, 0.1)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.1)
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.1)
Inguinal hernia	0	(0.0, 0.1)
Internal hernia	1 (0.0)	(0.0, 0.1)
Intestinal obstruction	1 (0.0)	(0.0, 0.1)
Intestinal polyp	0	(0.0, 0.1)
Intra-abdominal fluid collection	1 (0.0)	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Lip oedema	1 (0.0)	(0.0, 0.1)
Noninfective gingivitis	1 (0.0)	(0.0, 0.1)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.1)
Oesophageal spasm	0	(0.0, 0.1)
Oral discomfort	0	(0.0, 0.1)
Oral lichenoid reaction	1 (0.0)	(0.0, 0.1)
Pancreatic calcification	0	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)
Parotid duct obstruction	0	(0.0, 0.1)
Rectal haemorrhage	1 (0.0)	(0.0, 0.1)
Rectal polyp	1 (0.0)	(0.0, 0.1)
Retching	0	(0.0, 0.1)
Stomatitis	0	(0.0, 0.1)
Swollen tongue	1 (0.0)	(0.0, 0.1)
Tongue oedema	0	(0.0, 0.1)
Tongue pruritus	0	(0.0, 0.1)
Tongue ulceration	0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1246 (18.7)	(17.8, 19.6)
Injection site pain	715 (10.7)	(10.0, 11.5)
Pyrexia	442 (6.6)	(6.0, 7.3)
Chills	412 (6.2)	(5.6, 6.8)
Fatigue	372 (5.6)	(5.0, 6.2)
Pain	190 (2.9)	(2.5, 3.3)
Injection site erythema	50 (0.8)	(0.6, 1.0)
Injection site swelling	31 (0.5)	(0.3, 0.7)
Malaise	29 (0.4)	(0.3, 0.6)
Asthenia	9 (0.1)	(0.1, 0.3)
Injection site pruritus	9 (0.1)	(0.1, 0.3)
Chest pain	7 (0.1)	(0.0, 0.2)
Influenza like illness	7 (0.1)	(0.0, 0.2)
Injection site bruising	5 (0.1)	(0.0, 0.2)
Axillary pain	4 (0.1)	(0.0, 0.2)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	(95% CI[c])
Injection site warmth	3 (0.0)	(0.0, 0.1)
Feeling hot	3 (0.0)	(0.0, 0.1)
Injection site induration	1 (0.0)	(0.0, 0.1)
Oedema peripheral	2 (0.0)	(0.0, 0.1)
Peripheral swelling	2 (0.0)	(0.0, 0.1)
Injection site oedema	3 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)
Adverse drug reaction	2 (0.0)	(0.0, 0.1)
Cyst	1 (0.0)	(0.0, 0.1)
Face oedema	0	(0.0, 0.1)
Injection site discomfort	1 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)
Injection site nodule	1 (0.0)	(0.0, 0.1)
Injection site papule	2 (0.0)	(0.0, 0.1)
Swelling	1 (0.0)	(0.0, 0.1)
Application site erythema	1 (0.0)	(0.0, 0.1)
Application site pain	1 (0.0)	(0.0, 0.1)
Application site pruritus	0	(0.0, 0.1)
Application site reaction	1 (0.0)	(0.0, 0.1)
Chest discomfort	1 (0.0)	(0.0, 0.1)
Drug withdrawal syndrome	0	(0.0, 0.1)
Illness	1 (0.0)	(0.0, 0.1)
Induration	0	(0.0, 0.1)
Inflammation	1 (0.0)	(0.0, 0.1)
Injection site discolouration	1 (0.0)	(0.0, 0.1)
Injection site haemorrhage	0	(0.0, 0.1)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.1)
Injection site irritation	0	(0.0, 0.1)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.1)
Injection site mass	0	(0.0, 0.1)
Injection site paraesthesia	1 (0.0)	(0.0, 0.1)
Injection site rash	0	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	(95% CI[c])
Injection site reaction	0	(0.0, 0.1)
Medical device pain	1 (0.0)	(0.0, 0.1)
Sensation of foreign body	1 (0.0)	(0.0, 0.1)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)
Sluggishness	0	(0.0, 0.1)
Temperature intolerance	0	(0.0, 0.1)
Thirst	1 (0.0)	(0.0, 0.1)
Vaccination site induration	1 (0.0)	(0.0, 0.1)
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)
Vessel puncture site bruise	0	(0.0, 0.1)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	10 (0.2)	(0.1, 0.3)
Cholelithiasis	2 (0.0)	(0.0, 0.1)
Biliary colic	3 (0.0)	(0.0, 0.1)
Cholecystitis acute	2 (0.0)	(0.0, 0.1)
Bile duct stone	2 (0.0)	(0.0, 0.1)
Biliary dyskinesia	0	(0.0, 0.1)
Cholecystitis	1 (0.0)	(0.0, 0.1)
Cholelithiasis obstructive	1 (0.0)	(0.0, 0.1)
Gallbladder disorder	0	(0.0, 0.1)
Hepatic steatosis	0	(0.0, 0.1)
Jaundice	0	(0.0, 0.1)
Portosplenomesenteric venous thrombosis	0	(0.0, 0.1)
Steatohepatitis	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	12 (0.2)	(0.1, 0.3)
Seasonal allergy	4 (0.1)	(0.0, 0.2)
Drug hypersensitivity	2 (0.0)	(0.0, 0.1)
Hypersensitivity	2 (0.0)	(0.0, 0.1)
Allergy to arthropod bite	1 (0.0)	(0.0, 0.1)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.1)
Anaphylactic reaction	1 (0.0)	(0.0, 0.1)
Food allergy	0	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	(95% CI[c])
Jarisch-Herxheimer reaction	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	161 (2.4)	(2.1, 2.8)
Urinary tract infection	25 (0.4)	(0.2, 0.6)
Tooth infection	6 (0.1)	(0.0, 0.2)
Sinusitis	9 (0.1)	(0.1, 0.3)
Appendicitis	9 (0.1)	(0.1, 0.3)
Herpes zoster	5 (0.1)	(0.0, 0.2)
Cellulitis	6 (0.1)	(0.0, 0.2)
Conjunctivitis	4 (0.1)	(0.0, 0.2)
Cystitis	3 (0.0)	(0.0, 0.1)
Ear infection	5 (0.1)	(0.0, 0.2)
Diverticulitis	2 (0.0)	(0.0, 0.1)
Gastroenteritis	4 (0.1)	(0.0, 0.2)
Tooth abscess	3 (0.0)	(0.0, 0.1)
Hordeolum	2 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	4 (0.1)	(0.0, 0.2)
Folliculitis	5 (0.1)	(0.0, 0.2)
Rhinitis	5 (0.1)	(0.0, 0.2)
Nasopharyngitis	4 (0.1)	(0.0, 0.2)
Oral herpes	3 (0.0)	(0.0, 0.1)
Otitis externa	2 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	4 (0.1)	(0.0, 0.2)
Fungal skin infection	1 (0.0)	(0.0, 0.1)
Gingivitis	3 (0.0)	(0.0, 0.1)
Onychomycosis	0	(0.0, 0.1)
Paronychia	1 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	2 (0.0)	(0.0, 0.1)
Pneumonia	0	(0.0, 0.1)
Pyelonephritis	1 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	3 (0.0)	(0.0, 0.1)
Device related infection	0	(0.0, 0.1)
Herpes simplex	2 (0.0)	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	 (95% CI[c])
Influenza	1 (0.0)	(0.0, 0.1)
Kidney infection	1 (0.0)	(0.0, 0.1)
Laryngitis	0	(0.0, 0.1)
Localised infection	0	(0.0, 0.1)
Oral candidiasis	2 (0.0)	(0.0, 0.1)
Otitis media	1 (0.0)	(0.0, 0.1)
Otitis media acute	1 (0.0)	(0.0, 0.1)
Periodontitis	1 (0.0)	(0.0, 0.1)
Pustule	1 (0.0)	(0.0, 0.1)
Rash pustular	1 (0.0)	(0.0, 0.1)
Sepsis	0	(0.0, 0.1)
Sinusitis bacterial	2 (0.0)	(0.0, 0.1)
Skin infection	1 (0.0)	(0.0, 0.1)
Viral infection	2 (0.0)	(0.0, 0.1)
Abscess	1 (0.0)	(0.0, 0.1)
Abscess neck	1 (0.0)	(0.0, 0.1)
Abscess oral	1 (0.0)	(0.0, 0.1)
Acute sinusitis	0	(0.0, 0.1)
Appendicitis perforated	0	(0.0, 0.1)
Arthritis bacterial	1 (0.0)	(0.0, 0.1)
Bacteraemia	0	(0.0, 0.1)
Bacterial blepharitis	1 (0.0)	(0.0, 0.1)
Bacterial sepsis	0	(0.0, 0.1)
Bacterial vaginosis	1 (0.0)	(0.0, 0.1)
Bacterial vulvovaginitis	1 (0.0)	(0.0, 0.1)
Bartholinitis	1 (0.0)	(0.0, 0.1)
Bone abscess	0	(0.0, 0.1)
Bronchitis	0	(0.0, 0.1)
Cellulitis orbital	0	(0.0, 0.1)
Chronic sinusitis	1 (0.0)	(0.0, 0.1)
Clostridium difficile colitis	0	(0.0, 0.1)
Empyema	0	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Endocarditis	0	(0.0, 0.1)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.1)
Eye infection	0	(0.0, 0.1)
Fungal infection	0	(0.0, 0.1)
Furuncle	1 (0.0)	(0.0, 0.1)
Gangrene	1 (0.0)	(0.0, 0.1)
Gastroenteritis viral	1 (0.0)	(0.0, 0.1)
Gastrointestinal infection	1 (0.0)	(0.0, 0.1)
Genital herpes simplex	1 (0.0)	(0.0, 0.1)
Helicobacter gastritis	0	(0.0, 0.1)
Helicobacter infection	1 (0.0)	(0.0, 0.1)
Herpes zoster oticus	1 (0.0)	(0.0, 0.1)
Impetigo	0	(0.0, 0.1)
Infected bite	1 (0.0)	(0.0, 0.1)
Injection site abscess	0	(0.0, 0.1)
Mastoiditis	0	(0.0, 0.1)
Meningitis bacterial	0	(0.0, 0.1)
Mumps	1 (0.0)	(0.0, 0.1)
Papilloma viral infection	1 (0.0)	(0.0, 0.1)
Parasitic gastroenteritis	1 (0.0)	(0.0, 0.1)
Penile infection	0	(0.0, 0.1)
Peritoneal abscess	1 (0.0)	(0.0, 0.1)
Peritonitis	1 (0.0)	(0.0, 0.1)
Peritonsillar abscess	0	(0.0, 0.1)
Pharyngitis	1 (0.0)	(0.0, 0.1)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.1)
Pilonidal cyst	1 (0.0)	(0.0, 0.1)
Postoperative abscess	1 (0.0)	(0.0, 0.1)
Respiratory tract infection viral	0	(0.0, 0.1)
Sialoadenitis	0	(0.0, 0.1)
Staphylococcal infection	1 (0.0)	(0.0, 0.1)
Subcutaneous abscess	1 (0.0)	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	(95% CI[c])
Tinea versicolour	1 (0.0)	(0.0, 0.1)
Varicella	1 (0.0)	(0.0, 0.1)
Vulval abscess	1 (0.0)	(0.0, 0.1)
Vulvovaginitis	0	(0.0, 0.1)
Wound infection	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	100 (1.5)	(1.2, 1.8)
Fall	12 (0.2)	(0.1, 0.3)
Exposure during pregnancy	21 (0.3)	(0.2, 0.5)
Muscle strain	7 (0.1)	(0.0, 0.2)
Ligament sprain	3 (0.0)	(0.0, 0.1)
Contusion	8 (0.1)	(0.1, 0.2)
Procedural pain	6 (0.1)	(0.0, 0.2)
Road traffic accident	6 (0.1)	(0.0, 0.2)
Skin laceration	8 (0.1)	(0.1, 0.2)
Arthropod bite	1 (0.0)	(0.0, 0.1)
Limb injury	4 (0.1)	(0.0, 0.2)
Tooth fracture	2 (0.0)	(0.0, 0.1)
Ankle fracture	2 (0.0)	(0.0, 0.1)
Chest injury	1 (0.0)	(0.0, 0.1)
Foot fracture	3 (0.0)	(0.0, 0.1)
Hand fracture	2 (0.0)	(0.0, 0.1)
Joint dislocation	2 (0.0)	(0.0, 0.1)
Skin abrasion	2 (0.0)	(0.0, 0.1)
Joint injury	1 (0.0)	(0.0, 0.1)
Meniscus injury	2 (0.0)	(0.0, 0.1)
Wrist fracture	1 (0.0)	(0.0, 0.1)
Animal bite	2 (0.0)	(0.0, 0.1)
Arthropod sting	0	(0.0, 0.1)
Burns second degree	1 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.1)
Facial bones fracture	1 (0.0)	(0.0, 0.1)
Humerus fracture	0	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	 (95% CI[c])
Patella fracture	0	(0.0, 0.1)
Tibia fracture	1 (0.0)	(0.0, 0.1)
Upper limb fracture	2 (0.0)	(0.0, 0.1)
Vaccination complication	2 (0.0)	(0.0, 0.1)
Concussion	1 (0.0)	(0.0, 0.1)
Craniocerebral injury	1 (0.0)	(0.0, 0.1)
Ligament rupture	1 (0.0)	(0.0, 0.1)
Radius fracture	1 (0.0)	(0.0, 0.1)
Rib fracture	0	(0.0, 0.1)
Thermal burn	2 (0.0)	(0.0, 0.1)
Bone contusion	0	(0.0, 0.1)
Bone fissure	1 (0.0)	(0.0, 0.1)
Burn oral cavity	0	(0.0, 0.1)
Burns first degree	0	(0.0, 0.1)
Burns third degree	1 (0.0)	(0.0, 0.1)
Cartilage injury	0	(0.0, 0.1)
Chemical burns of eye	1 (0.0)	(0.0, 0.1)
Corneal abrasion	0	(0.0, 0.1)
Eyelid injury	1 (0.0)	(0.0, 0.1)
Fibula fracture	0	(0.0, 0.1)
Foreign body in eye	1 (0.0)	(0.0, 0.1)
Fractured sacrum	0	(0.0, 0.1)
Head injury	0	(0.0, 0.1)
Hip fracture	1 (0.0)	(0.0, 0.1)
Jaw fracture	0	(0.0, 0.1)
Limb fracture	0	(0.0, 0.1)
Limb traumatic amputation	1 (0.0)	(0.0, 0.1)
Maternal exposure before pregnancy	1 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	1 (0.0)	(0.0, 0.1)
Muscle contusion	0	(0.0, 0.1)
Muscle rupture	1 (0.0)	(0.0, 0.1)
Overdose	1 (0.0)	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	(95% CI[c])
Pelvic fracture	0	(0.0, 0.1)
Penis injury	1 (0.0)	(0.0, 0.1)
Post concussion syndrome	0	(0.0, 0.1)
Post procedural discomfort	1 (0.0)	(0.0, 0.1)
Post procedural swelling	1 (0.0)	(0.0, 0.1)
Procedural dizziness	0	(0.0, 0.1)
Spinal compression fracture	0	(0.0, 0.1)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.1)
Spinal fracture	0	(0.0, 0.1)
Stress fracture	0	(0.0, 0.1)
Subdural haematoma	0	(0.0, 0.1)
Sunburn	0	(0.0, 0.1)
Traumatic intracranial haemorrhage	0	(0.0, 0.1)
Ulna fracture	0	(0.0, 0.1)
INVESTIGATIONS	49 (0.7)	(0.5, 1.0)
Body temperature increased	30 (0.5)	(0.3, 0.6)
Blood glucose increased	0	(0.0, 0.1)
SARS-CoV-2 antibody test positive	2 (0.0)	(0.0, 0.1)
Blood pressure increased	4 (0.1)	(0.0, 0.2)
Blood cholesterol increased	2 (0.0)	(0.0, 0.1)
Alanine aminotransferase increased	2 (0.0)	(0.0, 0.1)
Blood thyroid stimulating hormone increased	2 (0.0)	(0.0, 0.1)
Weight increased	2 (0.0)	(0.0, 0.1)
Aspartate aminotransferase increased	1 (0.0)	(0.0, 0.1)
Blood creatinine decreased	1 (0.0)	(0.0, 0.1)
Blood glucose abnormal	1 (0.0)	(0.0, 0.1)
Blood immunoglobulin E increased	1 (0.0)	(0.0, 0.1)
Blood potassium decreased	0	(0.0, 0.1)
Blood triglycerides increased	0	(0.0, 0.1)
Body temperature decreased	0	(0.0, 0.1)
C-reactive protein	1 (0.0)	(0.0, 0.1)
Cardiac stress test abnormal	0	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	(95% CI[c])
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.1)
Fractional exhaled nitric oxide increased	0	(0.0, 0.1)
Glomerular filtration rate decreased	0	(0.0, 0.1)
Haemoglobin decreased	0	(0.0, 0.1)
Heart rate increased	0	(0.0, 0.1)
Intraocular pressure increased	0	(0.0, 0.1)
Liver function test increased	0	(0.0, 0.1)
Lymphocyte count decreased	0	(0.0, 0.1)
Mean cell volume decreased	0	(0.0, 0.1)
Platelet count decreased	0	(0.0, 0.1)
Respiratory rate increased	0	(0.0, 0.1)
Troponin increased	0	(0.0, 0.1)
Weight decreased	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	40 (0.6)	(0.4, 0.8)
Decreased appetite	11 (0.2)	(0.1, 0.3)
Hyperlipidaemia	3 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	6 (0.1)	(0.0, 0.2)
Vitamin D deficiency	2 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	4 (0.1)	(0.0, 0.2)
Dyslipidaemia	4 (0.1)	(0.0, 0.2)
Glucose tolerance impaired	1 (0.0)	(0.0, 0.1)
Gout	1 (0.0)	(0.0, 0.1)
Hyperglycaemia	0	(0.0, 0.1)
Hypertriglyceridaemia	1 (0.0)	(0.0, 0.1)
Hypoglycaemia	1 (0.0)	(0.0, 0.1)
Hypokalaemia	1 (0.0)	(0.0, 0.1)
Dehydration	1 (0.0)	(0.0, 0.1)
Hyperkalaemia	0	(0.0, 0.1)
Hyperuricaemia	0	(0.0, 0.1)
Obesity	2 (0.0)	(0.0, 0.1)
Diabetes mellitus	0	(0.0, 0.1)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	(95% CI[c])
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.1)
Hypocalcaemia	1 (0.0)	(0.0, 0.1)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.1)
Insulin resistance	0	(0.0, 0.1)
Metabolic syndrome	1 (0.0)	(0.0, 0.1)
Polydipsia	0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	539 (8.1)	(7.4, 8.8)
Myalgia	355 (5.3)	(4.8, 5.9)
Arthralgia	84 (1.3)	(1.0, 1.6)
Pain in extremity	44 (0.7)	(0.5, 0.9)
Back pain	34 (0.5)	(0.4, 0.7)
Neck pain	10 (0.2)	(0.1, 0.3)
Muscle spasms	9 (0.1)	(0.1, 0.3)
Osteoarthritis	2 (0.0)	(0.0, 0.1)
Tendonitis	6 (0.1)	(0.0, 0.2)
Musculoskeletal stiffness	1 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	3 (0.0)	(0.0, 0.1)
Arthritis	3 (0.0)	(0.0, 0.1)
Bursitis	2 (0.0)	(0.0, 0.1)
Muscular weakness	1 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	3 (0.0)	(0.0, 0.1)
Periarthritis	4 (0.1)	(0.0, 0.2)
Musculoskeletal discomfort	3 (0.0)	(0.0, 0.1)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.1)
Joint stiffness	1 (0.0)	(0.0, 0.1)
Muscle contracture	3 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	2 (0.0)	(0.0, 0.1)
Arthropathy	0	(0.0, 0.1)
Coccydynia	2 (0.0)	(0.0, 0.1)
Costochondritis	1 (0.0)	(0.0, 0.1)
Flank pain	1 (0.0)	(0.0, 0.1)
Joint range of motion decreased	2 (0.0)	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Limb discomfort	0	(0.0, 0.1)
Muscle twitching	1 (0.0)	(0.0, 0.1)
Musculoskeletal pain	1 (0.0)	(0.0, 0.1)
Pain in jaw	1 (0.0)	(0.0, 0.1)
Plantar fasciitis	1 (0.0)	(0.0, 0.1)
Spinal osteoarthritis	0	(0.0, 0.1)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.1)
Bone disorder	0	(0.0, 0.1)
Bone pain	0	(0.0, 0.1)
Groin pain	0	(0.0, 0.1)
Intervertebral disc compression	0	(0.0, 0.1)
Joint effusion	1 (0.0)	(0.0, 0.1)
Joint instability	0	(0.0, 0.1)
Joint swelling	1 (0.0)	(0.0, 0.1)
Mobility decreased	0	(0.0, 0.1)
Muscle fatigue	1 (0.0)	(0.0, 0.1)
Muscle tightness	1 (0.0)	(0.0, 0.1)
Osteochondritis	1 (0.0)	(0.0, 0.1)
Osteopenia	0	(0.0, 0.1)
Psoriatic arthropathy	0	(0.0, 0.1)
Spinal stenosis	1 (0.0)	(0.0, 0.1)
Spondylitis	0	(0.0, 0.1)
Synovial cyst	0	(0.0, 0.1)
Temporomandibular joint syndrome	1 (0.0)	(0.0, 0.1)
Torticollis	1 (0.0)	(0.0, 0.1)
Trigger finger	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	13 (0.2)	(0.1, 0.3)
Prostate cancer	0	(0.0, 0.1)
Basal cell carcinoma	0	(0.0, 0.1)
Lipoma	2 (0.0)	(0.0, 0.1)
Malignant melanoma	2 (0.0)	(0.0, 0.1)

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	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Breast cancer	0	(0.0, 0.1)
Invasive ductal breast carcinoma	1 (0.0)	(0.0, 0.1)
Skin papilloma	0	(0.0, 0.1)
Transitional cell carcinoma	1 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	0	(0.0, 0.1)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.1)
Adenoma benign	0	(0.0, 0.1)
Adrenal gland cancer	0	(0.0, 0.1)
Benign breast neoplasm	1 (0.0)	(0.0, 0.1)
Benign hydatidiform mole	1 (0.0)	(0.0, 0.1)
Benign uterine neoplasm	1 (0.0)	(0.0, 0.1)
Bladder cancer	0	(0.0, 0.1)
Borderline serous tumour of ovary	0	(0.0, 0.1)
Brain cancer metastatic	1 (0.0)	(0.0, 0.1)
Breast cancer in situ	0	(0.0, 0.1)
Carcinoid tumour of the stomach	0	(0.0, 0.1)
Chondroma	1 (0.0)	(0.0, 0.1)
Colon adenoma	0	(0.0, 0.1)
Fibroma	0	(0.0, 0.1)
Gallbladder cancer stage II	0	(0.0, 0.1)
Gastric cancer	0	(0.0, 0.1)
Malignant melanoma of eyelid	0	(0.0, 0.1)
Meningioma benign	0	(0.0, 0.1)
Non-small cell lung cancer stage IV	0	(0.0, 0.1)
Seborrhoeic keratosis	0	(0.0, 0.1)
Skin cancer	0	(0.0, 0.1)
Squamous cell carcinoma	0	(0.0, 0.1)
Squamous cell carcinoma of skin	0	(0.0, 0.1)
Thyroid cancer	0	(0.0, 0.1)
Uterine cancer	0	(0.0, 0.1)
Uterine leiomyoma	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	449 (6.7)	(6.1, 7.4)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Headache	359 (5.4)	(4.9, 6.0)
Dizziness	20 (0.3)	(0.2, 0.5)
Paraesthesia	12 (0.2)	(0.1, 0.3)
Lethargy	3 (0.0)	(0.0, 0.1)
Migraine	12 (0.2)	(0.1, 0.3)
Sciatica	6 (0.1)	(0.0, 0.2)
Tension headache	8 (0.1)	(0.1, 0.2)
Syncope	5 (0.1)	(0.0, 0.2)
Presyncope	5 (0.1)	(0.0, 0.2)
Tremor	2 (0.0)	(0.0, 0.1)
Dysgeusia	4 (0.1)	(0.0, 0.2)
Somnolence	2 (0.0)	(0.0, 0.1)
Disturbance in attention	2 (0.0)	(0.0, 0.1)
Facial paralysis	2 (0.0)	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.1)
Sinus headache	2 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)
Burning sensation	2 (0.0)	(0.0, 0.1)
Cerebrovascular accident	0	(0.0, 0.1)
Cervical radiculopathy	1 (0.0)	(0.0, 0.1)
Dizziness postural	0	(0.0, 0.1)
Migraine without aura	1 (0.0)	(0.0, 0.1)
Nerve compression	1 (0.0)	(0.0, 0.1)
Optic neuritis	2 (0.0)	(0.0, 0.1)
Restless legs syndrome	1 (0.0)	(0.0, 0.1)
Seizure	2 (0.0)	(0.0, 0.1)
Transient ischaemic attack	0	(0.0, 0.1)
Aphasia	0	(0.0, 0.1)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.1)
Depressed level of consciousness	1 (0.0)	(0.0, 0.1)
Dyskinesia	0	(0.0, 0.1)
Hyperaesthesia	1 (0.0)	(0.0, 0.1)

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	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.1)
Intracranial aneurysm	0	(0.0, 0.1)
Ischaemic stroke	0	(0.0, 0.1)
Neuralgia	0	(0.0, 0.1)
Parosmia	1 (0.0)	(0.0, 0.1)
Periodic limb movement disorder	0	(0.0, 0.1)
Peripheral nerve lesion	1 (0.0)	(0.0, 0.1)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.1)
Post herpetic neuralgia	0	(0.0, 0.1)
Radiculopathy	1 (0.0)	(0.0, 0.1)
Seizure like phenomena	1 (0.0)	(0.0, 0.1)
Toxic encephalopathy	0	(0.0, 0.1)
Transient global amnesia	0	(0.0, 0.1)
Uraemic encephalopathy	0	(0.0, 0.1)
Vocal cord paralysis	0	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	3 (0.0)	(0.0, 0.1)
Abortion spontaneous	2 (0.0)	(0.0, 0.1)
Exposure during pregnancy	1 (0.0)	(0.0, 0.1)
PRODUCT ISSUES	0	(0.0, 0.1)
Device connection issue	0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	42 (0.6)	(0.5, 0.9)
Insomnia	12 (0.2)	(0.1, 0.3)
Anxiety	13 (0.2)	(0.1, 0.3)
Depression	8 (0.1)	(0.1, 0.2)
Anxiety disorder	3 (0.0)	(0.0, 0.1)
Abnormal dreams	2 (0.0)	(0.0, 0.1)
Attention deficit hyperactivity disorder	3 (0.0)	(0.0, 0.1)
Irritability	2 (0.0)	(0.0, 0.1)
Sleep disorder	0	(0.0, 0.1)
Disorientation	0	(0.0, 0.1)
Nightmare	0	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Generalised anxiety disorder	1 (0.0)	(0.0, 0.1)
Libido increased	0	(0.0, 0.1)
Panic attack	1 (0.0)	(0.0, 0.1)
Restlessness	0	(0.0, 0.1)
Suicide attempt	0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	15 (0.2)	(0.1, 0.4)
Nephrolithiasis	6 (0.1)	(0.0, 0.2)
Dysuria	3 (0.0)	(0.0, 0.1)
Pollakiuria	3 (0.0)	(0.0, 0.1)
Haematuria	1 (0.0)	(0.0, 0.1)
Acute kidney injury	0	(0.0, 0.1)
Bladder spasm	0	(0.0, 0.1)
Renal colic	2 (0.0)	(0.0, 0.1)
Urinary retention	0	(0.0, 0.1)
Bladder irritation	0	(0.0, 0.1)
Chronic kidney disease	0	(0.0, 0.1)
Hypertonic bladder	0	(0.0, 0.1)
Micturition urgency	0	(0.0, 0.1)
Obstructive nephropathy	0	(0.0, 0.1)
Renal cyst	0	(0.0, 0.1)
Renal haematoma	0	(0.0, 0.1)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.1)
Urethral stenosis	0	(0.0, 0.1)
Urinary tract obstruction	0	(0.0, 0.1)
Vesical fistula	0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	30 (0.5)	(0.3, 0.6)
Dysmenorrhoea	4 (0.1)	(0.0, 0.2)
Ovarian cyst	2 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.1)
Breast pain	2 (0.0)	(0.0, 0.1)
Endometriosis	2 (0.0)	(0.0, 0.1)
Genital erythema	1 (0.0)	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	(95% CI[c])
Menorrhagia	2 (0.0)	(0.0, 0.1)
Menstruation irregular	2 (0.0)	(0.0, 0.1)
Amenorrhoea	1 (0.0)	(0.0, 0.1)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)
Cervical dysplasia	1 (0.0)	(0.0, 0.1)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.1)
Endometrial thickening	1 (0.0)	(0.0, 0.1)
Haematospermia	1 (0.0)	(0.0, 0.1)
Mammary duct ectasia	1 (0.0)	(0.0, 0.1)
Menometrorrhagia	1 (0.0)	(0.0, 0.1)
Metrorrhagia	1 (0.0)	(0.0, 0.1)
Pelvic pain	1 (0.0)	(0.0, 0.1)
Polycystic ovaries	1 (0.0)	(0.0, 0.1)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.1)
Prostatitis	0	(0.0, 0.1)
Prostatomegaly	1 (0.0)	(0.0, 0.1)
Pruritus genital	0	(0.0, 0.1)
Scrotal pain	1 (0.0)	(0.0, 0.1)
Testicular pain	0	(0.0, 0.1)
Testicular torsion	1 (0.0)	(0.0, 0.1)
Uterine prolapse	0	(0.0, 0.1)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	79 (1.2)	(0.9, 1.5)
Oropharyngeal pain	16 (0.2)	(0.1, 0.4)
Nasal congestion	14 (0.2)	(0.1, 0.4)
Cough	10 (0.2)	(0.1, 0.3)
Rhinorrhoea	3 (0.0)	(0.0, 0.1)
Rhinitis allergic	9 (0.1)	(0.1, 0.3)
Asthma	4 (0.1)	(0.0, 0.2)
Dyspnoea	4 (0.1)	(0.0, 0.2)
Pulmonary embolism	2 (0.0)	(0.0, 0.1)
Sleep apnoea syndrome	1 (0.0)	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Throat irritation	1 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	3 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	3 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	0	(0.0, 0.1)
Epistaxis	0	(0.0, 0.1)
Asthmatic crisis	2 (0.0)	(0.0, 0.1)
Bronchospasm	2 (0.0)	(0.0, 0.1)
Nasal polyps	1 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.1)
Respiratory tract congestion	1 (0.0)	(0.0, 0.1)
Sinus congestion	1 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	0	(0.0, 0.1)
Wheezing	1 (0.0)	(0.0, 0.1)
Allergic sinusitis	1 (0.0)	(0.0, 0.1)
Atelectasis	0	(0.0, 0.1)
Dry throat	1 (0.0)	(0.0, 0.1)
Dyspnoea exertional	0	(0.0, 0.1)
Emphysema	0	(0.0, 0.1)
Haemoptysis	0	(0.0, 0.1)
Interstitial lung disease	0	(0.0, 0.1)
Nasal septum deviation	0	(0.0, 0.1)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.1)
Paranasal sinus hypersecretion	0	(0.0, 0.1)
Pleurisy	0	(0.0, 0.1)
Pneumonitis	0	(0.0, 0.1)
Pneumothorax	0	(0.0, 0.1)
Reflux laryngitis	1 (0.0)	(0.0, 0.1)
Respiratory failure	0	(0.0, 0.1)
Sneezing	0	(0.0, 0.1)
Snoring	1 (0.0)	(0.0, 0.1)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	80 (1.2)	(1.0, 1.5)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Rash	24 (0.4)	(0.2, 0.5)
Hyperhidrosis	10 (0.2)	(0.1, 0.3)
Pruritus	4 (0.1)	(0.0, 0.2)
Dermatitis contact	5 (0.1)	(0.0, 0.2)
Urticaria	6 (0.1)	(0.0, 0.2)
Night sweats	4 (0.1)	(0.0, 0.2)
Rash pruritic	3 (0.0)	(0.0, 0.1)
Erythema	3 (0.0)	(0.0, 0.1)
Dermal cyst	0	(0.0, 0.1)
Dermatitis	2 (0.0)	(0.0, 0.1)
Eczema	2 (0.0)	(0.0, 0.1)
Acne	3 (0.0)	(0.0, 0.1)
Actinic keratosis	0	(0.0, 0.1)
Dermatitis allergic	2 (0.0)	(0.0, 0.1)
Rash maculo-papular	2 (0.0)	(0.0, 0.1)
Alopecia	1 (0.0)	(0.0, 0.1)
Acne cystic	1 (0.0)	(0.0, 0.1)
Angioedema	0	(0.0, 0.1)
Cold sweat	1 (0.0)	(0.0, 0.1)
Dermatitis exfoliative	0	(0.0, 0.1)
Diabetic foot	0	(0.0, 0.1)
Dry skin	0	(0.0, 0.1)
Ecchymosis	0	(0.0, 0.1)
Erythema nodosum	1 (0.0)	(0.0, 0.1)
Hand dermatitis	1 (0.0)	(0.0, 0.1)
Hangnail	1 (0.0)	(0.0, 0.1)
Intertrigo	1 (0.0)	(0.0, 0.1)
Macule	0	(0.0, 0.1)
Onycholysis	0	(0.0, 0.1)
Onychomadesis	0	(0.0, 0.1)
Pain of skin	0	(0.0, 0.1)
Papule	0	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	 (95% CI[c])
Pityriasis	1 (0.0)	(0.0, 0.1)
Pseudofolliculitis	0	(0.0, 0.1)
Psoriasis	0	(0.0, 0.1)
Purpura	0	(0.0, 0.1)
Rash erythematous	0	(0.0, 0.1)
Rash papular	1 (0.0)	(0.0, 0.1)
Rosacea	0	(0.0, 0.1)
Skin discolouration	0	(0.0, 0.1)
Skin irritation	1 (0.0)	(0.0, 0.1)
Skin ulcer	1 (0.0)	(0.0, 0.1)
Transient acantholytic dermatosis	1 (0.0)	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	2 (0.0)	(0.0, 0.1)
High risk sexual behaviour	1 (0.0)	(0.0, 0.1)
Miscarriage of partner	1 (0.0)	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	13 (0.2)	(0.1, 0.3)
Dental implantation	2 (0.0)	(0.0, 0.1)
Tooth extraction	2 (0.0)	(0.0, 0.1)
Wisdom teeth removal	2 (0.0)	(0.0, 0.1)
Botulinum toxin injection	0	(0.0, 0.1)
Cardioversion	0	(0.0, 0.1)
Carpal tunnel decompression	0	(0.0, 0.1)
Drug titration	1 (0.0)	(0.0, 0.1)
Endodontic procedure	1 (0.0)	(0.0, 0.1)
Facet joint block	0	(0.0, 0.1)
Finger amputation	0	(0.0, 0.1)
Gingival operation	1 (0.0)	(0.0, 0.1)
Inguinal hernia repair	0	(0.0, 0.1)
Lacrimal duct procedure	0	(0.0, 0.1)
Mammoplasty	1 (0.0)	(0.0, 0.1)
Meniscus operation	0	(0.0, 0.1)
Metabolic surgery	1 (0.0)	(0.0, 0.1)
Open reduction of fracture	0	(0.0, 0.1)

14.146. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Postoperative care	0	(0.0, 0.1)
Radioactive iodine therapy	0	(0.0, 0.1)
Retinal operation	1 (0.0)	(0.0, 0.1)
Rotator cuff repair	0	(0.0, 0.1)
Sclerotherapy	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	34 (0.5)	(0.4, 0.7)
Hypertension	19 (0.3)	(0.2, 0.4)
Deep vein thrombosis	2 (0.0)	(0.0, 0.1)
Hot flush	3 (0.0)	(0.0, 0.1)
Aortic aneurysm	0	(0.0, 0.1)
Haematoma	2 (0.0)	(0.0, 0.1)
Flushing	1 (0.0)	(0.0, 0.1)
Hypotension	2 (0.0)	(0.0, 0.1)
Aortic dilatation	0	(0.0, 0.1)
Arterial occlusive disease	0	(0.0, 0.1)
Essential hypertension	1 (0.0)	(0.0, 0.1)
Intermittent claudication	1 (0.0)	(0.0, 0.1)
Lymphorrhoea	0	(0.0, 0.1)
Peripheral vascular disorder	0	(0.0, 0.1)
Systolic hypertension	1 (0.0)	(0.0, 0.1)
Thrombophlebitis superficial	1 (0.0)	(0.0, 0.1)
Varicose vein	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s091 6m soc age pd2 p3

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	1441 (27.0)	(25.8, 28.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	26 (0.5)	(0.3, 0.7)
Lymphadenopathy	14 (0.3)	(0.1, 0.4)
Anaemia	3 (0.1)	(0.0, 0.2)
Iron deficiency anaemia	4 (0.1)	(0.0, 0.2)
Lymph node pain	0	(0.0, 0.1)
Leukopenia	1 (0.0)	(0.0, 0.1)
Blood loss anaemia	1 (0.0)	(0.0, 0.1)
Coagulopathy	1 (0.0)	(0.0, 0.1)
Lymphadenopathy mediastinal	1 (0.0)	(0.0, 0.1)
Lymphocytosis	1 (0.0)	(0.0, 0.1)
Lymphopenia	1 (0.0)	(0.0, 0.1)
Neutropenia	1 (0.0)	(0.0, 0.1)
Pancytopenia	1 (0.0)	(0.0, 0.1)
Splenic infarction	1 (0.0)	(0.0, 0.1)
Splenomegaly	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	39 (0.7)	(0.5, 1.0)
Atrial fibrillation	8 (0.1)	(0.1, 0.3)
Tachycardia	2 (0.0)	(0.0, 0.1)
Palpitations	4 (0.1)	(0.0, 0.2)
Coronary artery disease	5 (0.1)	(0.0, 0.2)
Acute myocardial infarction	3 (0.1)	(0.0, 0.2)
Angina pectoris	4 (0.1)	(0.0, 0.2)
Myocardial infarction	4 (0.1)	(0.0, 0.2)
Cardiac failure congestive	3 (0.1)	(0.0, 0.2)
Angina unstable	1 (0.0)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 0.1)
Arrhythmia	1 (0.0)	(0.0, 0.1)
Arrhythmia supraventricular	0	(0.0, 0.1)
Atrial flutter	1 (0.0)	(0.0, 0.1)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=5340) n[b] (%)	(95% CI[c])
Atrioventricular block first degree	0	(0.0, 0.1)
Bradycardia	0	(0.0, 0.1)
Bundle branch block right	0	(0.0, 0.1)
Cardiac arrest	1 (0.0)	(0.0, 0.1)
Cardiac disorder	0	(0.0, 0.1)
Cardiomegaly	1 (0.0)	(0.0, 0.1)
Coronary artery occlusion	1 (0.0)	(0.0, 0.1)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.1)
Mitral valve prolapse	1 (0.0)	(0.0, 0.1)
Pericarditis	1 (0.0)	(0.0, 0.1)
Sinus tachycardia	0	(0.0, 0.1)
Supraventricular tachycardia	0	(0.0, 0.1)
Ventricular tachycardia	1 (0.0)	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.1)
Congenital cystic kidney disease	0	(0.0, 0.1)
Gastrointestinal arteriovenous malformation	1 (0.0)	(0.0, 0.1)
Protein S deficiency	0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	22 (0.4)	(0.3, 0.6)
Vertigo	10 (0.2)	(0.1, 0.3)
Ear pain	3 (0.1)	(0.0, 0.2)
Tinnitus	3 (0.1)	(0.0, 0.2)
Vertigo positional	3 (0.1)	(0.0, 0.2)
Cerumen impaction	1 (0.0)	(0.0, 0.1)
Deafness neurosensory	2 (0.0)	(0.0, 0.1)
Ear discomfort	0	(0.0, 0.1)
Deafness unilateral	0	(0.0, 0.1)
Hyperacusis	0	(0.0, 0.1)
Sudden hearing loss	0	(0.0, 0.1)
ENDOCRINE DISORDERS	8 (0.1)	(0.1, 0.3)
Hypothyroidism	2 (0.0)	(0.0, 0.1)
Hyperthyroidism	1 (0.0)	(0.0, 0.1)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Hypogonadism	1 (0.0)	(0.0, 0.1)
Thyroid mass	2 (0.0)	(0.0, 0.1)
Goitre	1 (0.0)	(0.0, 0.1)
Hyperprolactinaemia	0	(0.0, 0.1)
Oestrogen deficiency	1 (0.0)	(0.0, 0.1)
Pituitary cyst	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	24 (0.4)	(0.3, 0.7)
Cataract	5 (0.1)	(0.0, 0.2)
Vision blurred	2 (0.0)	(0.0, 0.1)
Chalazion	2 (0.0)	(0.0, 0.1)
Eye irritation	1 (0.0)	(0.0, 0.1)
Eye pain	2 (0.0)	(0.0, 0.1)
Macular oedema	3 (0.1)	(0.0, 0.2)
Vitreous detachment	3 (0.1)	(0.0, 0.2)
Blepharitis	0	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)
Dry eye	1 (0.0)	(0.0, 0.1)
Glaucoma	1 (0.0)	(0.0, 0.1)
Retinal tear	1 (0.0)	(0.0, 0.1)
Asthenopia	0	(0.0, 0.1)
Choroidal neovascularisation	0	(0.0, 0.1)
Conjunctival haemorrhage	0	(0.0, 0.1)
Corneal irritation	0	(0.0, 0.1)
Episcleritis	0	(0.0, 0.1)
Eye pruritus	0	(0.0, 0.1)
Eyelid oedema	0	(0.0, 0.1)
Eyelid pain	0	(0.0, 0.1)
Eyelids pruritus	0	(0.0, 0.1)
Keratitis	1 (0.0)	(0.0, 0.1)
Ophthalmic vein thrombosis	1 (0.0)	(0.0, 0.1)
Photophobia	0	(0.0, 0.1)
Retinal artery occlusion	1 (0.0)	(0.0, 0.1)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Scleral discolouration	0	(0.0, 0.1)
Vitreous floaters	0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	176 (3.3)	(2.8, 3.8)
Nausea	52 (1.0)	(0.7, 1.3)
Diarrhoea	54 (1.0)	(0.8, 1.3)
Vomiting	7 (0.1)	(0.1, 0.3)
Toothache	7 (0.1)	(0.1, 0.3)
Abdominal pain	6 (0.1)	(0.0, 0.2)
Gastrooesophageal reflux disease	7 (0.1)	(0.1, 0.3)
Dyspepsia	5 (0.1)	(0.0, 0.2)
Abdominal pain upper	4 (0.1)	(0.0, 0.2)
Odynophagia	4 (0.1)	(0.0, 0.2)
Constipation	4 (0.1)	(0.0, 0.2)
Dental caries	2 (0.0)	(0.0, 0.1)
Irritable bowel syndrome	2 (0.0)	(0.0, 0.1)
Abdominal distension	3 (0.1)	(0.0, 0.2)
Flatulence	1 (0.0)	(0.0, 0.1)
Gastritis	1 (0.0)	(0.0, 0.1)
Hiatus hernia	3 (0.1)	(0.0, 0.2)
Large intestine polyp	3 (0.1)	(0.0, 0.2)
Aphthous ulcer	2 (0.0)	(0.0, 0.1)
Diverticulum	2 (0.0)	(0.0, 0.1)
Food poisoning	1 (0.0)	(0.0, 0.1)
Haemorrhoids	1 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.1)
Gastritis erosive	1 (0.0)	(0.0, 0.1)
Gastrointestinal disorder	0	(0.0, 0.1)
Glossodynia	2 (0.0)	(0.0, 0.1)
Haematochezia	1 (0.0)	(0.0, 0.1)
Impaired gastric emptying	1 (0.0)	(0.0, 0.1)
Oral pain	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Abdominal discomfort	1 (0.0)	(0.0, 0.1)
Abdominal pain lower	1 (0.0)	(0.0, 0.1)
Abdominal rigidity	1 (0.0)	(0.0, 0.1)
Angular cheilitis	0	(0.0, 0.1)
Cheilitis	0	(0.0, 0.1)
Coeliac disease	0	(0.0, 0.1)
Colitis microscopic	1 (0.0)	(0.0, 0.1)
Colitis ulcerative	1 (0.0)	(0.0, 0.1)
Crohn's disease	0	(0.0, 0.1)
Diverticulum intestinal	1 (0.0)	(0.0, 0.1)
Dry mouth	1 (0.0)	(0.0, 0.1)
Dysphagia	1 (0.0)	(0.0, 0.1)
Epiploic appendagitis	1 (0.0)	(0.0, 0.1)
Eructation	1 (0.0)	(0.0, 0.1)
Faeces soft	0	(0.0, 0.1)
Femoral hernia	1 (0.0)	(0.0, 0.1)
Gastric antral vascular ectasia	1 (0.0)	(0.0, 0.1)
Gastric ulcer	1 (0.0)	(0.0, 0.1)
Gastric ulcer haemorrhage	0	(0.0, 0.1)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)
Gastrointestinal pain	1 (0.0)	(0.0, 0.1)
Gingival pain	0	(0.0, 0.1)
Glossitis	1 (0.0)	(0.0, 0.1)
Haematemesis	1 (0.0)	(0.0, 0.1)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.1)
Hypoaesthesia oral	0	(0.0, 0.1)
Hypoaesthesia teeth	0	(0.0, 0.1)
Inguinal hernia	1 (0.0)	(0.0, 0.1)
Internal hernia	0	(0.0, 0.1)
Intestinal obstruction	0	(0.0, 0.1)
Intestinal polyp	1 (0.0)	(0.0, 0.1)
Intra-abdominal fluid collection	0	(0.0, 0.1)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Lip oedema	0	(0.0, 0.1)
Noninfective gingivitis	0	(0.0, 0.1)
Obstructive pancreatitis	0	(0.0, 0.1)
Oesophageal spasm	1 (0.0)	(0.0, 0.1)
Oral discomfort	1 (0.0)	(0.0, 0.1)
Oral lichenoid reaction	0	(0.0, 0.1)
Pancreatic calcification	1 (0.0)	(0.0, 0.1)
Pancreatitis	0	(0.0, 0.1)
Parotid duct obstruction	1 (0.0)	(0.0, 0.1)
Rectal haemorrhage	0	(0.0, 0.1)
Rectal polyp	0	(0.0, 0.1)
Retching	1 (0.0)	(0.0, 0.1)
Stomatitis	1 (0.0)	(0.0, 0.1)
Swollen tongue	0	(0.0, 0.1)
Tongue oedema	1 (0.0)	(0.0, 0.1)
Tongue pruritus	1 (0.0)	(0.0, 0.1)
Tongue ulceration	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	770 (14.4)	(13.5, 15.4)
Injection site pain	476 (8.9)	(8.2, 9.7)
Pyrexia	191 (3.6)	(3.1, 4.1)
Chills	194 (3.6)	(3.1, 4.2)
Fatigue	226 (4.2)	(3.7, 4.8)
Pain	87 (1.6)	(1.3, 2.0)
Injection site erythema	41 (0.8)	(0.6, 1.0)
Injection site swelling	29 (0.5)	(0.4, 0.8)
Malaise	17 (0.3)	(0.2, 0.5)
Asthenia	11 (0.2)	(0.1, 0.4)
Injection site pruritus	10 (0.2)	(0.1, 0.3)
Chest pain	7 (0.1)	(0.1, 0.3)
Influenza like illness	3 (0.1)	(0.0, 0.2)
Injection site bruising	3 (0.1)	(0.0, 0.2)
Axillary pain	2 (0.0)	(0.0, 0.1)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Injection site warmth	3 (0.1)	(0.0, 0.2)
Feeling hot	2 (0.0)	(0.0, 0.1)
Injection site induration	4 (0.1)	(0.0, 0.2)
Oedema peripheral	3 (0.1)	(0.0, 0.2)
Peripheral swelling	2 (0.0)	(0.0, 0.1)
Injection site oedema	0	(0.0, 0.1)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)
Adverse drug reaction	0	(0.0, 0.1)
Cyst	1 (0.0)	(0.0, 0.1)
Face oedema	2 (0.0)	(0.0, 0.1)
Injection site discomfort	1 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)
Injection site nodule	1 (0.0)	(0.0, 0.1)
Injection site papule	0	(0.0, 0.1)
Swelling	1 (0.0)	(0.0, 0.1)
Application site erythema	0	(0.0, 0.1)
Application site pain	0	(0.0, 0.1)
Application site pruritus	1 (0.0)	(0.0, 0.1)
Application site reaction	0	(0.0, 0.1)
Chest discomfort	0	(0.0, 0.1)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.1)
Illness	0	(0.0, 0.1)
Induration	1 (0.0)	(0.0, 0.1)
Inflammation	0	(0.0, 0.1)
Injection site discolouration	0	(0.0, 0.1)
Injection site haemorrhage	1 (0.0)	(0.0, 0.1)
Injection site hyperaesthesia	0	(0.0, 0.1)
Injection site irritation	1 (0.0)	(0.0, 0.1)
Injection site lymphadenopathy	0	(0.0, 0.1)
Injection site mass	1 (0.0)	(0.0, 0.1)
Injection site paraesthesia	0	(0.0, 0.1)
Injection site rash	1 (0.0)	(0.0, 0.1)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Injection site reaction	1 (0.0)	(0.0, 0.1)
Medical device pain	0	(0.0, 0.1)
Sensation of foreign body	0	(0.0, 0.1)
Shoulder injury related to vaccine administration	0	(0.0, 0.1)
Sluggishness	1 (0.0)	(0.0, 0.1)
Temperature intolerance	1 (0.0)	(0.0, 0.1)
Thirst	0	(0.0, 0.1)
Vaccination site induration	0	(0.0, 0.1)
Vascular stent occlusion	0	(0.0, 0.1)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.1)
Vessel puncture site haematoma	0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	11 (0.2)	(0.1, 0.4)
Cholelithiasis	5 (0.1)	(0.0, 0.2)
Biliary colic	1 (0.0)	(0.0, 0.1)
Cholecystitis acute	1 (0.0)	(0.0, 0.1)
Bile duct stone	0	(0.0, 0.1)
Biliary dyskinesia	1 (0.0)	(0.0, 0.1)
Cholecystitis	0	(0.0, 0.1)
Cholelithiasis obstructive	0	(0.0, 0.1)
Gallbladder disorder	1 (0.0)	(0.0, 0.1)
Hepatic steatosis	1 (0.0)	(0.0, 0.1)
Jaundice	1 (0.0)	(0.0, 0.1)
Portosplenomesenteric venous thrombosis	1 (0.0)	(0.0, 0.1)
Steatohepatitis	0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	3 (0.1)	(0.0, 0.2)
Seasonal allergy	2 (0.0)	(0.0, 0.1)
Drug hypersensitivity	0	(0.0, 0.1)
Hypersensitivity	0	(0.0, 0.1)
Allergy to arthropod bite	0	(0.0, 0.1)
Allergy to arthropod sting	0	(0.0, 0.1)
Anaphylactic reaction	0	(0.0, 0.1)
Food allergy	1 (0.0)	(0.0, 0.1)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Jarisch-Herxheimer reaction	0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	134 (2.5)	(2.1, 3.0)
Urinary tract infection	32 (0.6)	(0.4, 0.8)
Tooth infection	14 (0.3)	(0.1, 0.4)
Sinusitis	7 (0.1)	(0.1, 0.3)
Appendicitis	1 (0.0)	(0.0, 0.1)
Herpes zoster	5 (0.1)	(0.0, 0.2)
Cellulitis	3 (0.1)	(0.0, 0.2)
Conjunctivitis	4 (0.1)	(0.0, 0.2)
Cystitis	5 (0.1)	(0.0, 0.2)
Ear infection	3 (0.1)	(0.0, 0.2)
Diverticulitis	5 (0.1)	(0.0, 0.2)
Gastroenteritis	3 (0.1)	(0.0, 0.2)
Tooth abscess	4 (0.1)	(0.0, 0.2)
Hordeolum	4 (0.1)	(0.0, 0.2)
Upper respiratory tract infection	2 (0.0)	(0.0, 0.1)
Folliculitis	0	(0.0, 0.1)
Rhinitis	0	(0.0, 0.1)
Nasopharyngitis	0	(0.0, 0.1)
Oral herpes	1 (0.0)	(0.0, 0.1)
Otitis externa	2 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	0	(0.0, 0.1)
Fungal skin infection	2 (0.0)	(0.0, 0.1)
Gingivitis	0	(0.0, 0.1)
Onychomycosis	3 (0.1)	(0.0, 0.2)
Paronychia	2 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	1 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.1)	(0.0, 0.2)
Pyelonephritis	2 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	0	(0.0, 0.1)
Device related infection	2 (0.0)	(0.0, 0.1)
Herpes simplex	0	(0.0, 0.1)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Influenza	1 (0.0)	(0.0, 0.1)
Kidney infection	1 (0.0)	(0.0, 0.1)
Laryngitis	2 (0.0)	(0.0, 0.1)
Localised infection	2 (0.0)	(0.0, 0.1)
Oral candidiasis	0	(0.0, 0.1)
Otitis media	1 (0.0)	(0.0, 0.1)
Otitis media acute	1 (0.0)	(0.0, 0.1)
Periodontitis	1 (0.0)	(0.0, 0.1)
Pustule	1 (0.0)	(0.0, 0.1)
Rash pustular	1 (0.0)	(0.0, 0.1)
Sepsis	2 (0.0)	(0.0, 0.1)
Sinusitis bacterial	0	(0.0, 0.1)
Skin infection	1 (0.0)	(0.0, 0.1)
Viral infection	0	(0.0, 0.1)
Abscess	0	(0.0, 0.1)
Abscess neck	0	(0.0, 0.1)
Abscess oral	0	(0.0, 0.1)
Acute sinusitis	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)
Arthritis bacterial	0	(0.0, 0.1)
Bacteraemia	1 (0.0)	(0.0, 0.1)
Bacterial blepharitis	0	(0.0, 0.1)
Bacterial sepsis	1 (0.0)	(0.0, 0.1)
Bacterial vaginosis	0	(0.0, 0.1)
Bacterial vulvovaginitis	0	(0.0, 0.1)
Bartholinitis	0	(0.0, 0.1)
Bone abscess	1 (0.0)	(0.0, 0.1)
Bronchitis	1 (0.0)	(0.0, 0.1)
Cellulitis orbital	1 (0.0)	(0.0, 0.1)
Chronic sinusitis	0	(0.0, 0.1)
Clostridium difficile colitis	1 (0.0)	(0.0, 0.1)
Empyema	1 (0.0)	(0.0, 0.1)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Endocarditis	1 (0.0)	(0.0, 0.1)
Escherichia urinary tract infection	0	(0.0, 0.1)
Eye infection	1 (0.0)	(0.0, 0.1)
Fungal infection	1 (0.0)	(0.0, 0.1)
Furuncle	0	(0.0, 0.1)
Gangrene	0	(0.0, 0.1)
Gastroenteritis viral	0	(0.0, 0.1)
Gastrointestinal infection	0	(0.0, 0.1)
Genital herpes simplex	0	(0.0, 0.1)
Helicobacter gastritis	1 (0.0)	(0.0, 0.1)
Helicobacter infection	0	(0.0, 0.1)
Herpes zoster oticus	0	(0.0, 0.1)
Impetigo	1 (0.0)	(0.0, 0.1)
Infected bite	0	(0.0, 0.1)
Injection site abscess	1 (0.0)	(0.0, 0.1)
Mastoiditis	1 (0.0)	(0.0, 0.1)
Meningitis bacterial	1 (0.0)	(0.0, 0.1)
Mumps	0	(0.0, 0.1)
Papilloma viral infection	0	(0.0, 0.1)
Parasitic gastroenteritis	0	(0.0, 0.1)
Penile infection	1 (0.0)	(0.0, 0.1)
Peritoneal abscess	0	(0.0, 0.1)
Peritonitis	0	(0.0, 0.1)
Peritonsillar abscess	1 (0.0)	(0.0, 0.1)
Pharyngitis	0	(0.0, 0.1)
Pharyngotonsillitis	0	(0.0, 0.1)
Pilonidal cyst	0	(0.0, 0.1)
Postoperative abscess	0	(0.0, 0.1)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.1)
Sialoadenitis	1 (0.0)	(0.0, 0.1)
Staphylococcal infection	0	(0.0, 0.1)
Subcutaneous abscess	0	(0.0, 0.1)

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	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Tinea versicolour	0	(0.0, 0.1)
Varicella	0	(0.0, 0.1)
Vulval abscess	0	(0.0, 0.1)
Vulvovaginitis	1 (0.0)	(0.0, 0.1)
Wound infection	0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	107 (2.0)	(1.6, 2.4)
Fall	35 (0.7)	(0.5, 0.9)
Exposure during pregnancy	1 (0.0)	(0.0, 0.1)
Muscle strain	8 (0.1)	(0.1, 0.3)
Ligament sprain	10 (0.2)	(0.1, 0.3)
Contusion	4 (0.1)	(0.0, 0.2)
Procedural pain	5 (0.1)	(0.0, 0.2)
Road traffic accident	5 (0.1)	(0.0, 0.2)
Skin laceration	3 (0.1)	(0.0, 0.2)
Arthropod bite	6 (0.1)	(0.0, 0.2)
Limb injury	3 (0.1)	(0.0, 0.2)
Tooth fracture	4 (0.1)	(0.0, 0.2)
Ankle fracture	3 (0.1)	(0.0, 0.2)
Chest injury	4 (0.1)	(0.0, 0.2)
Foot fracture	2 (0.0)	(0.0, 0.1)
Hand fracture	3 (0.1)	(0.0, 0.2)
Joint dislocation	3 (0.1)	(0.0, 0.2)
Skin abrasion	3 (0.1)	(0.0, 0.2)
Joint injury	3 (0.1)	(0.0, 0.2)
Meniscus injury	2 (0.0)	(0.0, 0.1)
Wrist fracture	3 (0.1)	(0.0, 0.2)
Animal bite	1 (0.0)	(0.0, 0.1)
Arthropod sting	3 (0.1)	(0.0, 0.2)
Burns second degree	2 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	2 (0.0)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.1)
Humerus fracture	3 (0.1)	(0.0, 0.2)

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	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Patella fracture	3 (0.1)	(0.0, 0.2)
Tibia fracture	2 (0.0)	(0.0, 0.1)
Upper limb fracture	1 (0.0)	(0.0, 0.1)
Vaccination complication	1 (0.0)	(0.0, 0.1)
Concussion	1 (0.0)	(0.0, 0.1)
Craniocerebral injury	1 (0.0)	(0.0, 0.1)
Ligament rupture	1 (0.0)	(0.0, 0.1)
Radius fracture	1 (0.0)	(0.0, 0.1)
Rib fracture	2 (0.0)	(0.0, 0.1)
Thermal burn	0	(0.0, 0.1)
Bone contusion	1 (0.0)	(0.0, 0.1)
Bone fissure	0	(0.0, 0.1)
Burn oral cavity	1 (0.0)	(0.0, 0.1)
Burns first degree	1 (0.0)	(0.0, 0.1)
Burns third degree	0	(0.0, 0.1)
Cartilage injury	1 (0.0)	(0.0, 0.1)
Chemical burns of eye	0	(0.0, 0.1)
Corneal abrasion	1 (0.0)	(0.0, 0.1)
Eyelid injury	0	(0.0, 0.1)
Fibula fracture	1 (0.0)	(0.0, 0.1)
Foreign body in eye	0	(0.0, 0.1)
Fractured sacrum	1 (0.0)	(0.0, 0.1)
Head injury	1 (0.0)	(0.0, 0.1)
Hip fracture	0	(0.0, 0.1)
Jaw fracture	1 (0.0)	(0.0, 0.1)
Limb fracture	1 (0.0)	(0.0, 0.1)
Limb traumatic amputation	0	(0.0, 0.1)
Maternal exposure before pregnancy	0	(0.0, 0.1)
Maternal exposure during pregnancy	0	(0.0, 0.1)
Muscle contusion	1 (0.0)	(0.0, 0.1)
Muscle rupture	0	(0.0, 0.1)
Overdose	0	(0.0, 0.1)

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	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Pelvic fracture	1 (0.0)	(0.0, 0.1)
Penis injury	0	(0.0, 0.1)
Post concussion syndrome	1 (0.0)	(0.0, 0.1)
Post procedural discomfort	0	(0.0, 0.1)
Post procedural swelling	0	(0.0, 0.1)
Procedural dizziness	1 (0.0)	(0.0, 0.1)
Spinal compression fracture	1 (0.0)	(0.0, 0.1)
Spinal cord injury cervical	0	(0.0, 0.1)
Spinal fracture	1 (0.0)	(0.0, 0.1)
Stress fracture	1 (0.0)	(0.0, 0.1)
Subdural haematoma	1 (0.0)	(0.0, 0.1)
Sunburn	1 (0.0)	(0.0, 0.1)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)
Ulna fracture	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	45 (0.8)	(0.6, 1.1)
Body temperature increased	20 (0.4)	(0.2, 0.6)
Blood glucose increased	8 (0.1)	(0.1, 0.3)
SARS-CoV-2 antibody test positive	3 (0.1)	(0.0, 0.2)
Blood pressure increased	0	(0.0, 0.1)
Blood cholesterol increased	1 (0.0)	(0.0, 0.1)
Alanine aminotransferase increased	0	(0.0, 0.1)
Blood thyroid stimulating hormone increased	0	(0.0, 0.1)
Weight increased	0	(0.0, 0.1)
Aspartate aminotransferase increased	0	(0.0, 0.1)
Blood creatinine decreased	0	(0.0, 0.1)
Blood glucose abnormal	0	(0.0, 0.1)
Blood immunoglobulin E increased	0	(0.0, 0.1)
Blood potassium decreased	1 (0.0)	(0.0, 0.1)
Blood triglycerides increased	1 (0.0)	(0.0, 0.1)
Body temperature decreased	1 (0.0)	(0.0, 0.1)
C-reactive protein	0	(0.0, 0.1)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)

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	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Electrocardiogram QT prolonged	0	(0.0, 0.1)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.1)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.1)
Haemoglobin decreased	1 (0.0)	(0.0, 0.1)
Heart rate increased	1 (0.0)	(0.0, 0.1)
Intraocular pressure increased	1 (0.0)	(0.0, 0.1)
Liver function test increased	1 (0.0)	(0.0, 0.1)
Lymphocyte count decreased	1 (0.0)	(0.0, 0.1)
Mean cell volume decreased	1 (0.0)	(0.0, 0.1)
Platelet count decreased	1 (0.0)	(0.0, 0.1)
Respiratory rate increased	1 (0.0)	(0.0, 0.1)
Troponin increased	1 (0.0)	(0.0, 0.1)
Weight decreased	0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	41 (0.8)	(0.6, 1.0)
Decreased appetite	4 (0.1)	(0.0, 0.2)
Hyperlipidaemia	6 (0.1)	(0.0, 0.2)
Type 2 diabetes mellitus	3 (0.1)	(0.0, 0.2)
Vitamin D deficiency	6 (0.1)	(0.0, 0.2)
Hypercholesterolaemia	2 (0.0)	(0.0, 0.1)
Dyslipidaemia	1 (0.0)	(0.0, 0.1)
Glucose tolerance impaired	3 (0.1)	(0.0, 0.2)
Gout	2 (0.0)	(0.0, 0.1)
Hyperglycaemia	3 (0.1)	(0.0, 0.2)
Hypertriglyceridaemia	2 (0.0)	(0.0, 0.1)
Hypoglycaemia	2 (0.0)	(0.0, 0.1)
Hypokalaemia	2 (0.0)	(0.0, 0.1)
Dehydration	1 (0.0)	(0.0, 0.1)
Hyperkalaemia	2 (0.0)	(0.0, 0.1)
Hyperuricaemia	2 (0.0)	(0.0, 0.1)
Obesity	0	(0.0, 0.1)
Diabetes mellitus	1 (0.0)	(0.0, 0.1)
Diabetes mellitus inadequate control	0	(0.0, 0.1)

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	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Diabetic ketoacidosis	0	(0.0, 0.1)
Hypocalcaemia	0	(0.0, 0.1)
Hypocholesterolaemia	0	(0.0, 0.1)
Insulin resistance	1 (0.0)	(0.0, 0.1)
Metabolic syndrome	0	(0.0, 0.1)
Polydipsia	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	366 (6.9)	(6.2, 7.6)
Myalgia	194 (3.6)	(3.1, 4.2)
Arthralgia	69 (1.3)	(1.0, 1.6)
Pain in extremity	49 (0.9)	(0.7, 1.2)
Back pain	28 (0.5)	(0.3, 0.8)
Neck pain	10 (0.2)	(0.1, 0.3)
Muscle spasms	10 (0.2)	(0.1, 0.3)
Osteoarthritis	12 (0.2)	(0.1, 0.4)
Tendonitis	3 (0.1)	(0.0, 0.2)
Musculoskeletal stiffness	7 (0.1)	(0.1, 0.3)
Intervertebral disc protrusion	3 (0.1)	(0.0, 0.2)
Arthritis	2 (0.0)	(0.0, 0.1)
Bursitis	3 (0.1)	(0.0, 0.2)
Muscular weakness	4 (0.1)	(0.0, 0.2)
Musculoskeletal chest pain	2 (0.0)	(0.0, 0.1)
Periarthritis	1 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	1 (0.0)	(0.0, 0.1)
Intervertebral disc degeneration	2 (0.0)	(0.0, 0.1)
Joint stiffness	2 (0.0)	(0.0, 0.1)
Muscle contracture	0	(0.0, 0.1)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.1)
Arthropathy	2 (0.0)	(0.0, 0.1)
Coccydynia	0	(0.0, 0.1)
Costochondritis	1 (0.0)	(0.0, 0.1)
Flank pain	1 (0.0)	(0.0, 0.1)
Joint range of motion decreased	0	(0.0, 0.1)

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	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Limb discomfort	2 (0.0)	(0.0, 0.1)
Muscle twitching	1 (0.0)	(0.0, 0.1)
Musculoskeletal pain	1 (0.0)	(0.0, 0.1)
Pain in jaw	1 (0.0)	(0.0, 0.1)
Plantar fasciitis	1 (0.0)	(0.0, 0.1)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.1)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.1)
Bone disorder	1 (0.0)	(0.0, 0.1)
Bone pain	1 (0.0)	(0.0, 0.1)
Groin pain	1 (0.0)	(0.0, 0.1)
Intervertebral disc compression	1 (0.0)	(0.0, 0.1)
Joint effusion	0	(0.0, 0.1)
Joint instability	1 (0.0)	(0.0, 0.1)
Joint swelling	0	(0.0, 0.1)
Mobility decreased	1 (0.0)	(0.0, 0.1)
Muscle fatigue	0	(0.0, 0.1)
Muscle tightness	0	(0.0, 0.1)
Osteochondritis	0	(0.0, 0.1)
Osteopenia	1 (0.0)	(0.0, 0.1)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.1)
Spinal stenosis	0	(0.0, 0.1)
Spondylitis	1 (0.0)	(0.0, 0.1)
Synovial cyst	1 (0.0)	(0.0, 0.1)
Temporomandibular joint syndrome	0	(0.0, 0.1)
Torticollis	0	(0.0, 0.1)
Trigger finger	0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	40 (0.7)	(0.5, 1.0)
Prostate cancer	5 (0.1)	(0.0, 0.2)
Basal cell carcinoma	4 (0.1)	(0.0, 0.2)
Lipoma	2 (0.0)	(0.0, 0.1)
Malignant melanoma	2 (0.0)	(0.0, 0.1)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Breast cancer	3 (0.1)	(0.0, 0.2)
Invasive ductal breast carcinoma	1 (0.0)	(0.0, 0.1)
Skin papilloma	2 (0.0)	(0.0, 0.1)
Transitional cell carcinoma	1 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.1)
Adenocarcinoma pancreas	0	(0.0, 0.1)
Adenoma benign	1 (0.0)	(0.0, 0.1)
Adrenal gland cancer	1 (0.0)	(0.0, 0.1)
Benign breast neoplasm	0	(0.0, 0.1)
Benign hydatidiform mole	0	(0.0, 0.1)
Benign uterine neoplasm	0	(0.0, 0.1)
Bladder cancer	1 (0.0)	(0.0, 0.1)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.1)
Brain cancer metastatic	0	(0.0, 0.1)
Breast cancer in situ	1 (0.0)	(0.0, 0.1)
Carcinoid tumour of the stomach	1 (0.0)	(0.0, 0.1)
Chondroma	0	(0.0, 0.1)
Colon adenoma	1 (0.0)	(0.0, 0.1)
Fibroma	1 (0.0)	(0.0, 0.1)
Gallbladder cancer stage II	1 (0.0)	(0.0, 0.1)
Gastric cancer	1 (0.0)	(0.0, 0.1)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.1)
Meningioma benign	1 (0.0)	(0.0, 0.1)
Non-small cell lung cancer stage IV	1 (0.0)	(0.0, 0.1)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.1)
Skin cancer	1 (0.0)	(0.0, 0.1)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.1)
Squamous cell carcinoma of skin	1 (0.0)	(0.0, 0.1)
Thyroid cancer	1 (0.0)	(0.0, 0.1)
Uterine cancer	1 (0.0)	(0.0, 0.1)
Uterine leiomyoma	0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	277 (5.2)	(4.6, 5.8)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Headache	213 (4.0)	(3.5, 4.5)
Dizziness	23 (0.4)	(0.3, 0.6)
Paraesthesia	3 (0.1)	(0.0, 0.2)
Lethargy	11 (0.2)	(0.1, 0.4)
Migraine	2 (0.0)	(0.0, 0.1)
Sciatica	3 (0.1)	(0.0, 0.2)
Tension headache	1 (0.0)	(0.0, 0.1)
Syncope	3 (0.1)	(0.0, 0.2)
Presyncope	1 (0.0)	(0.0, 0.1)
Tremor	4 (0.1)	(0.0, 0.2)
Dysgeusia	1 (0.0)	(0.0, 0.1)
Somnolence	2 (0.0)	(0.0, 0.1)
Disturbance in attention	1 (0.0)	(0.0, 0.1)
Facial paralysis	1 (0.0)	(0.0, 0.1)
Hypoaesthesia	2 (0.0)	(0.0, 0.1)
Sinus headache	1 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)
Burning sensation	0	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)
Cervical radiculopathy	1 (0.0)	(0.0, 0.1)
Dizziness postural	2 (0.0)	(0.0, 0.1)
Migraine without aura	1 (0.0)	(0.0, 0.1)
Nerve compression	1 (0.0)	(0.0, 0.1)
Optic neuritis	0	(0.0, 0.1)
Restless legs syndrome	1 (0.0)	(0.0, 0.1)
Seizure	0	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)
Aphasia	1 (0.0)	(0.0, 0.1)
Carpal tunnel syndrome	0	(0.0, 0.1)
Depressed level of consciousness	0	(0.0, 0.1)
Dyskinesia	1 (0.0)	(0.0, 0.1)
Hyperaesthesia	0	(0.0, 0.1)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Idiopathic intracranial hypertension	0	(0.0, 0.1)
Intracranial aneurysm	1 (0.0)	(0.0, 0.1)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)
Neuralgia	1 (0.0)	(0.0, 0.1)
Parosmia	0	(0.0, 0.1)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.1)
Peripheral nerve lesion	0	(0.0, 0.1)
Peripheral sensory neuropathy	0	(0.0, 0.1)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.1)
Radiculopathy	0	(0.0, 0.1)
Seizure like phenomena	0	(0.0, 0.1)
Toxic encephalopathy	1 (0.0)	(0.0, 0.1)
Transient global amnesia	1 (0.0)	(0.0, 0.1)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)
Vocal cord paralysis	1 (0.0)	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.1)
Abortion spontaneous	0	(0.0, 0.1)
Exposure during pregnancy	0	(0.0, 0.1)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.1)
Device connection issue	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	23 (0.4)	(0.3, 0.6)
Insomnia	5 (0.1)	(0.0, 0.2)
Anxiety	3 (0.1)	(0.0, 0.2)
Depression	3 (0.1)	(0.0, 0.2)
Anxiety disorder	1 (0.0)	(0.0, 0.1)
Abnormal dreams	1 (0.0)	(0.0, 0.1)
Attention deficit hyperactivity disorder	0	(0.0, 0.1)
Irritability	1 (0.0)	(0.0, 0.1)
Sleep disorder	3 (0.1)	(0.0, 0.2)
Disorientation	2 (0.0)	(0.0, 0.1)
Nightmare	2 (0.0)	(0.0, 0.1)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Generalised anxiety disorder	0	(0.0, 0.1)
Libido increased	1 (0.0)	(0.0, 0.1)
Panic attack	0	(0.0, 0.1)
Restlessness	1 (0.0)	(0.0, 0.1)
Suicide attempt	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	27 (0.5)	(0.3, 0.7)
Nephrolithiasis	5 (0.1)	(0.0, 0.2)
Dysuria	3 (0.1)	(0.0, 0.2)
Pollakiuria	2 (0.0)	(0.0, 0.1)
Haematuria	2 (0.0)	(0.0, 0.1)
Acute kidney injury	2 (0.0)	(0.0, 0.1)
Bladder spasm	2 (0.0)	(0.0, 0.1)
Renal colic	0	(0.0, 0.1)
Urinary retention	2 (0.0)	(0.0, 0.1)
Bladder irritation	1 (0.0)	(0.0, 0.1)
Chronic kidney disease	1 (0.0)	(0.0, 0.1)
Hypertonic bladder	1 (0.0)	(0.0, 0.1)
Micturition urgency	1 (0.0)	(0.0, 0.1)
Obstructive nephropathy	1 (0.0)	(0.0, 0.1)
Renal cyst	1 (0.0)	(0.0, 0.1)
Renal haematoma	1 (0.0)	(0.0, 0.1)
Subcapsular renal haematoma	0	(0.0, 0.1)
Urethral stenosis	1 (0.0)	(0.0, 0.1)
Urinary tract obstruction	1 (0.0)	(0.0, 0.1)
Vesical fistula	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	6 (0.1)	(0.0, 0.2)
Dysmenorrhoea	0	(0.0, 0.1)
Ovarian cyst	1 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.1)
Breast pain	0	(0.0, 0.1)
Endometriosis	0	(0.0, 0.1)
Genital erythema	1 (0.0)	(0.0, 0.1)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Menorrhagia	0	(0.0, 0.1)
Menstruation irregular	0	(0.0, 0.1)
Amenorrhoea	0	(0.0, 0.1)
Breast hyperplasia	0	(0.0, 0.1)
Cervical dysplasia	0	(0.0, 0.1)
Dysfunctional uterine bleeding	0	(0.0, 0.1)
Endometrial thickening	0	(0.0, 0.1)
Haematospermia	0	(0.0, 0.1)
Mammary duct ectasia	0	(0.0, 0.1)
Menometrorrhagia	0	(0.0, 0.1)
Metrorrhagia	0	(0.0, 0.1)
Pelvic pain	0	(0.0, 0.1)
Polycystic ovaries	0	(0.0, 0.1)
Postmenopausal haemorrhage	0	(0.0, 0.1)
Prostatitis	1 (0.0)	(0.0, 0.1)
Prostatomegaly	0	(0.0, 0.1)
Pruritus genital	1 (0.0)	(0.0, 0.1)
Scrotal pain	0	(0.0, 0.1)
Testicular pain	1 (0.0)	(0.0, 0.1)
Testicular torsion	0	(0.0, 0.1)
Uterine prolapse	1 (0.0)	(0.0, 0.1)
Vaginal haemorrhage	0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	66 (1.2)	(1.0, 1.6)
Oropharyngeal pain	8 (0.1)	(0.1, 0.3)
Nasal congestion	7 (0.1)	(0.1, 0.3)
Cough	7 (0.1)	(0.1, 0.3)
Rhinorrhoea	9 (0.2)	(0.1, 0.3)
Rhinitis allergic	0	(0.0, 0.1)
Asthma	4 (0.1)	(0.0, 0.2)
Dyspnoea	2 (0.0)	(0.0, 0.1)
Pulmonary embolism	4 (0.1)	(0.0, 0.2)
Sleep apnoea syndrome	4 (0.1)	(0.0, 0.2)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Throat irritation	4 (0.1)	(0.0, 0.2)
Upper-airway cough syndrome	2 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	1 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	3 (0.1)	(0.0, 0.2)
Epistaxis	3 (0.1)	(0.0, 0.2)
Asthmatic crisis	0	(0.0, 0.1)
Bronchospasm	0	(0.0, 0.1)
Nasal polyps	1 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.1)
Respiratory tract congestion	1 (0.0)	(0.0, 0.1)
Sinus congestion	1 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)
Wheezing	1 (0.0)	(0.0, 0.1)
Allergic sinusitis	0	(0.0, 0.1)
Atelectasis	1 (0.0)	(0.0, 0.1)
Dry throat	0	(0.0, 0.1)
Dyspnoea exertional	1 (0.0)	(0.0, 0.1)
Emphysema	1 (0.0)	(0.0, 0.1)
Haemoptysis	1 (0.0)	(0.0, 0.1)
Interstitial lung disease	1 (0.0)	(0.0, 0.1)
Nasal septum deviation	1 (0.0)	(0.0, 0.1)
Oropharyngeal discomfort	0	(0.0, 0.1)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.1)
Pleurisy	1 (0.0)	(0.0, 0.1)
Pneumonitis	1 (0.0)	(0.0, 0.1)
Pneumothorax	1 (0.0)	(0.0, 0.1)
Reflux laryngitis	0	(0.0, 0.1)
Respiratory failure	1 (0.0)	(0.0, 0.1)
Sneezing	1 (0.0)	(0.0, 0.1)
Snoring	0	(0.0, 0.1)
Tonsillar hypertrophy	0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	73 (1.4)	(1.1, 1.7)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Rash	11 (0.2)	(0.1, 0.4)
Hyperhidrosis	6 (0.1)	(0.0, 0.2)
Pruritus	11 (0.2)	(0.1, 0.4)
Dermatitis contact	6 (0.1)	(0.0, 0.2)
Urticaria	5 (0.1)	(0.0, 0.2)
Night sweats	4 (0.1)	(0.0, 0.2)
Rash pruritic	3 (0.1)	(0.0, 0.2)
Erythema	2 (0.0)	(0.0, 0.1)
Dermal cyst	4 (0.1)	(0.0, 0.2)
Dermatitis	2 (0.0)	(0.0, 0.1)
Eczema	2 (0.0)	(0.0, 0.1)
Acne	0	(0.0, 0.1)
Actinic keratosis	3 (0.1)	(0.0, 0.2)
Dermatitis allergic	1 (0.0)	(0.0, 0.1)
Rash maculo-papular	1 (0.0)	(0.0, 0.1)
Alopecia	1 (0.0)	(0.0, 0.1)
Acne cystic	0	(0.0, 0.1)
Angioedema	1 (0.0)	(0.0, 0.1)
Cold sweat	0	(0.0, 0.1)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.1)
Diabetic foot	1 (0.0)	(0.0, 0.1)
Dry skin	1 (0.0)	(0.0, 0.1)
Ecchymosis	1 (0.0)	(0.0, 0.1)
Erythema nodosum	0	(0.0, 0.1)
Hand dermatitis	0	(0.0, 0.1)
Hangnail	0	(0.0, 0.1)
Intertrigo	0	(0.0, 0.1)
Macule	1 (0.0)	(0.0, 0.1)
Onycholysis	1 (0.0)	(0.0, 0.1)
Onychomadesis	1 (0.0)	(0.0, 0.1)
Pain of skin	1 (0.0)	(0.0, 0.1)
Papule	1 (0.0)	(0.0, 0.1)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Pityriasis	0	(0.0, 0.1)
Pseudofolliculitis	1 (0.0)	(0.0, 0.1)
Psoriasis	1 (0.0)	(0.0, 0.1)
Purpura	1 (0.0)	(0.0, 0.1)
Rash erythematous	1 (0.0)	(0.0, 0.1)
Rash papular	0	(0.0, 0.1)
Rosacea	1 (0.0)	(0.0, 0.1)
Skin discolouration	1 (0.0)	(0.0, 0.1)
Skin irritation	0	(0.0, 0.1)
Skin ulcer	0	(0.0, 0.1)
Transient acantholytic dermatosis	0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	0	(0.0, 0.1)
High risk sexual behaviour	0	(0.0, 0.1)
Miscarriage of partner	0	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	16 (0.3)	(0.2, 0.5)
Dental implantation	3 (0.1)	(0.0, 0.2)
Tooth extraction	1 (0.0)	(0.0, 0.1)
Wisdom teeth removal	0	(0.0, 0.1)
Botulinum toxin injection	1 (0.0)	(0.0, 0.1)
Cardioversion	1 (0.0)	(0.0, 0.1)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.1)
Drug titration	0	(0.0, 0.1)
Endodontic procedure	0	(0.0, 0.1)
Facet joint block	1 (0.0)	(0.0, 0.1)
Finger amputation	1 (0.0)	(0.0, 0.1)
Gingival operation	0	(0.0, 0.1)
Inguinal hernia repair	1 (0.0)	(0.0, 0.1)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.1)
Mammoplasty	0	(0.0, 0.1)
Meniscus operation	1 (0.0)	(0.0, 0.1)
Metabolic surgery	0	(0.0, 0.1)
Open reduction of fracture	1 (0.0)	(0.0, 0.1)

14.147. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Postoperative care	1 (0.0)	(0.0, 0.1)
Radioactive iodine therapy	1 (0.0)	(0.0, 0.1)
Retinal operation	0	(0.0, 0.1)
Rotator cuff repair	1 (0.0)	(0.0, 0.1)
Sclerotherapy	0	(0.0, 0.1)
VASCULAR DISORDERS	44 (0.8)	(0.6, 1.1)
Hypertension	29 (0.5)	(0.4, 0.8)
Deep vein thrombosis	4 (0.1)	(0.0, 0.2)
Hot flush	3 (0.1)	(0.0, 0.2)
Aortic aneurysm	3 (0.1)	(0.0, 0.2)
Haematoma	1 (0.0)	(0.0, 0.1)
Flushing	1 (0.0)	(0.0, 0.1)
Hypotension	0	(0.0, 0.1)
Aortic dilatation	1 (0.0)	(0.0, 0.1)
Arterial occlusive disease	1 (0.0)	(0.0, 0.1)
Essential hypertension	0	(0.0, 0.1)
Intermittent claudication	0	(0.0, 0.1)
Lymphorrhoea	1 (0.0)	(0.0, 0.1)
Peripheral vascular disorder	1 (0.0)	(0.0, 0.1)
Systolic hypertension	0	(0.0, 0.1)
Thrombophlebitis superficial	0	(0.0, 0.1)
Varicose vein	0	(0.0, 0.1)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s091 6m soc age pd2 p3

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	3092 (25.8)	(25.0, 26.5)	572 (4.8)	(4.4, 5.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	57 (0.5)	(0.4, 0.6)	14 (0.1)	(0.1, 0.2)
Lymphadenopathy	47 (0.4)	(0.3, 0.5)	3 (0.0)	(0.0, 0.1)
Anaemia	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Lymph node pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukopenia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Blood loss anaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coagulopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy mediastinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphocytosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Splenic infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Splenomegaly	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	31 (0.3)	(0.2, 0.4)	28 (0.2)	(0.2, 0.3)
Atrial fibrillation	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Tachycardia	8 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Palpitations	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Cardiac failure congestive	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block first degree	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)
Bundle branch block right	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cardiac arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiomegaly	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mitral valve prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Supraventricular tachycardia	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)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal arteriovenous malformation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Protein S deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	37 (0.3)	(0.2, 0.4)	12 (0.1)	(0.1, 0.2)
Vertigo	14 (0.1)	(0.1, 0.2)	7 (0.1)	(0.0, 0.1)
Ear pain	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tinnitus	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vertigo positional	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerumen impaction	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Deafness neurosensory	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sudden hearing loss	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
ENDOCRINE DISORDERS	9 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Hypothyroidism	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hyperthyroidism	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypogonadism	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thyroid mass	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oestrogen deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pituitary cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	36 (0.3)	(0.2, 0.4)	12 (0.1)	(0.1, 0.2)
Cataract	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Vision blurred	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chalazion	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye irritation	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Eye pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Macular oedema	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Vitreous detachment	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Blepharitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diplopia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glaucoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Retinal tear	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Asthenopia	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)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Episcleritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Keratitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ophthalmic vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scleral discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	359 (3.0)	(2.7, 3.3)	57 (0.5)	(0.4, 0.6)
Nausea	137 (1.1)	(1.0, 1.3)	4 (0.0)	(0.0, 0.1)
Diarrhoea	116 (1.0)	(0.8, 1.2)	8 (0.1)	(0.0, 0.1)
Vomiting	33 (0.3)	(0.2, 0.4)	2 (0.0)	(0.0, 0.1)
Toothache	16 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Abdominal pain	11 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)
Gastrooesophageal reflux disease	9 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dyspepsia	9 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Abdominal pain upper	7 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Odynophagia	10 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Constipation	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dental caries	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Irritable bowel syndrome	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Abdominal distension	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Flatulence	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Hiatus hernia	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Large intestine polyp	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Aphthous ulcer	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticulum	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Food poisoning	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Haemorrhoids	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal disorder	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Glossodynia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematochezia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impaired gastric emptying	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Small intestinal obstruction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain lower	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angular cheilitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cheilitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coeliac disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis microscopic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis ulcerative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Crohn's disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry mouth	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysphagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eructation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Femoral hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric antral vascular ectasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematemesis	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)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Internal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intestinal polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intra-abdominal fluid collection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral lichenoid reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatic calcification	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rectal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rectal polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stomatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swollen tongue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1996 (16.6)	(16.0, 17.3)	23 (0.2)	(0.1, 0.3)
Injection site pain	1189 (9.9)	(9.4, 10.5)	4 (0.0)	(0.0, 0.1)
Pyrexia	630 (5.2)	(4.9, 5.7)	3 (0.0)	(0.0, 0.1)
Chills	603 (5.0)	(4.6, 5.4)	3 (0.0)	(0.0, 0.1)
Fatigue	596 (5.0)	(4.6, 5.4)	3 (0.0)	(0.0, 0.1)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pain	277 (2.3)	(2.0, 2.6)	0	(0.0, 0.0)
Injection site erythema	91 (0.8)	(0.6, 0.9)	0	(0.0, 0.0)
Injection site swelling	60 (0.5)	(0.4, 0.6)	0	(0.0, 0.0)
Malaise	46 (0.4)	(0.3, 0.5)	0	(0.0, 0.0)
Asthenia	19 (0.2)	(0.1, 0.2)	1 (0.0)	(0.0, 0.0)
Injection site pruritus	19 (0.2)	(0.1, 0.2)	0	(0.0, 0.0)
Chest pain	8 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Influenza like illness	10 (0.1)	(0.0, 0.2)	0	(0.0, 0.0)
Injection site bruising	8 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Axillary pain	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site warmth	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling hot	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site induration	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oedema peripheral	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Peripheral swelling	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site oedema	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Adverse drug reaction	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cyst	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Face oedema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site haematoma	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site nodule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site papule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Application site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chest discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site mass	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site paraesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sensation of foreign body	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)
Sluggishness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thirst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site induration	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)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	9 (0.1)	(0.0, 0.1)	12 (0.1)	(0.1, 0.2)
Cholelithiasis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Biliary colic	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Bile duct stone	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Biliary dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholelithiasis obstructive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gallbladder disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic steatosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Jaundice	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Portosplenomesenteric venous thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Steatohepatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	13 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Seasonal allergy	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypersensitivity	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergy to arthropod bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food allergy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Jarisch-Herxheimer reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	206 (1.7)	(1.5, 2.0)	94 (0.8)	(0.6, 1.0)
Urinary tract infection	34 (0.3)	(0.2, 0.4)	24 (0.2)	(0.1, 0.3)
Tooth infection	17 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Sinusitis	14 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Appendicitis	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Herpes zoster	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cellulitis	8 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Conjunctivitis	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Cystitis	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ear infection	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Diverticulitis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Gastroenteritis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth abscess	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Hordeolum	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper respiratory tract infection	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Folliculitis	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rhinitis	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Nasopharyngitis	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Oral herpes	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Otitis externa	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vulvovaginal mycotic infection	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Gingivitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Onychomycosis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Paronychia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pyelonephritis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vulvovaginal candidiasis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Device related infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Influenza	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Kidney infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Laryngitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Localised infection	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral candidiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Otitis media	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Otitis media acute	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Periodontitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pustule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash pustular	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sepsis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sinusitis bacterial	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin infection	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute sinusitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthritis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacteraemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial blepharitis	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)
Bacterial vaginosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial vulvovaginitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bartholinitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bronchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cellulitis orbital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic sinusitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clostridium difficile colitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Escherichia urinary tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Furuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gangrene	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Genital herpes simplex	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Helicobacter infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes zoster oticus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impetigo	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Infected bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mastoiditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mumps	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Papilloma viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Parasitic gastroenteritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile infection	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)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sialoadenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea versicolour	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Varicella	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vulval abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	116 (1.0)	(0.8, 1.2)	93 (0.8)	(0.6, 0.9)
Fall	26 (0.2)	(0.1, 0.3)	21 (0.2)	(0.1, 0.3)
Exposure during pregnancy	5 (0.0)	(0.0, 0.1)	17 (0.1)	(0.1, 0.2)
Muscle strain	10 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)
Ligament sprain	10 (0.1)	(0.0, 0.2)	3 (0.0)	(0.0, 0.1)
Contusion	8 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Procedural pain	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Road traffic accident	4 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Skin laceration	7 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Arthropod bite	7 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Limb injury	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth fracture	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Ankle fracture	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Chest injury	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Foot fracture	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hand fracture	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Joint dislocation	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Skin abrasion	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint injury	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Meniscus injury	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Wrist fracture	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Animal bite	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arthropod sting	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burns second degree	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Patella fracture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Tibia fracture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper limb fracture	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Vaccination complication	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Concussion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Craniocerebral injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Ligament rupture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Radius fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rib fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thermal burn	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bone contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bone fissure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns third degree	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cartilage injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chemical burns of eye	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Corneal abrasion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Fibula fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Foreign body in eye	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fractured sacrum	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hip fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Jaw fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Maternal exposure before pregnancy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle rupture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Overdose	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post concussion syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Procedural dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal compression fracture	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	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subdural haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sunburn	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulna fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	80 (0.7)	(0.5, 0.8)	14 (0.1)	(0.1, 0.2)
Body temperature increased	50 (0.4)	(0.3, 0.5)	0	(0.0, 0.0)
Blood glucose increased	8 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
SARS-CoV-2 antibody test positive	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Blood pressure increased	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Blood cholesterol increased	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Alanine aminotransferase increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood thyroid stimulating hormone increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aspartate aminotransferase increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood immunoglobulin E increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood potassium decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood triglycerides increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemoglobin decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart rate increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intraocular pressure increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Liver function test increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphocyte count decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mean cell volume decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Platelet count decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Troponin increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	48 (0.4)	(0.3, 0.5)	35 (0.3)	(0.2, 0.4)
Decreased appetite	15 (0.1)	(0.1, 0.2)	0	(0.0, 0.0)
Hyperlipidaemia	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Vitamin D deficiency	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dyslipidaemia	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Glucose tolerance impaired	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Gout	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperglycaemia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypertriglyceridaemia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypoglycaemia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypokalaemia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dehydration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyperkalaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyperuricaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Obesity	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diabetes mellitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Insulin resistance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metabolic syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	843 (7.0)	(6.6, 7.5)	69 (0.6)	(0.4, 0.7)
Myalgia	544 (4.5)	(4.2, 4.9)	6 (0.0)	(0.0, 0.1)
Arthralgia	140 (1.2)	(1.0, 1.4)	13 (0.1)	(0.1, 0.2)
Pain in extremity	88 (0.7)	(0.6, 0.9)	5 (0.0)	(0.0, 0.1)
Back pain	53 (0.4)	(0.3, 0.6)	9 (0.1)	(0.0, 0.1)
Neck pain	14 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Muscle spasms	16 (0.1)	(0.1, 0.2)	3 (0.0)	(0.0, 0.1)
Osteoarthritis	7 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Tendonitis	7 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	7 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Arthritis	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Bursitis	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Muscular weakness	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Joint stiffness	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle contracture	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rotator cuff syndrome	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arthropathy	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coccydynia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Costochondritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flank pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint range of motion decreased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Limb discomfort	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Muscle twitching	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Plantar fasciitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bone disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bone pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intervertebral disc compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint instability	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mobility decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle fatigue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spondylitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Synovial cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Torticollis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Trigger finger	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	15 (0.1)	(0.1, 0.2)	38 (0.3)	(0.2, 0.4)
Prostate cancer	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Basal cell carcinoma	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Lipoma	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Malignant melanoma	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Breast cancer	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Skin papilloma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Transitional cell carcinoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Adenoma benign	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)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign hydatidiform mole	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Benign uterine neoplasm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bladder cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Borderline serous tumour of ovary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Brain cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cancer in situ	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carcinoid tumour of the stomach	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibroma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gallbladder cancer stage II	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma benign	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Non-small cell lung cancer stage IV	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma of skin	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)
Uterine cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	683 (5.7)	(5.3, 6.1)	45 (0.4)	(0.3, 0.5)
Headache	564 (4.7)	(4.3, 5.1)	8 (0.1)	(0.0, 0.1)
Dizziness	39 (0.3)	(0.2, 0.4)	4 (0.0)	(0.0, 0.1)
Paraesthesia	14 (0.1)	(0.1, 0.2)	1 (0.0)	(0.0, 0.0)
Lethargy	14 (0.1)	(0.1, 0.2)	0	(0.0, 0.0)
Migraine	12 (0.1)	(0.1, 0.2)	2 (0.0)	(0.0, 0.1)
Sciatica	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Tension headache	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Syncope	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Presyncope	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tremor	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Dysgeusia	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Somnolence	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disturbance in attention	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial paralysis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypoaesthesia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinus headache	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Burning sensation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cervical radiculopathy	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness postural	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Migraine without aura	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nerve compression	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Optic neuritis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Restless legs syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Seizure	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Aphasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Carpal tunnel syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depressed level of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Idiopathic intracranial hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intracranial aneurysm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Neuralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral nerve lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radiculopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Seizure like phenomena	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxic encephalopathy	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)
Vocal cord paralysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Abortion spontaneous	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Exposure during pregnancy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Device connection issue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	51 (0.4)	(0.3, 0.6)	15 (0.1)	(0.1, 0.2)
Insomnia	16 (0.1)	(0.1, 0.2)	1 (0.0)	(0.0, 0.0)
Anxiety	11 (0.1)	(0.0, 0.2)	5 (0.0)	(0.0, 0.1)
Depression	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Anxiety disorder	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Abnormal dreams	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Attention deficit hyperactivity disorder	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Irritability	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep disorder	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disorientation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nightmare	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Generalised anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Libido increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	26 (0.2)	(0.1, 0.3)	16 (0.1)	(0.1, 0.2)
Nephrolithiasis	3 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Dysuria	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pollakiuria	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematuria	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Acute kidney injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bladder spasm	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Renal colic	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary retention	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bladder irritation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertonic bladder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Obstructive nephropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Renal cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Renal haematoma	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)
Urethral stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary tract obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vesical fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	29 (0.2)	(0.2, 0.3)	7 (0.1)	(0.0, 0.1)
Dysmenorrhoea	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ovarian cyst	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Endometriosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Genital erythema	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menstruation irregular	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Amenorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endometrial thickening	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haematospermia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mammary duct ectasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menometrorrhagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metrorrhagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Polycystic ovaries	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostatomegaly	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Scrotal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Testicular pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Testicular torsion	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)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	114 (0.9)	(0.8, 1.1)	31 (0.3)	(0.2, 0.4)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Oropharyngeal pain	24 (0.2)	(0.1, 0.3)	0	(0.0, 0.0)
Nasal congestion	17 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.1)
Cough	17 (0.1)	(0.1, 0.2)	0	(0.0, 0.0)
Rhinorrhoea	10 (0.1)	(0.0, 0.2)	2 (0.0)	(0.0, 0.1)
Rhinitis allergic	8 (0.1)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Asthma	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Dyspnoea	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pulmonary embolism	0	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Sleep apnoea syndrome	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Throat irritation	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper-airway cough syndrome	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Epistaxis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Asthmatic crisis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bronchospasm	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Productive cough	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Respiratory tract congestion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus congestion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Wheezing	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergic sinusitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Atelectasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyspnoea exertional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Emphysema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemoptysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	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)
Oropharyngeal discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Reflux laryngitis	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)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Sneezing	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	120 (1.0)	(0.8, 1.2)	35 (0.3)	(0.2, 0.4)
Rash	27 (0.2)	(0.1, 0.3)	8 (0.1)	(0.0, 0.1)
Hyperhidrosis	16 (0.1)	(0.1, 0.2)	0	(0.0, 0.0)
Pruritus	14 (0.1)	(0.1, 0.2)	1 (0.0)	(0.0, 0.0)
Dermatitis contact	10 (0.1)	(0.0, 0.2)	1 (0.0)	(0.0, 0.0)
Urticaria	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Night sweats	8 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Rash pruritic	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Erythema	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dermal cyst	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Dermatitis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Eczema	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Acne	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Actinic keratosis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dermatitis allergic	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash maculo-papular	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Alopecia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acne cystic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic foot	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry skin	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Erythema nodosum	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hand dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intertrigo	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Onycholysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Onychomadesis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pseudofolliculitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Purpura	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rash papular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rosacea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transient acantholytic dermatosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
High risk sexual behaviour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Miscarriage of partner	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	21 (0.2)	(0.1, 0.3)	8 (0.1)	(0.0, 0.1)
Dental implantation	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tooth extraction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Wisdom teeth removal	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Botulinum toxin injection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardioversion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug titration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endodontic procedure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facet joint block	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Finger amputation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mammoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meniscus operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Metabolic surgery	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Open reduction of fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Radioactive iodine therapy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rotator cuff repair	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	34 (0.3)	(0.2, 0.4)	44 (0.4)	(0.3, 0.5)

14.148. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypertension	16 (0.1)	(0.1, 0.2)	32 (0.3)	(0.2, 0.4)
Deep vein thrombosis	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hot flush	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Haematoma	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flushing	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypotension	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic dilatation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arterial occlusive disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral vascular disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Systolic hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombophlebitis superficial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varicose vein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 15APR2021 (07:35)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA_RR/adae_s130_all_bnt_tp_p3_saf

14.149. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	2245 (18.7)	(18.0, 19.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	32 (0.3)	(0.2, 0.4)
Lymphadenopathy	29 (0.2)	(0.2, 0.3)
Lymph node pain	3 (0.0)	(0.0, 0.1)
Leukopenia	1 (0.0)	(0.0, 0.0)
Lymphopenia	1 (0.0)	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	8 (0.1)	(0.0, 0.1)
Tachycardia	6 (0.0)	(0.0, 0.1)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	8 (0.1)	(0.0, 0.1)
Vertigo	6 (0.0)	(0.0, 0.1)
Ear discomfort	1 (0.0)	(0.0, 0.0)
Ear pain	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	6 (0.0)	(0.0, 0.1)
Eye irritation	2 (0.0)	(0.0, 0.1)
Eye pain	2 (0.0)	(0.0, 0.1)
Photophobia	1 (0.0)	(0.0, 0.0)
Vision blurred	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	223 (1.9)	(1.6, 2.1)
Nausea	123 (1.0)	(0.9, 1.2)
Diarrhoea	91 (0.8)	(0.6, 0.9)
Vomiting	24 (0.2)	(0.1, 0.3)
Dyspepsia	4 (0.0)	(0.0, 0.1)
Abdominal pain	3 (0.0)	(0.0, 0.1)
Abdominal pain upper	3 (0.0)	(0.0, 0.1)
Toothache	3 (0.0)	(0.0, 0.1)
Glossodynia	2 (0.0)	(0.0, 0.1)
Abdominal discomfort	1 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)

14.149. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Flatulence	1 (0.0)	(0.0, 0.0)
Gingival pain	1 (0.0)	(0.0, 0.0)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.0)
Irritable bowel syndrome	1 (0.0)	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1944 (16.2)	(15.5, 16.9)
Injection site pain	1189 (9.9)	(9.4, 10.5)
Pyrexia	624 (5.2)	(4.8, 5.6)
Chills	600 (5.0)	(4.6, 5.4)
Fatigue	577 (4.8)	(4.4, 5.2)
Pain	274 (2.3)	(2.0, 2.6)
Injection site erythema	91 (0.8)	(0.6, 0.9)
Injection site swelling	59 (0.5)	(0.4, 0.6)
Malaise	45 (0.4)	(0.3, 0.5)
Injection site pruritus	19 (0.2)	(0.1, 0.2)
Asthenia	15 (0.1)	(0.1, 0.2)
Influenza like illness	10 (0.1)	(0.0, 0.2)
Injection site bruising	8 (0.1)	(0.0, 0.1)
Injection site warmth	6 (0.0)	(0.0, 0.1)
Feeling hot	5 (0.0)	(0.0, 0.1)
Injection site induration	5 (0.0)	(0.0, 0.1)
Axillary pain	3 (0.0)	(0.0, 0.1)
Injection site oedema	3 (0.0)	(0.0, 0.1)
Adverse drug reaction	2 (0.0)	(0.0, 0.1)
Injection site discomfort	2 (0.0)	(0.0, 0.1)
Injection site haematoma	2 (0.0)	(0.0, 0.1)
Injection site nodule	2 (0.0)	(0.0, 0.1)
Injection site papule	2 (0.0)	(0.0, 0.1)
Application site erythema	1 (0.0)	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)

14.149. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Application site pruritus	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)
Chest pain	1 (0.0)	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)
Injection site mass	1 (0.0)	(0.0, 0.0)
Injection site paraesthesia	1 (0.0)	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)
Injection site reaction	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)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	6 (0.0)	(0.0, 0.1)
Rhinitis	2 (0.0)	(0.0, 0.1)
Gastrointestinal infection	1 (0.0)	(0.0, 0.0)
Influenza	1 (0.0)	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)
Oral candidiasis	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	8 (0.1)	(0.0, 0.1)
Procedural pain	4 (0.0)	(0.0, 0.1)
Vaccination complication	3 (0.0)	(0.0, 0.1)
Contusion	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	52 (0.4)	(0.3, 0.6)
Body temperature increased	46 (0.4)	(0.3, 0.5)
Blood glucose increased	2 (0.0)	(0.0, 0.1)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)
Blood pressure increased	1 (0.0)	(0.0, 0.0)

14.149. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Respiratory rate increased	1 (0.0)	(0.0, 0.0)
SARS-CoV-2 antibody test positive	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	15 (0.1)	(0.1, 0.2)
Decreased appetite	13 (0.1)	(0.1, 0.2)
Gout	1 (0.0)	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	676 (5.6)	(5.2, 6.1)
Myalgia	531 (4.4)	(4.1, 4.8)
Arthralgia	95 (0.8)	(0.6, 1.0)
Pain in extremity	73 (0.6)	(0.5, 0.8)
Back pain	14 (0.1)	(0.1, 0.2)
Musculoskeletal stiffness	6 (0.0)	(0.0, 0.1)
Muscle spasms	5 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	4 (0.0)	(0.0, 0.1)
Neck pain	3 (0.0)	(0.0, 0.1)
Joint range of motion decreased	2 (0.0)	(0.0, 0.1)
Joint stiffness	2 (0.0)	(0.0, 0.1)
Muscle twitching	2 (0.0)	(0.0, 0.1)
Muscular weakness	2 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	2 (0.0)	(0.0, 0.1)
Limb discomfort	1 (0.0)	(0.0, 0.0)
Mobility decreased	1 (0.0)	(0.0, 0.0)
Muscle fatigue	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.0)
Pain in jaw	1 (0.0)	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)
Tendonitis	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	575 (4.8)	(4.4, 5.2)
Headache	522 (4.3)	(4.0, 4.7)
Dizziness	25 (0.2)	(0.1, 0.3)
Lethargy	14 (0.1)	(0.1, 0.2)
Paraesthesia	6 (0.0)	(0.0, 0.1)

14.149. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Somnolence	4 (0.0)	(0.0, 0.1)
Disturbance in attention	3 (0.0)	(0.0, 0.1)
Dysgeusia	3 (0.0)	(0.0, 0.1)
Migraine	3 (0.0)	(0.0, 0.1)
Dizziness postural	2 (0.0)	(0.0, 0.1)
Hypoaesthesia	2 (0.0)	(0.0, 0.1)
Migraine without aura	2 (0.0)	(0.0, 0.1)
Sinus headache	2 (0.0)	(0.0, 0.1)
Tension headache	2 (0.0)	(0.0, 0.1)
Tremor	2 (0.0)	(0.0, 0.1)
Dyskinesia	1 (0.0)	(0.0, 0.0)
Facial paralysis	1 (0.0)	(0.0, 0.0)
Hyperaesthesia	1 (0.0)	(0.0, 0.0)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.0)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.0)
Presyncope	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	22 (0.2)	(0.1, 0.3)
Insomnia	12 (0.1)	(0.1, 0.2)
Abnormal dreams	3 (0.0)	(0.0, 0.1)
Disorientation	2 (0.0)	(0.0, 0.1)
Irritability	2 (0.0)	(0.0, 0.1)
Anxiety	1 (0.0)	(0.0, 0.0)
Nightmare	1 (0.0)	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	3 (0.0)	(0.0, 0.1)
Bladder spasm	1 (0.0)	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)
Pollakiuria	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	3 (0.0)	(0.0, 0.1)
Menorrhagia	2 (0.0)	(0.0, 0.1)
Menstruation irregular	1 (0.0)	(0.0, 0.0)

14.149. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Scrotal pain	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	38 (0.3)	(0.2, 0.4)
Nasal congestion	10 (0.1)	(0.0, 0.2)
Oropharyngeal pain	10 (0.1)	(0.0, 0.2)
Cough	4 (0.0)	(0.0, 0.1)
Rhinorrhoea	4 (0.0)	(0.0, 0.1)
Throat irritation	4 (0.0)	(0.0, 0.1)
Asthma	2 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.1)
Pleurisy	1 (0.0)	(0.0, 0.0)
Productive cough	1 (0.0)	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.0)
Upper respiratory tract congestion	1 (0.0)	(0.0, 0.0)
Upper-airway cough syndrome	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	55 (0.5)	(0.3, 0.6)
Hyperhidrosis	15 (0.1)	(0.1, 0.2)
Rash	12 (0.1)	(0.1, 0.2)
Night sweats	8 (0.1)	(0.0, 0.1)
Urticaria	5 (0.0)	(0.0, 0.1)
Erythema	4 (0.0)	(0.0, 0.1)
Pruritus	3 (0.0)	(0.0, 0.1)
Rash pruritic	2 (0.0)	(0.0, 0.1)
Cold sweat	1 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	5 (0.0)	(0.0, 0.1)
Flushing	2 (0.0)	(0.0, 0.1)
Hot flush	2 (0.0)	(0.0, 0.1)
Hypertension	1 (0.0)	(0.0, 0.0)

14.149. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_pd2_rel_p3_saf

14.150. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	1386 (20.8)	(19.8, 21.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	24 (0.4)	(0.2, 0.5)
Lymphadenopathy	22 (0.3)	(0.2, 0.5)
Lymph node pain	3 (0.0)	(0.0, 0.1)
Leukopenia	0	(0.0, 0.1)
Lymphopenia	0	(0.0, 0.1)
Neutropenia	0	(0.0, 0.1)
CARDIAC DISORDERS	7 (0.1)	(0.0, 0.2)
Tachycardia	5 (0.1)	(0.0, 0.2)
Sinus tachycardia	1 (0.0)	(0.0, 0.1)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	3 (0.0)	(0.0, 0.1)
Vertigo	1 (0.0)	(0.0, 0.1)
Ear discomfort	1 (0.0)	(0.0, 0.1)
Ear pain	1 (0.0)	(0.0, 0.1)
EYE DISORDERS	4 (0.1)	(0.0, 0.2)
Eye irritation	2 (0.0)	(0.0, 0.1)
Eye pain	1 (0.0)	(0.0, 0.1)
Photophobia	1 (0.0)	(0.0, 0.1)
Vision blurred	0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	132 (2.0)	(1.7, 2.3)
Nausea	76 (1.1)	(0.9, 1.4)
Diarrhoea	50 (0.8)	(0.6, 1.0)
Vomiting	19 (0.3)	(0.2, 0.4)
Dyspepsia	3 (0.0)	(0.0, 0.1)
Abdominal pain	2 (0.0)	(0.0, 0.1)
Abdominal pain upper	2 (0.0)	(0.0, 0.1)
Toothache	2 (0.0)	(0.0, 0.1)
Glossodynia	0	(0.0, 0.1)
Abdominal discomfort	0	(0.0, 0.1)

14.150. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Faeces soft	1 (0.0)	(0.0, 0.1)
Flatulence	1 (0.0)	(0.0, 0.1)
Gingival pain	1 (0.0)	(0.0, 0.1)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.1)
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.1)
Irritable bowel syndrome	1 (0.0)	(0.0, 0.1)
Oral discomfort	0	(0.0, 0.1)
Retching	0	(0.0, 0.1)
Tongue pruritus	0	(0.0, 0.1)
Tongue ulceration	0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1211 (18.2)	(17.2, 19.1)
Injection site pain	713 (10.7)	(10.0, 11.5)
Pyrexia	438 (6.6)	(6.0, 7.2)
Chills	410 (6.2)	(5.6, 6.8)
Fatigue	358 (5.4)	(4.8, 5.9)
Pain	189 (2.8)	(2.5, 3.3)
Injection site erythema	50 (0.8)	(0.6, 1.0)
Injection site swelling	31 (0.5)	(0.3, 0.7)
Malaise	28 (0.4)	(0.3, 0.6)
Injection site pruritus	9 (0.1)	(0.1, 0.3)
Asthenia	7 (0.1)	(0.0, 0.2)
Influenza like illness	7 (0.1)	(0.0, 0.2)
Injection site bruising	5 (0.1)	(0.0, 0.2)
Injection site warmth	3 (0.0)	(0.0, 0.1)
Feeling hot	3 (0.0)	(0.0, 0.1)
Injection site induration	1 (0.0)	(0.0, 0.1)
Axillary pain	1 (0.0)	(0.0, 0.1)
Injection site oedema	3 (0.0)	(0.0, 0.1)
Adverse drug reaction	2 (0.0)	(0.0, 0.1)
Injection site discomfort	1 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)
Injection site nodule	1 (0.0)	(0.0, 0.1)
Injection site papule	2 (0.0)	(0.0, 0.1)

14.150. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Application site erythema	1 (0.0)	(0.0, 0.1)
Application site pain	1 (0.0)	(0.0, 0.1)
Application site pruritus	0	(0.0, 0.1)
Application site reaction	1 (0.0)	(0.0, 0.1)
Chest pain	1 (0.0)	(0.0, 0.1)
Induration	0	(0.0, 0.1)
Injection site discolouration	1 (0.0)	(0.0, 0.1)
Injection site haemorrhage	0	(0.0, 0.1)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.1)
Injection site irritation	0	(0.0, 0.1)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.1)
Injection site mass	0	(0.0, 0.1)
Injection site paraesthesia	1 (0.0)	(0.0, 0.1)
Injection site rash	0	(0.0, 0.1)
Injection site reaction	0	(0.0, 0.1)
Peripheral swelling	1 (0.0)	(0.0, 0.1)
Sensation of foreign body	1 (0.0)	(0.0, 0.1)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)
Sluggishness	0	(0.0, 0.1)
Swelling	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	4 (0.1)	(0.0, 0.2)
Rhinitis	2 (0.0)	(0.0, 0.1)
Gastrointestinal infection	1 (0.0)	(0.0, 0.1)
Influenza	0	(0.0, 0.1)
Injection site abscess	0	(0.0, 0.1)
Oral candidiasis	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	6 (0.1)	(0.0, 0.2)
Procedural pain	4 (0.1)	(0.0, 0.2)
Vaccination complication	2 (0.0)	(0.0, 0.1)
Contusion	0	(0.0, 0.1)
INVESTIGATIONS	32 (0.5)	(0.3, 0.7)
Body temperature increased	29 (0.4)	(0.3, 0.6)

14.150. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Blood glucose increased	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)
Respiratory rate increased	0	(0.0, 0.1)
SARS-CoV-2 antibody test positive	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	11 (0.2)	(0.1, 0.3)
Decreased appetite	10 (0.2)	(0.1, 0.3)
Gout	1 (0.0)	(0.0, 0.1)
Polydipsia	0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	427 (6.4)	(5.8, 7.0)
Myalgia	347 (5.2)	(4.7, 5.8)
Arthralgia	54 (0.8)	(0.6, 1.1)
Pain in extremity	31 (0.5)	(0.3, 0.7)
Back pain	12 (0.2)	(0.1, 0.3)
Musculoskeletal stiffness	0	(0.0, 0.1)
Muscle spasms	2 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	3 (0.0)	(0.0, 0.1)
Neck pain	1 (0.0)	(0.0, 0.1)
Joint range of motion decreased	2 (0.0)	(0.0, 0.1)
Joint stiffness	1 (0.0)	(0.0, 0.1)
Muscle twitching	1 (0.0)	(0.0, 0.1)
Muscular weakness	0	(0.0, 0.1)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.1)
Limb discomfort	0	(0.0, 0.1)
Mobility decreased	0	(0.0, 0.1)
Muscle fatigue	1 (0.0)	(0.0, 0.1)
Muscle tightness	1 (0.0)	(0.0, 0.1)
Musculoskeletal pain	1 (0.0)	(0.0, 0.1)
Pain in jaw	1 (0.0)	(0.0, 0.1)
Periarthritis	1 (0.0)	(0.0, 0.1)
Tendonitis	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	356 (5.3)	(4.8, 5.9)

14.150. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Headache	324 (4.9)	(4.4, 5.4)
Dizziness	13 (0.2)	(0.1, 0.3)
Lethargy	3 (0.0)	(0.0, 0.1)
Paraesthesia	6 (0.1)	(0.0, 0.2)
Somnolence	2 (0.0)	(0.0, 0.1)
Disturbance in attention	2 (0.0)	(0.0, 0.1)
Dysgeusia	3 (0.0)	(0.0, 0.1)
Migraine	3 (0.0)	(0.0, 0.1)
Dizziness postural	0	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.1)
Migraine without aura	1 (0.0)	(0.0, 0.1)
Sinus headache	1 (0.0)	(0.0, 0.1)
Tension headache	2 (0.0)	(0.0, 0.1)
Tremor	2 (0.0)	(0.0, 0.1)
Dyskinesia	0	(0.0, 0.1)
Facial paralysis	1 (0.0)	(0.0, 0.1)
Hyperaesthesia	1 (0.0)	(0.0, 0.1)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.1)
Post herpetic neuralgia	0	(0.0, 0.1)
Presyncope	1 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	11 (0.2)	(0.1, 0.3)
Insomnia	7 (0.1)	(0.0, 0.2)
Abnormal dreams	2 (0.0)	(0.0, 0.1)
Disorientation	0	(0.0, 0.1)
Irritability	1 (0.0)	(0.0, 0.1)
Anxiety	1 (0.0)	(0.0, 0.1)
Nightmare	0	(0.0, 0.1)
Restlessness	0	(0.0, 0.1)
Sleep disorder	0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.1)
Bladder spasm	0	(0.0, 0.1)

14.150. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Micturition urgency	0	(0.0, 0.1)
Pollakiuria	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	3 (0.0)	(0.0, 0.1)
Menorrhagia	2 (0.0)	(0.0, 0.1)
Menstruation irregular	1 (0.0)	(0.0, 0.1)
Scrotal pain	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	23 (0.3)	(0.2, 0.5)
Nasal congestion	7 (0.1)	(0.0, 0.2)
Oropharyngeal pain	7 (0.1)	(0.0, 0.2)
Cough	4 (0.1)	(0.0, 0.2)
Rhinorrhoea	1 (0.0)	(0.0, 0.1)
Throat irritation	1 (0.0)	(0.0, 0.1)
Asthma	1 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	2 (0.0)	(0.0, 0.1)
Pleurisy	0	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.1)
Sneezing	0	(0.0, 0.1)
Upper respiratory tract congestion	0	(0.0, 0.1)
Upper-airway cough syndrome	0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	31 (0.5)	(0.3, 0.7)
Hyperhidrosis	9 (0.1)	(0.1, 0.3)
Rash	9 (0.1)	(0.1, 0.3)
Night sweats	4 (0.1)	(0.0, 0.2)
Urticaria	3 (0.0)	(0.0, 0.1)
Erythema	2 (0.0)	(0.0, 0.1)
Pruritus	1 (0.0)	(0.0, 0.1)
Rash pruritic	2 (0.0)	(0.0, 0.1)
Cold sweat	1 (0.0)	(0.0, 0.1)
Ecchymosis	0	(0.0, 0.1)
Macule	0	(0.0, 0.1)
Pain of skin	0	(0.0, 0.1)
Rash erythematous	0	(0.0, 0.1)

14.150. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Skin discolouration	0	(0.0, 0.1)
VASCULAR DISORDERS	3 (0.0)	(0.0, 0.1)
Flushing	1 (0.0)	(0.0, 0.1)
Hot flush	1 (0.0)	(0.0, 0.1)
Hypertension	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 29MAR2021 (04:19)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 pd2 rel age p3 saf

14.151. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	859 (16.1)	(15.1, 17.1)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	8 (0.1)	(0.1, 0.3)
Lymphadenopathy	7 (0.1)	(0.1, 0.3)
Lymph node pain	0	(0.0, 0.1)
Leukopenia	1 (0.0)	(0.0, 0.1)
Lymphopenia	1 (0.0)	(0.0, 0.1)
Neutropenia	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	1 (0.0)	(0.0, 0.1)
Tachycardia	1 (0.0)	(0.0, 0.1)
Sinus tachycardia	0	(0.0, 0.1)
Supraventricular tachycardia	0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	5 (0.1)	(0.0, 0.2)
Vertigo	5 (0.1)	(0.0, 0.2)
Ear discomfort	0	(0.0, 0.1)
Ear pain	0	(0.0, 0.1)
EYE DISORDERS	2 (0.0)	(0.0, 0.1)
Eye irritation	0	(0.0, 0.1)
Eye pain	1 (0.0)	(0.0, 0.1)
Photophobia	0	(0.0, 0.1)
Vision blurred	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	91 (1.7)	(1.4, 2.1)
Nausea	47 (0.9)	(0.6, 1.2)
Diarrhoea	41 (0.8)	(0.6, 1.0)
Vomiting	5 (0.1)	(0.0, 0.2)
Dyspepsia	1 (0.0)	(0.0, 0.1)
Abdominal pain	1 (0.0)	(0.0, 0.1)
Abdominal pain upper	1 (0.0)	(0.0, 0.1)
Toothache	1 (0.0)	(0.0, 0.1)
Glossodynia	2 (0.0)	(0.0, 0.1)
Abdominal discomfort	1 (0.0)	(0.0, 0.1)

14.151. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Faeces soft	0	(0.0, 0.1)
Flatulence	0	(0.0, 0.1)
Gingival pain	0	(0.0, 0.1)
Hypoaesthesia oral	0	(0.0, 0.1)
Hypoaesthesia teeth	0	(0.0, 0.1)
Irritable bowel syndrome	0	(0.0, 0.1)
Oral discomfort	1 (0.0)	(0.0, 0.1)
Retching	1 (0.0)	(0.0, 0.1)
Tongue pruritus	1 (0.0)	(0.0, 0.1)
Tongue ulceration	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	733 (13.7)	(12.8, 14.7)
Injection site pain	476 (8.9)	(8.2, 9.7)
Pyrexia	186 (3.5)	(3.0, 4.0)
Chills	190 (3.6)	(3.1, 4.1)
Fatigue	219 (4.1)	(3.6, 4.7)
Pain	85 (1.6)	(1.3, 2.0)
Injection site erythema	41 (0.8)	(0.6, 1.0)
Injection site swelling	28 (0.5)	(0.3, 0.8)
Malaise	17 (0.3)	(0.2, 0.5)
Injection site pruritus	10 (0.2)	(0.1, 0.3)
Asthenia	8 (0.1)	(0.1, 0.3)
Influenza like illness	3 (0.1)	(0.0, 0.2)
Injection site bruising	3 (0.1)	(0.0, 0.2)
Injection site warmth	3 (0.1)	(0.0, 0.2)
Feeling hot	2 (0.0)	(0.0, 0.1)
Injection site induration	4 (0.1)	(0.0, 0.2)
Axillary pain	2 (0.0)	(0.0, 0.1)
Injection site oedema	0	(0.0, 0.1)
Adverse drug reaction	0	(0.0, 0.1)
Injection site discomfort	1 (0.0)	(0.0, 0.1)
Injection site haematoma	1 (0.0)	(0.0, 0.1)
Injection site nodule	1 (0.0)	(0.0, 0.1)

14.151. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Injection site papule	0	(0.0, 0.1)
Application site erythema	0	(0.0, 0.1)
Application site pain	0	(0.0, 0.1)
Application site pruritus	1 (0.0)	(0.0, 0.1)
Application site reaction	0	(0.0, 0.1)
Chest pain	0	(0.0, 0.1)
Induration	1 (0.0)	(0.0, 0.1)
Injection site discolouration	0	(0.0, 0.1)
Injection site haemorrhage	1 (0.0)	(0.0, 0.1)
Injection site hyperaesthesia	0	(0.0, 0.1)
Injection site irritation	1 (0.0)	(0.0, 0.1)
Injection site lymphadenopathy	0	(0.0, 0.1)
Injection site mass	1 (0.0)	(0.0, 0.1)
Injection site paraesthesia	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)
Peripheral swelling	0	(0.0, 0.1)
Sensation of foreign body	0	(0.0, 0.1)
Shoulder injury related to vaccine administration	0	(0.0, 0.1)
Sluggishness	1 (0.0)	(0.0, 0.1)
Swelling	0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	2 (0.0)	(0.0, 0.1)
Rhinitis	0	(0.0, 0.1)
Gastrointestinal infection	0	(0.0, 0.1)
Influenza	1 (0.0)	(0.0, 0.1)
Injection site abscess	1 (0.0)	(0.0, 0.1)
Oral candidiasis	0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.0)	(0.0, 0.1)
Procedural pain	0	(0.0, 0.1)
Vaccination complication	1 (0.0)	(0.0, 0.1)
Contusion	1 (0.0)	(0.0, 0.1)

14.151. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
INVESTIGATIONS	20 (0.4)	(0.2, 0.6)
Body temperature increased	17 (0.3)	(0.2, 0.5)
Blood glucose increased	2 (0.0)	(0.0, 0.1)
Blood glucose abnormal	0	(0.0, 0.1)
Blood pressure increased	0	(0.0, 0.1)
Respiratory rate increased	1 (0.0)	(0.0, 0.1)
SARS-CoV-2 antibody test positive	0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	4 (0.1)	(0.0, 0.2)
Decreased appetite	3 (0.1)	(0.0, 0.2)
Gout	0	(0.0, 0.1)
Polydipsia	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	249 (4.7)	(4.1, 5.3)
Myalgia	184 (3.4)	(3.0, 4.0)
Arthralgia	41 (0.8)	(0.6, 1.0)
Pain in extremity	42 (0.8)	(0.6, 1.1)
Back pain	2 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	6 (0.1)	(0.0, 0.2)
Muscle spasms	3 (0.1)	(0.0, 0.2)
Musculoskeletal discomfort	1 (0.0)	(0.0, 0.1)
Neck pain	2 (0.0)	(0.0, 0.1)
Joint range of motion decreased	0	(0.0, 0.1)
Joint stiffness	1 (0.0)	(0.0, 0.1)
Muscle twitching	1 (0.0)	(0.0, 0.1)
Muscular weakness	2 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.1)
Limb discomfort	1 (0.0)	(0.0, 0.1)
Mobility decreased	1 (0.0)	(0.0, 0.1)
Muscle fatigue	0	(0.0, 0.1)
Muscle tightness	0	(0.0, 0.1)
Musculoskeletal pain	0	(0.0, 0.1)
Pain in jaw	0	(0.0, 0.1)
Periarthritis	0	(0.0, 0.1)

14.151. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Tendonitis	0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	219 (4.1)	(3.6, 4.7)
Headache	198 (3.7)	(3.2, 4.2)
Dizziness	12 (0.2)	(0.1, 0.4)
Lethargy	11 (0.2)	(0.1, 0.4)
Paraesthesia	0	(0.0, 0.1)
Somnolence	2 (0.0)	(0.0, 0.1)
Disturbance in attention	1 (0.0)	(0.0, 0.1)
Dysgeusia	0	(0.0, 0.1)
Migraine	0	(0.0, 0.1)
Dizziness postural	2 (0.0)	(0.0, 0.1)
Hypoaesthesia	1 (0.0)	(0.0, 0.1)
Migraine without aura	1 (0.0)	(0.0, 0.1)
Sinus headache	1 (0.0)	(0.0, 0.1)
Tension headache	0	(0.0, 0.1)
Tremor	0	(0.0, 0.1)
Dyskinesia	1 (0.0)	(0.0, 0.1)
Facial paralysis	0	(0.0, 0.1)
Hyperaesthesia	0	(0.0, 0.1)
Peripheral sensory neuropathy	0	(0.0, 0.1)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.1)
Presyncope	0	(0.0, 0.1)
Syncope	0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	11 (0.2)	(0.1, 0.4)
Insomnia	5 (0.1)	(0.0, 0.2)
Abnormal dreams	1 (0.0)	(0.0, 0.1)
Disorientation	2 (0.0)	(0.0, 0.1)
Irritability	1 (0.0)	(0.0, 0.1)
Anxiety	0	(0.0, 0.1)
Nightmare	1 (0.0)	(0.0, 0.1)
Restlessness	1 (0.0)	(0.0, 0.1)
Sleep disorder	1 (0.0)	(0.0, 0.1)

14.151. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
RENAL AND URINARY DISORDERS	2 (0.0)	(0.0, 0.1)
Bladder spasm	1 (0.0)	(0.0, 0.1)
Micturition urgency	1 (0.0)	(0.0, 0.1)
Pollakiuria	0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 0.1)
Menorrhagia	0	(0.0, 0.1)
Menstruation irregular	0	(0.0, 0.1)
Scrotal pain	0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	15 (0.3)	(0.2, 0.5)
Nasal congestion	3 (0.1)	(0.0, 0.2)
Oropharyngeal pain	3 (0.1)	(0.0, 0.2)
Cough	0	(0.0, 0.1)
Rhinorrhoea	3 (0.1)	(0.0, 0.2)
Throat irritation	3 (0.1)	(0.0, 0.2)
Asthma	1 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	0	(0.0, 0.1)
Pleurisy	1 (0.0)	(0.0, 0.1)
Productive cough	0	(0.0, 0.1)
Sneezing	1 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	1 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	24 (0.4)	(0.3, 0.7)
Hyperhidrosis	6 (0.1)	(0.0, 0.2)
Rash	3 (0.1)	(0.0, 0.2)
Night sweats	4 (0.1)	(0.0, 0.2)
Urticaria	2 (0.0)	(0.0, 0.1)
Erythema	2 (0.0)	(0.0, 0.1)
Pruritus	2 (0.0)	(0.0, 0.1)
Rash pruritic	0	(0.0, 0.1)
Cold sweat	0	(0.0, 0.1)
Ecchymosis	1 (0.0)	(0.0, 0.1)

14.151. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Macule	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)
Skin discolouration	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	2 (0.0)	(0.0, 0.1)
Flushing	1 (0.0)	(0.0, 0.1)
Hot flush	1 (0.0)	(0.0, 0.1)
Hypertension	0	(0.0, 0.1)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 29MAR2021 (04:19)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_pd2_rel_age_p3_saf

SUPPLEMENTAL TABLES

Phase 2/3

Adverse Events

14.152. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=582, TE[b]=0.6)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	132	222.9	(186.5, 264.3)
Related[f]	124	209.4	(174.2, 249.7)
Severe	3	5.1	(1.0, 14.8)
Life-threatening	2	3.4	(0.4, 12.2)
Any serious adverse event	2	3.4	(0.4, 12.2)
Related[f]	0	0.0	(0.0, 6.2)
Severe	1	1.7	(0.0, 9.4)
Life-threatening	2	3.4	(0.4, 12.2)
Any adverse event leading to withdrawal	1	1.7	(0.0, 9.4)
Related[f]	0	0.0	(0.0, 6.2)
Severe	0	0.0	(0.0, 6.2)
Life-threatening	0	0.0	(0.0, 6.2)
Death	0	0.0	(0.0, 6.2)

14.152. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)		
		BNT162b2 (30 µg) (N[a]=582, TE[b]=0.6)	
Adverse Event	**n[c]**	**IR (/100 PY)[d]**	**(95% CI[e])**

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: Dose 3 = First dose of BNT162b2 (30 µg).
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s092_base_p3x_saf

14.153. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
Adverse Event	**n[c]**	**IR (/100 PY)[d]**	**(95% CI[e])**
Any event	4737	205.4	(199.6, 211.3)
Related[f]	4370	189.5	(183.9, 195.2)
Severe	138	6.0	(5.0, 7.1)
Life-threatening	9	0.4	(0.2, 0.7)
Any serious adverse event	63	2.7	(2.1, 3.5)
Related[f]	1	0.0	(0.0, 0.2)
Severe	36	1.6	(1.1, 2.2)
Life-threatening	9	0.4	(0.2, 0.7)
Any adverse event leading to withdrawal	18	0.8	(0.5, 1.2)
Related[f]	12	0.5	(0.3, 0.9)
Severe	2	0.1	(0.0, 0.3)
Life-threatening	4	0.2	(0.0, 0.4)
Death	2	0.1	(0.0, 0.3)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: Dose 3 = First dose of BNT162b2 (30 µg).
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s092 base p3x saf

14.154. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 3 to 7 Days After Dose 3, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=19525)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	3189 (16.3)	(15.8, 16.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	27 (0.1)	(0.1, 0.2)
Lymphadenopathy	23 (0.1)	(0.1, 0.2)
Iron deficiency anaemia	2 (0.0)	(0.0, 0.0)
Lymph node pain	2 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	5 (0.0)	(0.0, 0.1)
Atrial fibrillation	2 (0.0)	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.0)
Ischaemic cardiomyopathy	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)
BRCA2 gene mutation	1 (0.0)	(0.0, 0.0)
Factor II mutation	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	2 (0.0)	(0.0, 0.0)
Cerumen impaction	1 (0.0)	(0.0, 0.0)
Ear discomfort	1 (0.0)	(0.0, 0.0)
Hypoacusis	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	1 (0.0)	(0.0, 0.0)
Thyroid disorder	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	13 (0.1)	(0.0, 0.1)
Eye pain	3 (0.0)	(0.0, 0.0)
Lacrimation increased	2 (0.0)	(0.0, 0.0)
Cataract	1 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)
Keratitis	1 (0.0)	(0.0, 0.0)
Meibomianitis	1 (0.0)	(0.0, 0.0)
Ocular discomfort	1 (0.0)	(0.0, 0.0)
Visual impairment	1 (0.0)	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.0)

14.154. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 3 to 7 Days After Dose 3, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=19525)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
GASTROINTESTINAL DISORDERS	122 (0.6)	(0.5, 0.7)
Diarrhoea	50 (0.3)	(0.2, 0.3)
Nausea	46 (0.2)	(0.2, 0.3)
Vomiting	15 (0.1)	(0.0, 0.1)
Abdominal pain	3 (0.0)	(0.0, 0.0)
Abdominal pain upper	3 (0.0)	(0.0, 0.0)
Constipation	3 (0.0)	(0.0, 0.0)
Dyspepsia	2 (0.0)	(0.0, 0.0)
Gastrooesophageal reflux disease	2 (0.0)	(0.0, 0.0)
Hiatus hernia	2 (0.0)	(0.0, 0.0)
Abdominal pain lower	1 (0.0)	(0.0, 0.0)
Anal fistula	1 (0.0)	(0.0, 0.0)
Chronic gastritis	1 (0.0)	(0.0, 0.0)
Dry mouth	1 (0.0)	(0.0, 0.0)
Gastrointestinal sounds abnormal	1 (0.0)	(0.0, 0.0)
Gingival bleeding	1 (0.0)	(0.0, 0.0)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)
Oral mucosal blistering	1 (0.0)	(0.0, 0.0)
Oral pain	1 (0.0)	(0.0, 0.0)
Oral pruritus	1 (0.0)	(0.0, 0.0)
Submaxillary gland enlargement	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2860 (14.6)	(14.2, 15.2)
Injection site pain	2385 (12.2)	(11.8, 12.7)
Fatigue	575 (2.9)	(2.7, 3.2)
Chills	285 (1.5)	(1.3, 1.6)
Pyrexia	239 (1.2)	(1.1, 1.4)
Pain	128 (0.7)	(0.5, 0.8)
Injection site swelling	37 (0.2)	(0.1, 0.3)
Malaise	35 (0.2)	(0.1, 0.2)
Injection site erythema	32 (0.2)	(0.1, 0.2)
Asthenia	20 (0.1)	(0.1, 0.2)
Injection site bruising	9 (0.0)	(0.0, 0.1)
Injection site pruritus	6 (0.0)	(0.0, 0.1)

14.154. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 3 to 7 Days After Dose 3, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=19525)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Peripheral swelling	3 (0.0)	(0.0, 0.0)
Vaccination site pain	3 (0.0)	(0.0, 0.0)
Discomfort	2 (0.0)	(0.0, 0.0)
Feeling cold	2 (0.0)	(0.0, 0.0)
Feeling hot	2 (0.0)	(0.0, 0.0)
Injection site oedema	2 (0.0)	(0.0, 0.0)
Injection site reaction	2 (0.0)	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)
Axillary pain	1 (0.0)	(0.0, 0.0)
Chest discomfort	1 (0.0)	(0.0, 0.0)
Chest pain	1 (0.0)	(0.0, 0.0)
Crying	1 (0.0)	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.0)
Feeling abnormal	1 (0.0)	(0.0, 0.0)
Implant site pain	1 (0.0)	(0.0, 0.0)
Inflammation	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 haemorrhage	1 (0.0)	(0.0, 0.0)
Injection site hypersensitivity	1 (0.0)	(0.0, 0.0)
Injection site mass	1 (0.0)	(0.0, 0.0)
Injection site nodule	1 (0.0)	(0.0, 0.0)
Injection site warmth	1 (0.0)	(0.0, 0.0)
Pelvic mass	1 (0.0)	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)
Vaccination site reaction	1 (0.0)	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	3 (0.0)	(0.0, 0.0)
Allergy to vaccine	1 (0.0)	(0.0, 0.0)
Anaphylactoid reaction	1 (0.0)	(0.0, 0.0)
Seasonal allergy	1 (0.0)	(0.0, 0.0)

14.154. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 3 to 7 Days After Dose 3, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=19525)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
INFECTIONS AND INFESTATIONS	20 (0.1)	(0.1, 0.2)
Urinary tract infection	5 (0.0)	(0.0, 0.1)
Conjunctivitis	3 (0.0)	(0.0, 0.0)
Tooth abscess	2 (0.0)	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)
Genital herpes	1 (0.0)	(0.0, 0.0)
Herpes zoster	1 (0.0)	(0.0, 0.0)
Hordeolum	1 (0.0)	(0.0, 0.0)
Oral herpes	1 (0.0)	(0.0, 0.0)
Rhinitis	1 (0.0)	(0.0, 0.0)
Tooth infection	1 (0.0)	(0.0, 0.0)
Urosepsis	1 (0.0)	(0.0, 0.0)
Vulvitis	1 (0.0)	(0.0, 0.0)
Vulvovaginal mycotic infection	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	14 (0.1)	(0.0, 0.1)
Fall	2 (0.0)	(0.0, 0.0)
Foot fracture	2 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.0)
Skin laceration	2 (0.0)	(0.0, 0.0)
Arthropod bite	1 (0.0)	(0.0, 0.0)
Exposure during pregnancy	1 (0.0)	(0.0, 0.0)
Joint dislocation	1 (0.0)	(0.0, 0.0)
Ligament sprain	1 (0.0)	(0.0, 0.0)
Procedural pain	1 (0.0)	(0.0, 0.0)
Tooth fracture	1 (0.0)	(0.0, 0.0)
Wound	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	29 (0.1)	(0.1, 0.2)
Body temperature increased	26 (0.1)	(0.1, 0.2)
Blood pressure increased	2 (0.0)	(0.0, 0.0)
Alanine aminotransferase increased	1 (0.0)	(0.0, 0.0)
Aspartate aminotransferase increased	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	12 (0.1)	(0.0, 0.1)

14.154. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 3 to 7 Days After Dose 3, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=19525)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Decreased appetite	5 (0.0)	(0.0, 0.1)
Hyperglycaemia	2 (0.0)	(0.0, 0.0)
Dyslipidaemia	1 (0.0)	(0.0, 0.0)
Glucose tolerance impaired	1 (0.0)	(0.0, 0.0)
Hypercholesterolaemia	1 (0.0)	(0.0, 0.0)
Insulin resistance	1 (0.0)	(0.0, 0.0)
Type 2 diabetes mellitus	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	439 (2.2)	(2.0, 2.5)
Myalgia	313 (1.6)	(1.4, 1.8)
Pain in extremity	81 (0.4)	(0.3, 0.5)
Arthralgia	42 (0.2)	(0.2, 0.3)
Back pain	11 (0.1)	(0.0, 0.1)
Neck pain	4 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	3 (0.0)	(0.0, 0.0)
Joint range of motion decreased	2 (0.0)	(0.0, 0.0)
Arthritis	1 (0.0)	(0.0, 0.0)
Flank pain	1 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)
Plantar fasciitis	1 (0.0)	(0.0, 0.0)
Trigger finger	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	3 (0.0)	(0.0, 0.0)
Lipoma	1 (0.0)	(0.0, 0.0)
Neoplasm	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	491 (2.5)	(2.3, 2.7)
Headache	456 (2.3)	(2.1, 2.6)
Dizziness	18 (0.1)	(0.1, 0.1)
Somnolence	8 (0.0)	(0.0, 0.1)
Paraesthesia	5 (0.0)	(0.0, 0.1)
Migraine	2 (0.0)	(0.0, 0.0)
Amnesia	1 (0.0)	(0.0, 0.0)

14.154. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 3 to 7 Days After Dose 3, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=19525)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Balance disorder	1 (0.0)	(0.0, 0.0)
Facial paralysis	1 (0.0)	(0.0, 0.0)
Lethargy	1 (0.0)	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)
Presyncope	1 (0.0)	(0.0, 0.0)
Radiculopathy	1 (0.0)	(0.0, 0.0)
Sciatica	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)
Transient ischaemic attack	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	12 (0.1)	(0.0, 0.1)
Insomnia	4 (0.0)	(0.0, 0.1)
Anxiety	2 (0.0)	(0.0, 0.0)
Depression	2 (0.0)	(0.0, 0.0)
Completed suicide	1 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	1 (0.0)	(0.0, 0.0)
Irritability	1 (0.0)	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	3 (0.0)	(0.0, 0.0)
Dysuria	2 (0.0)	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	7 (0.0)	(0.0, 0.1)
Metrorrhagia	2 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	1 (0.0)	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.0)
Pelvic pain	1 (0.0)	(0.0, 0.0)
Sexual dysfunction	1 (0.0)	(0.0, 0.0)
Testicular pain	1 (0.0)	(0.0, 0.0)
Uterine haemorrhage	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	9 (0.0)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.0)
Rhinitis allergic	2 (0.0)	(0.0, 0.0)

14.154. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 3 to 7 Days After Dose 3, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=19525)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Acute respiratory failure	1 (0.0)	(0.0, 0.0)
Epistaxis	1 (0.0)	(0.0, 0.0)
Oropharyngeal pain	1 (0.0)	(0.0, 0.0)
Rhinorrhoea	1 (0.0)	(0.0, 0.0)
Sinus congestion	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	26 (0.1)	(0.1, 0.2)
Rash	8 (0.0)	(0.0, 0.1)
Hyperhidrosis	4 (0.0)	(0.0, 0.1)
Night sweats	4 (0.0)	(0.0, 0.1)
Urticaria	4 (0.0)	(0.0, 0.1)
Pruritus	3 (0.0)	(0.0, 0.0)
Actinic keratosis	1 (0.0)	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.0)
Dermatitis contact	1 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	3 (0.0)	(0.0, 0.0)
Finger repair operation	1 (0.0)	(0.0, 0.0)
Hysterectomy	1 (0.0)	(0.0, 0.0)
Injection	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	11 (0.1)	(0.0, 0.1)
Hypertension	3 (0.0)	(0.0, 0.0)
Flushing	2 (0.0)	(0.0, 0.0)
Aortic aneurysm	1 (0.0)	(0.0, 0.0)
Blood pressure fluctuation	1 (0.0)	(0.0, 0.0)
Deep vein thrombosis	1 (0.0)	(0.0, 0.0)
Haematoma	1 (0.0)	(0.0, 0.0)
Hot flush	1 (0.0)	(0.0, 0.0)
Thrombosis	1 (0.0)	(0.0, 0.0)

14.154. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 3 to 7 Days After Dose 3, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=19525)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])

Note: Dose 3 = first dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 cr pd2 p3 saf

14.155. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 4 to 7 Days After Dose 4, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=15911)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	2772 (17.4)	(16.8, 18.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	56 (0.4)	(0.3, 0.5)
Lymphadenopathy	49 (0.3)	(0.2, 0.4)
Lymph node pain	4 (0.0)	(0.0, 0.1)
Lymphadenitis	2 (0.0)	(0.0, 0.0)
Coagulopathy	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	4 (0.0)	(0.0, 0.1)
Arrhythmia	1 (0.0)	(0.0, 0.0)
Atrial fibrillation	1 (0.0)	(0.0, 0.0)
Palpitations	1 (0.0)	(0.0, 0.0)
Tachycardia	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	7 (0.0)	(0.0, 0.1)
Vertigo	4 (0.0)	(0.0, 0.1)
Deafness unilateral	1 (0.0)	(0.0, 0.0)
Ear pain	1 (0.0)	(0.0, 0.0)
Tinnitus	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	6 (0.0)	(0.0, 0.1)
Eye pain	2 (0.0)	(0.0, 0.0)
Cataract	1 (0.0)	(0.0, 0.0)
Dacryostenosis acquired	1 (0.0)	(0.0, 0.0)
Eye swelling	1 (0.0)	(0.0, 0.0)
Lacrimation increased	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	191 (1.2)	(1.0, 1.4)
Nausea	119 (0.7)	(0.6, 0.9)
Diarrhoea	43 (0.3)	(0.2, 0.4)
Vomiting	32 (0.2)	(0.1, 0.3)
Abdominal pain	6 (0.0)	(0.0, 0.1)
Abdominal pain upper	5 (0.0)	(0.0, 0.1)
Abdominal discomfort	4 (0.0)	(0.0, 0.1)
Dry mouth	2 (0.0)	(0.0, 0.0)

14.155. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 4 to 7 Days After Dose 4, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=15911) n[b] (%)	(95% CI[c])
Gastrooesophageal reflux disease	2 (0.0)	(0.0, 0.0)
Abdominal pain lower	1 (0.0)	(0.0, 0.0)
Dyspepsia	1 (0.0)	(0.0, 0.0)
Gastritis	1 (0.0)	(0.0, 0.0)
Irritable bowel syndrome	1 (0.0)	(0.0, 0.0)
Oedema mouth	1 (0.0)	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)
Stomatitis	1 (0.0)	(0.0, 0.0)
Submaxillary gland enlargement	1 (0.0)	(0.0, 0.0)
Tongue oedema	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2428 (15.3)	(14.7, 15.8)
Injection site pain	1213 (7.6)	(7.2, 8.0)
Fatigue	941 (5.9)	(5.6, 6.3)
Chills	754 (4.7)	(4.4, 5.1)
Pyrexia	726 (4.6)	(4.2, 4.9)
Pain	287 (1.8)	(1.6, 2.0)
Malaise	49 (0.3)	(0.2, 0.4)
Injection site erythema	34 (0.2)	(0.1, 0.3)
Injection site swelling	32 (0.2)	(0.1, 0.3)
Asthenia	17 (0.1)	(0.1, 0.2)
Injection site pruritus	12 (0.1)	(0.0, 0.1)
Injection site bruising	6 (0.0)	(0.0, 0.1)
Feeling abnormal	5 (0.0)	(0.0, 0.1)
Feeling hot	4 (0.0)	(0.0, 0.1)
Injection site rash	4 (0.0)	(0.0, 0.1)
Injection site warmth	3 (0.0)	(0.0, 0.1)
Peripheral swelling	3 (0.0)	(0.0, 0.1)
Chest pain	2 (0.0)	(0.0, 0.0)
Injection site discomfort	2 (0.0)	(0.0, 0.0)
Injection site hypoaesthesia	2 (0.0)	(0.0, 0.0)
Oedema peripheral	2 (0.0)	(0.0, 0.0)
Swelling face	2 (0.0)	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)

14.155. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 4 to 7 Days After Dose 4, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=15911) n[b] (%)	(95% CI[c])
Axillary pain	1 (0.0)	(0.0, 0.0)
Feeling cold	1 (0.0)	(0.0, 0.0)
Gait disturbance	1 (0.0)	(0.0, 0.0)
Implant site pain	1 (0.0)	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.0)
Injection site induration	1 (0.0)	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)
Injection site nodule	1 (0.0)	(0.0, 0.0)
Injection site reaction	1 (0.0)	(0.0, 0.0)
Injection site urticaria	1 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)
Swelling	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	21 (0.1)	(0.1, 0.2)
Herpes zoster	3 (0.0)	(0.0, 0.1)
Genital herpes simplex	2 (0.0)	(0.0, 0.0)
Sinusitis	2 (0.0)	(0.0, 0.0)
Conjunctivitis	1 (0.0)	(0.0, 0.0)
Diverticulitis	1 (0.0)	(0.0, 0.0)
Herpes simplex	1 (0.0)	(0.0, 0.0)
Oral candidiasis	1 (0.0)	(0.0, 0.0)
Oral herpes	1 (0.0)	(0.0, 0.0)
Otitis externa	1 (0.0)	(0.0, 0.0)
Pneumonia	1 (0.0)	(0.0, 0.0)
Rhinitis	1 (0.0)	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)
Taeniasis	1 (0.0)	(0.0, 0.0)
Tinea pedis	1 (0.0)	(0.0, 0.0)
Tonsillitis	1 (0.0)	(0.0, 0.0)
Tooth infection	1 (0.0)	(0.0, 0.0)
Urinary tract infection	1 (0.0)	(0.0, 0.0)
Vulvovaginal candidiasis	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	9 (0.1)	(0.0, 0.1)

14.155. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 4 to 7 Days After Dose 4, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=15911) n[b] (%)	(95% CI[c])
Contusion	3 (0.0)	(0.0, 0.1)
Fall	3 (0.0)	(0.0, 0.1)
Ligament sprain	2 (0.0)	(0.0, 0.0)
Skin laceration	2 (0.0)	(0.0, 0.0)
Eye contusion	1 (0.0)	(0.0, 0.0)
Injection related reaction	1 (0.0)	(0.0, 0.0)
Lower limb fracture	1 (0.0)	(0.0, 0.0)
Muscle strain	1 (0.0)	(0.0, 0.0)
Procedural pain	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	69 (0.4)	(0.3, 0.5)
Body temperature increased	67 (0.4)	(0.3, 0.5)
Antinuclear antibody positive	1 (0.0)	(0.0, 0.0)
C-reactive protein increased	1 (0.0)	(0.0, 0.0)
Heart rate increased	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	10 (0.1)	(0.0, 0.1)
Decreased appetite	9 (0.1)	(0.0, 0.1)
Insulin resistance	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	857 (5.4)	(5.0, 5.7)
Myalgia	686 (4.3)	(4.0, 4.6)
Arthralgia	102 (0.6)	(0.5, 0.8)
Pain in extremity	85 (0.5)	(0.4, 0.7)
Back pain	13 (0.1)	(0.0, 0.1)
Muscular weakness	4 (0.0)	(0.0, 0.1)
Musculoskeletal stiffness	4 (0.0)	(0.0, 0.1)
Neck pain	4 (0.0)	(0.0, 0.1)
Muscle fatigue	2 (0.0)	(0.0, 0.0)
Bursitis	1 (0.0)	(0.0, 0.0)
Flank pain	1 (0.0)	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)
Limb discomfort	1 (0.0)	(0.0, 0.0)
Mobility decreased	1 (0.0)	(0.0, 0.0)

14.155. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 4 to 7 Days After Dose 4, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=15911) n[b] (%)	(95% CI[c])
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.0)
Musculoskeletal pain	1 (0.0)	(0.0, 0.0)
Osteoporosis	1 (0.0)	(0.0, 0.0)
Synovial cyst	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	4 (0.0)	(0.0, 0.1)
Brain neoplasm	1 (0.0)	(0.0, 0.0)
Breast cancer	1 (0.0)	(0.0, 0.0)
Breast cancer stage II	1 (0.0)	(0.0, 0.0)
Rectal cancer	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	774 (4.9)	(4.5, 5.2)
Headache	733 (4.6)	(4.3, 4.9)
Dizziness	22 (0.1)	(0.1, 0.2)
Lethargy	8 (0.1)	(0.0, 0.1)
Paraesthesia	8 (0.1)	(0.0, 0.1)
Somnolence	5 (0.0)	(0.0, 0.1)
Disturbance in attention	4 (0.0)	(0.0, 0.1)
Dysgeusia	2 (0.0)	(0.0, 0.0)
Hyperaesthesia	2 (0.0)	(0.0, 0.0)
Hypoaesthesia	2 (0.0)	(0.0, 0.0)
Tremor	2 (0.0)	(0.0, 0.0)
Balance disorder	1 (0.0)	(0.0, 0.0)
Cognitive disorder	1 (0.0)	(0.0, 0.0)
Facial paralysis	1 (0.0)	(0.0, 0.0)
Head discomfort	1 (0.0)	(0.0, 0.0)
Hypogeusia	1 (0.0)	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)
Migraine	1 (0.0)	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.0)
Speech disorder	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	16 (0.1)	(0.1, 0.2)
Insomnia	6 (0.0)	(0.0, 0.1)

14.155. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 4 to 7 Days After Dose 4, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=15911) n[b] (%)	(95% CI[c])
Confusional state	2 (0.0)	(0.0, 0.0)
Abnormal dreams	1 (0.0)	(0.0, 0.0)
Anxiety	1 (0.0)	(0.0, 0.0)
Attention deficit hyperactivity disorder	1 (0.0)	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.0)
Irritability	1 (0.0)	(0.0, 0.0)
Mental fatigue	1 (0.0)	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)
Sleep disorder	1 (0.0)	(0.0, 0.0)
Thinking abnormal	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	5 (0.0)	(0.0, 0.1)
Dysuria	2 (0.0)	(0.0, 0.0)
Haematuria	1 (0.0)	(0.0, 0.0)
Urinary hesitation	1 (0.0)	(0.0, 0.0)
Urinary retention	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	3 (0.0)	(0.0, 0.1)
Breast cyst	1 (0.0)	(0.0, 0.0)
Breast discharge	1 (0.0)	(0.0, 0.0)
Vaginal lesion	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	18 (0.1)	(0.1, 0.2)
Nasal congestion	4 (0.0)	(0.0, 0.1)
Rhinorrhoea	4 (0.0)	(0.0, 0.1)
Cough	2 (0.0)	(0.0, 0.0)
Epistaxis	2 (0.0)	(0.0, 0.0)
Asthma	1 (0.0)	(0.0, 0.0)
Dyspnoea	1 (0.0)	(0.0, 0.0)
Immune-mediated pneumonitis	1 (0.0)	(0.0, 0.0)
Paranasal sinus discomfort	1 (0.0)	(0.0, 0.0)
Pleuritic pain	1 (0.0)	(0.0, 0.0)
Pulmonary embolism	1 (0.0)	(0.0, 0.0)
Upper respiratory tract congestion	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	39 (0.2)	(0.2, 0.3)

14.155. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 4 to 7 Days After Dose 4, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=15911) n[b] (%)	 (95% CI[c])
Hyperhidrosis	11 (0.1)	(0.0, 0.1)
Rash	6 (0.0)	(0.0, 0.1)
Night sweats	3 (0.0)	(0.0, 0.1)
Skin lesion	3 (0.0)	(0.0, 0.1)
Pruritus	2 (0.0)	(0.0, 0.0)
Rash erythematous	2 (0.0)	(0.0, 0.0)
Urticaria	2 (0.0)	(0.0, 0.0)
Acne	1 (0.0)	(0.0, 0.0)
Alopecia	1 (0.0)	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)
Dermatitis contact	1 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)
Erythema	1 (0.0)	(0.0, 0.0)
Erythema nodosum	1 (0.0)	(0.0, 0.0)
Ingrowing nail	1 (0.0)	(0.0, 0.0)
Lichen sclerosus	1 (0.0)	(0.0, 0.0)
Petechiae	1 (0.0)	(0.0, 0.0)
Rash pruritic	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	10 (0.1)	(0.0, 0.1)
Hypertension	5 (0.0)	(0.0, 0.1)
Flushing	2 (0.0)	(0.0, 0.0)
Hot flush	1 (0.0)	(0.0, 0.0)
Peripheral coldness	1 (0.0)	(0.0, 0.0)
Venous thrombosis limb	1 (0.0)	(0.0, 0.0)

14.155. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 4 to 7 Days After Dose 4, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=15911)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])

Note: Dose 4 = second dose of BNT162b2 (30 µg).
Note: Subjects who did not receive Dose 4 or who received a different vaccine at Dose 3 and Dose 4 were excluded from this table.
Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_pd2_d4_p3_saf

14.156. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=582, TE[b]=0.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	132	222.9	(186.5, 264.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	2	3.4	(0.4, 12.2)
Lymphadenopathy	2	3.4	(0.4, 12.2)
EYE DISORDERS	1	1.7	(0.0, 9.4)
Eye pain	1	1.7	(0.0, 9.4)
GASTROINTESTINAL DISORDERS	5	8.4	(2.7, 19.7)
Diarrhoea	3	5.1	(1.0, 14.8)
Gastrointestinal necrosis	1	1.7	(0.0, 9.4)
Nausea	2	3.4	(0.4, 12.2)
Small intestinal obstruction	1	1.7	(0.0, 9.4)
Vomiting	1	1.7	(0.0, 9.4)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	108	182.4	(149.6, 220.2)
Asthenia	1	1.7	(0.0, 9.4)
Chills	30	50.7	(34.2, 72.3)
Fatigue	30	50.7	(34.2, 72.3)
Injection site erythema	1	1.7	(0.0, 9.4)
Injection site pain	80	135.1	(107.1, 168.1)
Injection site pruritus	1	1.7	(0.0, 9.4)
Injection site swelling	3	5.1	(1.0, 14.8)
Malaise	2	3.4	(0.4, 12.2)
Pain	9	15.2	(6.9, 28.9)
Pyrexia	21	35.5	(22.0, 54.2)
Swelling	1	1.7	(0.0, 9.4)
INFECTIONS AND INFESTATIONS	2	3.4	(0.4, 12.2)
Ear infection	1	1.7	(0.0, 9.4)
Tooth infection	1	1.7	(0.0, 9.4)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3	5.1	(1.0, 14.8)
Exposure during pregnancy	1	1.7	(0.0, 9.4)
Maternal exposure during pregnancy	1	1.7	(0.0, 9.4)

14.156. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=582, TE[b]=0.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Postoperative ileus	1	1.7	(0.0, 9.4)
INVESTIGATIONS	2	3.4	(0.4, 12.2)
Body temperature increased	2	3.4	(0.4, 12.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	43	72.6	(52.6, 97.8)
Arthralgia	3	5.1	(1.0, 14.8)
Back pain	3	5.1	(1.0, 14.8)
Myalgia	38	64.2	(45.4, 88.1)
Pain in extremity	2	3.4	(0.4, 12.2)
Sjogren's syndrome	1	1.7	(0.0, 9.4)
NERVOUS SYSTEM DISORDERS	40	67.5	(48.3, 92.0)
Dizziness	2	3.4	(0.4, 12.2)
Facial paralysis	1	1.7	(0.0, 9.4)
Headache	39	65.9	(46.8, 90.0)
Paraesthesia	1	1.7	(0.0, 9.4)
PSYCHIATRIC DISORDERS	3	5.1	(1.0, 14.8)
Attention deficit hyperactivity disorder	1	1.7	(0.0, 9.4)
Confusional state	1	1.7	(0.0, 9.4)
Depression	1	1.7	(0.0, 9.4)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1	1.7	(0.0, 9.4)
Skin lesion	1	1.7	(0.0, 9.4)

14.156. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=582, TE^b=0.6)		
System Organ Class Preferred Term	**n[c]**	**IR (/100 PY)[d]**	**(95% CI[e])**

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 base p3x saf

14.157. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	4737	205.4	(199.6, 211.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	86	3.7	(3.0, 4.6)
Anaemia	2	0.1	(0.0, 0.3)
Coagulopathy	1	0.0	(0.0, 0.2)
Iron deficiency anaemia	2	0.1	(0.0, 0.3)
Lymph node pain	6	0.3	(0.1, 0.6)
Lymphadenitis	2	0.1	(0.0, 0.3)
Lymphadenopathy	74	3.2	(2.5, 4.0)
CARDIAC DISORDERS	17	0.7	(0.4, 1.2)
Acute myocardial infarction	1	0.0	(0.0, 0.2)
Angina pectoris	1	0.0	(0.0, 0.2)
Arrhythmia	1	0.0	(0.0, 0.2)
Arteriospasm coronary	1	0.0	(0.0, 0.2)
Atrial fibrillation	5	0.2	(0.1, 0.5)
Atrial flutter	1	0.0	(0.0, 0.2)
Cardiac failure congestive	1	0.0	(0.0, 0.2)
Cardio-respiratory arrest	1	0.0	(0.0, 0.2)
Cardiovascular disorder	1	0.0	(0.0, 0.2)
Coronary artery disease	1	0.0	(0.0, 0.2)
Ischaemic cardiomyopathy	1	0.0	(0.0, 0.2)
Myocardial infarction	1	0.0	(0.0, 0.2)
Palpitations	1	0.0	(0.0, 0.2)
Supraventricular tachycardia	1	0.0	(0.0, 0.2)
Tachycardia	2	0.1	(0.0, 0.3)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	4	0.2	(0.0, 0.4)
Atrial septal defect	1	0.0	(0.0, 0.2)
BRCA2 gene mutation	1	0.0	(0.0, 0.2)
Factor II mutation	1	0.0	(0.0, 0.2)
Hypertrophic cardiomyopathy	1	0.0	(0.0, 0.2)
EAR AND LABYRINTH DISORDERS	18	0.8	(0.5, 1.2)
Cerumen impaction	1	0.0	(0.0, 0.2)

14.157. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Deafness neurosensory	1	0.0	(0.0, 0.2)
Deafness unilateral	1	0.0	(0.0, 0.2)
Ear discomfort	1	0.0	(0.0, 0.2)
Ear pain	4	0.2	(0.0, 0.4)
Eustachian tube dysfunction	2	0.1	(0.0, 0.3)
Hypoacusis	1	0.0	(0.0, 0.2)
Meniere's disease	1	0.0	(0.0, 0.2)
Sudden hearing loss	1	0.0	(0.0, 0.2)
Tinnitus	2	0.1	(0.0, 0.3)
Vertigo	6	0.3	(0.1, 0.6)
ENDOCRINE DISORDERS	4	0.2	(0.0, 0.4)
Hypothyroidism	2	0.1	(0.0, 0.3)
Thyroid disorder	1	0.0	(0.0, 0.2)
Thyroid mass	1	0.0	(0.0, 0.2)
EYE DISORDERS	25	1.1	(0.7, 1.6)
Blepharitis	1	0.0	(0.0, 0.2)
Cataract	4	0.2	(0.0, 0.4)
Conjunctival haemorrhage	1	0.0	(0.0, 0.2)
Dacryostenosis acquired	1	0.0	(0.0, 0.2)
Diplopia	1	0.0	(0.0, 0.2)
Dry eye	1	0.0	(0.0, 0.2)
Erythema of eyelid	1	0.0	(0.0, 0.2)
Eye irritation	1	0.0	(0.0, 0.2)
Eye pain	4	0.2	(0.0, 0.4)
Eye swelling	1	0.0	(0.0, 0.2)
Keratitis	2	0.1	(0.0, 0.3)
Lacrimation increased	3	0.1	(0.0, 0.4)
Meibomianitis	1	0.0	(0.0, 0.2)
Ocular discomfort	1	0.0	(0.0, 0.2)
Visual impairment	1	0.0	(0.0, 0.2)
Vitreous floaters	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	331	14.4	(12.8, 16.0)

14.157. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Abdominal discomfort	4	0.2	(0.0, 0.4)
Abdominal distension	1	0.0	(0.0, 0.2)
Abdominal pain	12	0.5	(0.3, 0.9)
Abdominal pain lower	2	0.1	(0.0, 0.3)
Abdominal pain upper	13	0.6	(0.3, 1.0)
Anal fistula	2	0.1	(0.0, 0.3)
Anal prolapse	1	0.0	(0.0, 0.2)
Chronic gastritis	1	0.0	(0.0, 0.2)
Constipation	4	0.2	(0.0, 0.4)
Dental caries	1	0.0	(0.0, 0.2)
Diarrhoea	88	3.8	(3.1, 4.7)
Dry mouth	3	0.1	(0.0, 0.4)
Duodenitis	1	0.0	(0.0, 0.2)
Dyspepsia	5	0.2	(0.1, 0.5)
Gastric ulcer	1	0.0	(0.0, 0.2)
Gastritis	5	0.2	(0.1, 0.5)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.2)
Gastrointestinal sounds abnormal	1	0.0	(0.0, 0.2)
Gastrooesophageal reflux disease	7	0.3	(0.1, 0.6)
Gingival bleeding	1	0.0	(0.0, 0.2)
Haemorrhoids	1	0.0	(0.0, 0.2)
Hiatus hernia	2	0.1	(0.0, 0.3)
Hyperaesthesia teeth	1	0.0	(0.0, 0.2)
Hypoaesthesia oral	1	0.0	(0.0, 0.2)
Intestinal obstruction	1	0.0	(0.0, 0.2)
Intestinal ulcer perforation	1	0.0	(0.0, 0.2)
Irritable bowel syndrome	2	0.1	(0.0, 0.3)
Large intestine polyp	1	0.0	(0.0, 0.2)
Nausea	157	6.8	(5.8, 8.0)
Oedema mouth	1	0.0	(0.0, 0.2)
Oral mucosal blistering	1	0.0	(0.0, 0.2)
Oral pain	1	0.0	(0.0, 0.2)
Oral pruritus	1	0.0	(0.0, 0.2)

14.157. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pancreatitis acute	2	0.1	(0.0, 0.3)
Retching	1	0.0	(0.0, 0.2)
Stomatitis	2	0.1	(0.0, 0.3)
Submaxillary gland enlargement	1	0.0	(0.0, 0.2)
Tongue disorder	1	0.0	(0.0, 0.2)
Tongue oedema	1	0.0	(0.0, 0.2)
Vomiting	47	2.0	(1.5, 2.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4047	175.5	(170.1, 181.0)
Application site pain	2	0.1	(0.0, 0.3)
Asthenia	35	1.5	(1.1, 2.1)
Axillary pain	3	0.1	(0.0, 0.4)
Chest discomfort	2	0.1	(0.0, 0.3)
Chest pain	4	0.2	(0.0, 0.4)
Chills	960	41.6	(39.0, 44.3)
Crying	1	0.0	(0.0, 0.2)
Discomfort	2	0.1	(0.0, 0.3)
Drug withdrawal syndrome	1	0.0	(0.0, 0.2)
Facial pain	1	0.0	(0.0, 0.2)
Fatigue	1339	58.1	(55.0, 61.3)
Feeling abnormal	6	0.3	(0.1, 0.6)
Feeling cold	2	0.1	(0.0, 0.3)
Feeling hot	5	0.2	(0.1, 0.5)
Gait disturbance	1	0.0	(0.0, 0.2)
Implant site pain	1	0.0	(0.0, 0.2)
Inflammation	1	0.0	(0.0, 0.2)
Influenza like illness	1	0.0	(0.0, 0.2)
Injection site bruising	16	0.7	(0.4, 1.1)
Injection site discomfort	3	0.1	(0.0, 0.4)
Injection site erythema	64	2.8	(2.1, 3.5)
Injection site haematoma	2	0.1	(0.0, 0.3)
Injection site haemorrhage	1	0.0	(0.0, 0.2)
Injection site hypersensitivity	1	0.0	(0.0, 0.2)

14.157. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site hypoaesthesia	2	0.1	(0.0, 0.3)
Injection site induration	1	0.0	(0.0, 0.2)
Injection site irritation	1	0.0	(0.0, 0.2)
Injection site lymphadenopathy	1	0.0	(0.0, 0.2)
Injection site mass	1	0.0	(0.0, 0.2)
Injection site nodule	2	0.1	(0.0, 0.3)
Injection site oedema	2	0.1	(0.0, 0.3)
Injection site pain	2853	123.7	(119.2, 128.3)
Injection site pruritus	15	0.7	(0.4, 1.1)
Injection site rash	4	0.2	(0.0, 0.4)
Injection site reaction	2	0.1	(0.0, 0.3)
Injection site swelling	62	2.7	(2.1, 3.4)
Injection site urticaria	1	0.0	(0.0, 0.2)
Injection site warmth	3	0.1	(0.0, 0.4)
Malaise	81	3.5	(2.8, 4.4)
Non-cardiac chest pain	1	0.0	(0.0, 0.2)
Oedema peripheral	2	0.1	(0.0, 0.3)
Pain	381	16.5	(14.9, 18.3)
Pelvic mass	1	0.0	(0.0, 0.2)
Peripheral swelling	7	0.3	(0.1, 0.6)
Pyrexia	884	38.3	(35.8, 40.9)
Swelling	2	0.1	(0.0, 0.3)
Swelling face	4	0.2	(0.0, 0.4)
Vaccination site pain	3	0.1	(0.0, 0.4)
Vaccination site reaction	1	0.0	(0.0, 0.2)
Vessel puncture site haematoma	1	0.0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	3	0.1	(0.0, 0.4)
Cholecystitis	1	0.0	(0.0, 0.2)
Cholelithiasis	1	0.0	(0.0, 0.2)
Hepatitis acute	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	7	0.3	(0.1, 0.6)
Allergy to vaccine	1	0.0	(0.0, 0.2)

14.157. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Anaphylactoid reaction	1	0.0	(0.0, 0.2)
Hypersensitivity	1	0.0	(0.0, 0.2)
Seasonal allergy	4	0.2	(0.0, 0.4)
INFECTIONS AND INFESTATIONS	134	5.8	(4.9, 6.9)
Abscess	1	0.0	(0.0, 0.2)
Appendicitis perforated	1	0.0	(0.0, 0.2)
Asymptomatic bacteriuria	1	0.0	(0.0, 0.2)
COVID-19 pneumonia	1	0.0	(0.0, 0.2)
Candida infection	1	0.0	(0.0, 0.2)
Cellulitis	3	0.1	(0.0, 0.4)
Chlamydial infection	1	0.0	(0.0, 0.2)
Clostridium difficile infection	1	0.0	(0.0, 0.2)
Conjunctivitis	6	0.3	(0.1, 0.6)
Cystitis	1	0.0	(0.0, 0.2)
Demodicidosis	1	0.0	(0.0, 0.2)
Diverticulitis	2	0.1	(0.0, 0.3)
Ear infection	7	0.3	(0.1, 0.6)
Eye infection	1	0.0	(0.0, 0.2)
Focal peritonitis	1	0.0	(0.0, 0.2)
Folliculitis	1	0.0	(0.0, 0.2)
Fungal skin infection	3	0.1	(0.0, 0.4)
Genital herpes	1	0.0	(0.0, 0.2)
Genital herpes simplex	2	0.1	(0.0, 0.3)
Helicobacter gastritis	1	0.0	(0.0, 0.2)
Herpes simplex	2	0.1	(0.0, 0.3)
Herpes zoster	8	0.3	(0.1, 0.7)
Hordeolum	2	0.1	(0.0, 0.3)
Infected cyst	1	0.0	(0.0, 0.2)
Infection	1	0.0	(0.0, 0.2)
Labyrinthitis	1	0.0	(0.0, 0.2)
Localised infection	2	0.1	(0.0, 0.3)
Mastitis	1	0.0	(0.0, 0.2)
Onychomycosis	1	0.0	(0.0, 0.2)

14.157. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Oral candidiasis	1	0.0	(0.0, 0.2)
Oral herpes	3	0.1	(0.0, 0.4)
Osteomyelitis	1	0.0	(0.0, 0.2)
Otitis externa	2	0.1	(0.0, 0.3)
Otitis media	2	0.1	(0.0, 0.3)
Pelvic abscess	1	0.0	(0.0, 0.2)
Pneumonia	2	0.1	(0.0, 0.3)
Postoperative wound infection	1	0.0	(0.0, 0.2)
Rhinitis	2	0.1	(0.0, 0.3)
Sinusitis	7	0.3	(0.1, 0.6)
Subcutaneous abscess	2	0.1	(0.0, 0.3)
Suspected COVID-19	1	0.0	(0.0, 0.2)
Taeniasis	1	0.0	(0.0, 0.2)
Tinea infection	1	0.0	(0.0, 0.2)
Tinea pedis	2	0.1	(0.0, 0.3)
Tonsillitis	2	0.1	(0.0, 0.3)
Tooth abscess	4	0.2	(0.0, 0.4)
Tooth infection	11	0.5	(0.2, 0.9)
Urinary tract infection	30	1.3	(0.9, 1.9)
Urosepsis	1	0.0	(0.0, 0.2)
Vulvitis	1	0.0	(0.0, 0.2)
Vulvovaginal candidiasis	3	0.1	(0.0, 0.4)
Vulvovaginal mycotic infection	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	86	3.7	(3.0, 4.6)
Animal bite	1	0.0	(0.0, 0.2)
Ankle fracture	2	0.1	(0.0, 0.3)
Arthropod bite	3	0.1	(0.0, 0.4)
Chest injury	1	0.0	(0.0, 0.2)
Contusion	9	0.4	(0.2, 0.7)
Corneal abrasion	1	0.0	(0.0, 0.2)
Exposure during pregnancy	4	0.2	(0.0, 0.4)
Eye contusion	1	0.0	(0.0, 0.2)
Facial bones fracture	1	0.0	(0.0, 0.2)

14.157. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Fall	20	0.9	(0.5, 1.3)
Fibula fracture	2	0.1	(0.0, 0.3)
Foot fracture	4	0.2	(0.0, 0.4)
Frostbite	1	0.0	(0.0, 0.2)
Hand fracture	3	0.1	(0.0, 0.4)
Head injury	1	0.0	(0.0, 0.2)
Injection related reaction	1	0.0	(0.0, 0.2)
Joint dislocation	1	0.0	(0.0, 0.2)
Ligament injury	1	0.0	(0.0, 0.2)
Ligament sprain	6	0.3	(0.1, 0.6)
Limb injury	4	0.2	(0.0, 0.4)
Lip injury	1	0.0	(0.0, 0.2)
Lower limb fracture	1	0.0	(0.0, 0.2)
Maternal exposure during pregnancy	2	0.1	(0.0, 0.3)
Meniscus injury	1	0.0	(0.0, 0.2)
Muscle rupture	1	0.0	(0.0, 0.2)
Muscle strain	2	0.1	(0.0, 0.3)
Procedural pain	5	0.2	(0.1, 0.5)
Radius fracture	1	0.0	(0.0, 0.2)
Road traffic accident	2	0.1	(0.0, 0.3)
Scapula fracture	1	0.0	(0.0, 0.2)
Seroma	1	0.0	(0.0, 0.2)
Skin abrasion	2	0.1	(0.0, 0.3)
Skin laceration	10	0.4	(0.2, 0.8)
Spinal fracture	1	0.0	(0.0, 0.2)
Subdural haematoma	1	0.0	(0.0, 0.2)
Tendon injury	1	0.0	(0.0, 0.2)
Tendon rupture	1	0.0	(0.0, 0.2)
Thermal burn	2	0.1	(0.0, 0.3)
Tooth fracture	6	0.3	(0.1, 0.6)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.2)
Upper limb fracture	2	0.1	(0.0, 0.3)
Wound	1	0.0	(0.0, 0.2)

14.157. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Wrist fracture	1	0.0	(0.0, 0.2)
INVESTIGATIONS	104	4.5	(3.7, 5.5)
Alanine aminotransferase increased	2	0.1	(0.0, 0.3)
Antinuclear antibody positive	1	0.0	(0.0, 0.2)
Aspartate aminotransferase increased	2	0.1	(0.0, 0.3)
Blood cholesterol increased	3	0.1	(0.0, 0.4)
Blood pressure increased	6	0.3	(0.1, 0.6)
Blood testosterone decreased	2	0.1	(0.0, 0.3)
Body temperature increased	88	3.8	(3.1, 4.7)
C-reactive protein increased	1	0.0	(0.0, 0.2)
Heart rate increased	1	0.0	(0.0, 0.2)
SARS-CoV-2 antibody test positive	1	0.0	(0.0, 0.2)
Troponin increased	1	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	29	1.3	(0.8, 1.8)
Decreased appetite	14	0.6	(0.3, 1.0)
Diabetes mellitus	1	0.0	(0.0, 0.2)
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.2)
Dyslipidaemia	2	0.1	(0.0, 0.3)
Glucose tolerance impaired	2	0.1	(0.0, 0.3)
Gout	1	0.0	(0.0, 0.2)
Hypercholesterolaemia	1	0.0	(0.0, 0.2)
Hyperglycaemia	2	0.1	(0.0, 0.3)
Insulin resistance	2	0.1	(0.0, 0.3)
Lactic acidosis	1	0.0	(0.0, 0.2)
Type 2 diabetes mellitus	2	0.1	(0.0, 0.3)
Vitamin D deficiency	1	0.0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1197	51.9	(49.0, 54.9)
Arthralgia	145	6.3	(5.3, 7.4)
Arthritis	3	0.1	(0.0, 0.4)
Back pain	28	1.2	(0.8, 1.8)
Bursitis	1	0.0	(0.0, 0.2)
Flank pain	2	0.1	(0.0, 0.3)

14.157. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Foot deformity	1	0.0	(0.0, 0.2)
Groin pain	1	0.0	(0.0, 0.2)
Intervertebral disc protrusion	2	0.1	(0.0, 0.3)
Joint range of motion decreased	2	0.1	(0.0, 0.3)
Joint swelling	1	0.0	(0.0, 0.2)
Limb discomfort	1	0.0	(0.0, 0.2)
Mobility decreased	1	0.0	(0.0, 0.2)
Muscle fatigue	2	0.1	(0.0, 0.3)
Muscle spasms	1	0.0	(0.0, 0.2)
Muscular weakness	4	0.2	(0.0, 0.4)
Musculoskeletal chest pain	1	0.0	(0.0, 0.2)
Musculoskeletal pain	1	0.0	(0.0, 0.2)
Musculoskeletal stiffness	11	0.5	(0.2, 0.9)
Myalgia	884	38.3	(35.8, 40.9)
Neck pain	11	0.5	(0.2, 0.9)
Osteoarthritis	9	0.4	(0.2, 0.7)
Osteoporosis	1	0.0	(0.0, 0.2)
Pain in extremity	151	6.5	(5.5, 7.7)
Periarthritis	1	0.0	(0.0, 0.2)
Plantar fasciitis	3	0.1	(0.0, 0.4)
Rheumatoid arthritis	1	0.0	(0.0, 0.2)
Rotator cuff syndrome	2	0.1	(0.0, 0.3)
Sacroiliitis	1	0.0	(0.0, 0.2)
Synovial cyst	1	0.0	(0.0, 0.2)
Temporomandibular joint syndrome	1	0.0	(0.0, 0.2)
Tendonitis	1	0.0	(0.0, 0.2)
Trigger finger	1	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	13	0.6	(0.3, 1.0)
Bladder neoplasm	1	0.0	(0.0, 0.2)
Bowen's disease	1	0.0	(0.0, 0.2)
Brain neoplasm	1	0.0	(0.0, 0.2)
Breast cancer	1	0.0	(0.0, 0.2)

14.157. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Breast cancer stage II	1	0.0	(0.0, 0.2)
Hepatic cancer	1	0.0	(0.0, 0.2)
Lipoma	1	0.0	(0.0, 0.2)
Meningioma	1	0.0	(0.0, 0.2)
Neoplasm	1	0.0	(0.0, 0.2)
Non-small cell lung cancer stage III	1	0.0	(0.0, 0.2)
Rectal cancer	1	0.0	(0.0, 0.2)
Seborrhoeic keratosis	1	0.0	(0.0, 0.2)
Skin papilloma	1	0.0	(0.0, 0.2)
Squamous cell carcinoma	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	1156	50.1	(47.3, 53.1)
Amnesia	1	0.0	(0.0, 0.2)
Arachnoid cyst	1	0.0	(0.0, 0.2)
Balance disorder	2	0.1	(0.0, 0.3)
Brachial plexopathy	1	0.0	(0.0, 0.2)
Carpal tunnel syndrome	1	0.0	(0.0, 0.2)
Cerebrovascular accident	4	0.2	(0.0, 0.4)
Cervical radiculopathy	1	0.0	(0.0, 0.2)
Cognitive disorder	1	0.0	(0.0, 0.2)
Disturbance in attention	4	0.2	(0.0, 0.4)
Dizziness	45	2.0	(1.4, 2.6)
Dysgeusia	2	0.1	(0.0, 0.3)
Encephalopathy	1	0.0	(0.0, 0.2)
Facial paralysis	2	0.1	(0.0, 0.3)
Head discomfort	1	0.0	(0.0, 0.2)
Headache	1064	46.1	(43.4, 49.0)
Hemiplegia	1	0.0	(0.0, 0.2)
Hyperaesthesia	2	0.1	(0.0, 0.3)
Hypoaesthesia	2	0.1	(0.0, 0.3)
Hypogeusia	1	0.0	(0.0, 0.2)
Lethargy	9	0.4	(0.2, 0.7)
Loss of consciousness	1	0.0	(0.0, 0.2)
Mental impairment	2	0.1	(0.0, 0.3)

14.157. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Migraine	6	0.3	(0.1, 0.6)
Migraine with aura	1	0.0	(0.0, 0.2)
Nerve compression	1	0.0	(0.0, 0.2)
Paraesthesia	13	0.6	(0.3, 1.0)
Parosmia	1	0.0	(0.0, 0.2)
Piriformis syndrome	1	0.0	(0.0, 0.2)
Presyncope	1	0.0	(0.0, 0.2)
Radiculopathy	1	0.0	(0.0, 0.2)
Sciatica	1	0.0	(0.0, 0.2)
Seizure	1	0.0	(0.0, 0.2)
Somnolence	13	0.6	(0.3, 1.0)
Speech disorder	1	0.0	(0.0, 0.2)
Syncope	4	0.2	(0.0, 0.4)
Transient ischaemic attack	2	0.1	(0.0, 0.3)
Tremor	2	0.1	(0.0, 0.3)
Visual field defect	1	0.0	(0.0, 0.2)
PSYCHIATRIC DISORDERS	40	1.7	(1.2, 2.4)
Abnormal dreams	1	0.0	(0.0, 0.2)
Alcohol withdrawal syndrome	1	0.0	(0.0, 0.2)
Anxiety	9	0.4	(0.2, 0.7)
Attention deficit hyperactivity disorder	2	0.1	(0.0, 0.3)
Bipolar disorder	1	0.0	(0.0, 0.2)
Completed suicide	1	0.0	(0.0, 0.2)
Confusional state	1	0.0	(0.0, 0.2)
Depression	2	0.1	(0.0, 0.3)
Generalised anxiety disorder	1	0.0	(0.0, 0.2)
Insomnia	12	0.5	(0.3, 0.9)
Irritability	2	0.1	(0.0, 0.3)
Major depression	1	0.0	(0.0, 0.2)
Mental fatigue	1	0.0	(0.0, 0.2)
Mental status changes	1	0.0	(0.0, 0.2)
Restlessness	2	0.1	(0.0, 0.3)
Sleep disorder	2	0.1	(0.0, 0.3)

14.157. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Suicidal ideation	1	0.0	(0.0, 0.2)
Suicide attempt	1	0.0	(0.0, 0.2)
Thinking abnormal	1	0.0	(0.0, 0.2)
RENAL AND URINARY DISORDERS	21	0.9	(0.6, 1.4)
Acute kidney injury	1	0.0	(0.0, 0.2)
Bladder neck obstruction	1	0.0	(0.0, 0.2)
Chronic kidney disease	1	0.0	(0.0, 0.2)
Dysuria	6	0.3	(0.1, 0.6)
Haematuria	1	0.0	(0.0, 0.2)
Hypertonic bladder	2	0.1	(0.0, 0.3)
Nephrolithiasis	4	0.2	(0.0, 0.4)
Pollakiuria	1	0.0	(0.0, 0.2)
Urinary bladder polyp	1	0.0	(0.0, 0.2)
Urinary hesitation	1	0.0	(0.0, 0.2)
Urinary retention	1	0.0	(0.0, 0.2)
Urinary tract obstruction	1	0.0	(0.0, 0.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	12	0.5	(0.3, 0.9)
Benign prostatic hyperplasia	3	0.1	(0.0, 0.4)
Breast cyst	1	0.0	(0.0, 0.2)
Breast discharge	1	0.0	(0.0, 0.2)
Endometriosis	1	0.0	(0.0, 0.2)
Metrorrhagia	2	0.1	(0.0, 0.3)
Ovarian cyst	1	0.0	(0.0, 0.2)
Pelvic pain	1	0.0	(0.0, 0.2)
Sexual dysfunction	1	0.0	(0.0, 0.2)
Testicular pain	1	0.0	(0.0, 0.2)
Uterine haemorrhage	1	0.0	(0.0, 0.2)
Vaginal lesion	1	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	37	1.6	(1.1, 2.2)
Acute respiratory failure	2	0.1	(0.0, 0.3)
Asthma	1	0.0	(0.0, 0.2)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.2)

14.157. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Cough	3	0.1	(0.0, 0.4)
Dyspnoea	2	0.1	(0.0, 0.3)
Epistaxis	3	0.1	(0.0, 0.4)
Immune-mediated pneumonitis	1	0.0	(0.0, 0.2)
Nasal congestion	5	0.2	(0.1, 0.5)
Nasal septum deviation	1	0.0	(0.0, 0.2)
Oropharyngeal pain	1	0.0	(0.0, 0.2)
Paranasal sinus discomfort	1	0.0	(0.0, 0.2)
Pleuritic pain	1	0.0	(0.0, 0.2)
Pulmonary embolism	4	0.2	(0.0, 0.4)
Rhinitis allergic	4	0.2	(0.0, 0.4)
Rhinorrhoea	6	0.3	(0.1, 0.6)
Sinus congestion	1	0.0	(0.0, 0.2)
Upper respiratory tract congestion	1	0.0	(0.0, 0.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	84	3.6	(2.9, 4.5)
Acne	1	0.0	(0.0, 0.2)
Actinic keratosis	3	0.1	(0.0, 0.4)
Alopecia	2	0.1	(0.0, 0.3)
Angioedema	1	0.0	(0.0, 0.2)
Cold sweat	1	0.0	(0.0, 0.2)
Dermatitis	2	0.1	(0.0, 0.3)
Dermatitis contact	6	0.3	(0.1, 0.6)
Dry skin	1	0.0	(0.0, 0.2)
Ecchymosis	3	0.1	(0.0, 0.4)
Erythema	2	0.1	(0.0, 0.3)
Erythema nodosum	1	0.0	(0.0, 0.2)
Hyperhidrosis	15	0.7	(0.4, 1.1)
Ingrowing nail	3	0.1	(0.0, 0.4)
Lichen sclerosus	1	0.0	(0.0, 0.2)
Night sweats	7	0.3	(0.1, 0.6)
Petechiae	1	0.0	(0.0, 0.2)
Pruritus	6	0.3	(0.1, 0.6)
Rash	16	0.7	(0.4, 1.1)

14.157. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Rash erythematous	2	0.1	(0.0, 0.3)
Rash pruritic	1	0.0	(0.0, 0.2)
Rash vesicular	1	0.0	(0.0, 0.2)
Skin lesion	3	0.1	(0.0, 0.4)
Skin ulcer	1	0.0	(0.0, 0.2)
Urticaria	7	0.3	(0.1, 0.6)
SURGICAL AND MEDICAL PROCEDURES	9	0.4	(0.2, 0.7)
Blepharoplasty	1	0.0	(0.0, 0.2)
Chondroplasty	1	0.0	(0.0, 0.2)
Finger repair operation	1	0.0	(0.0, 0.2)
Hysterectomy	2	0.1	(0.0, 0.3)
Injection	1	0.0	(0.0, 0.2)
Spinal fusion surgery	1	0.0	(0.0, 0.2)
Tooth extraction	2	0.1	(0.0, 0.3)
VASCULAR DISORDERS	45	2.0	(1.4, 2.6)
Aortic aneurysm	1	0.0	(0.0, 0.2)
Aortic arteriosclerosis	1	0.0	(0.0, 0.2)
Aortic stenosis	1	0.0	(0.0, 0.2)
Blood pressure fluctuation	1	0.0	(0.0, 0.2)
Deep vein thrombosis	3	0.1	(0.0, 0.4)
Flushing	5	0.2	(0.1, 0.5)
Haematoma	2	0.1	(0.0, 0.3)
Hot flush	2	0.1	(0.0, 0.3)
Hypertension	25	1.1	(0.7, 1.6)
Hypotension	1	0.0	(0.0, 0.2)
Peripheral coldness	1	0.0	(0.0, 0.2)
Thrombosis	1	0.0	(0.0, 0.2)
Venous thrombosis limb	1	0.0	(0.0, 0.2)

14.157. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	**n[c]**	**IR (/100 PY)[d]**	**(95% CI[e])**

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 base p3x saf

14.158. Incidence Rates of at Least 1 Related Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	4508	189.5	(184.0, 195.1)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	79	3.3	(2.6, 4.1)
Lymph node pain	6	0.3	(0.1, 0.5)
Lymphadenitis	1	0.0	(0.0, 0.2)
Lymphadenopathy	72	3.0	(2.4, 3.8)
CARDIAC DISORDERS	2	0.1	(0.0, 0.3)
Angina pectoris	1	0.0	(0.0, 0.2)
Tachycardia	1	0.0	(0.0, 0.2)
EAR AND LABYRINTH DISORDERS	4	0.2	(0.0, 0.4)
Ear discomfort	1	0.0	(0.0, 0.2)
Ear pain	1	0.0	(0.0, 0.2)
Hypoacusis	1	0.0	(0.0, 0.2)
Vertigo	2	0.1	(0.0, 0.3)
EYE DISORDERS	9	0.4	(0.2, 0.7)
Dry eye	1	0.0	(0.0, 0.2)
Erythema of eyelid	1	0.0	(0.0, 0.2)
Eye pain	4	0.2	(0.0, 0.4)
Lacrimation increased	1	0.0	(0.0, 0.2)
Ocular discomfort	1	0.0	(0.0, 0.2)
Visual impairment	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	277	11.6	(10.3, 13.1)
Abdominal discomfort	4	0.2	(0.0, 0.4)
Abdominal pain	7	0.3	(0.1, 0.6)
Abdominal pain upper	4	0.2	(0.0, 0.4)
Anal fistula	1	0.0	(0.0, 0.2)
Diarrhoea	88	3.7	(3.0, 4.6)
Dry mouth	2	0.1	(0.0, 0.3)
Dyspepsia	3	0.1	(0.0, 0.4)
Gastritis	1	0.0	(0.0, 0.2)
Gastrointestinal sounds abnormal	1	0.0	(0.0, 0.2)

14.158. Incidence Rates of at Least 1 Related Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hypoaesthesia oral	1	0.0	(0.0, 0.2)
Nausea	158	6.6	(5.6, 7.8)
Oedema mouth	1	0.0	(0.0, 0.2)
Oral pruritus	1	0.0	(0.0, 0.2)
Retching	1	0.0	(0.0, 0.2)
Tongue oedema	1	0.0	(0.0, 0.2)
Vomiting	47	2.0	(1.5, 2.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4147	174.3	(169.1, 179.7)
Application site pain	2	0.1	(0.0, 0.3)
Asthenia	35	1.5	(1.0, 2.0)
Axillary pain	2	0.1	(0.0, 0.3)
Chest discomfort	1	0.0	(0.0, 0.2)
Chest pain	1	0.0	(0.0, 0.2)
Chills	993	41.7	(39.2, 44.4)
Crying	1	0.0	(0.0, 0.2)
Discomfort	1	0.0	(0.0, 0.2)
Facial pain	1	0.0	(0.0, 0.2)
Fatigue	1373	57.7	(54.7, 60.9)
Feeling abnormal	5	0.2	(0.1, 0.5)
Feeling cold	2	0.1	(0.0, 0.3)
Feeling hot	6	0.3	(0.1, 0.5)
Implant site pain	1	0.0	(0.0, 0.2)
Influenza like illness	1	0.0	(0.0, 0.2)
Injection site bruising	16	0.7	(0.4, 1.1)
Injection site discomfort	2	0.1	(0.0, 0.3)
Injection site erythema	66	2.8	(2.1, 3.5)
Injection site haematoma	2	0.1	(0.0, 0.3)
Injection site haemorrhage	1	0.0	(0.0, 0.2)
Injection site hypersensitivity	1	0.0	(0.0, 0.2)
Injection site hypoaesthesia	2	0.1	(0.0, 0.3)
Injection site induration	1	0.0	(0.0, 0.2)
Injection site irritation	1	0.0	(0.0, 0.2)

14.158. Incidence Rates of at Least 1 Related Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site lymphadenopathy	1	0.0	(0.0, 0.2)
Injection site mass	1	0.0	(0.0, 0.2)
Injection site nodule	2	0.1	(0.0, 0.3)
Injection site oedema	2	0.1	(0.0, 0.3)
Injection site pain	2938	123.5	(119.1, 128.1)
Injection site pruritus	18	0.8	(0.4, 1.2)
Injection site rash	4	0.2	(0.0, 0.4)
Injection site reaction	2	0.1	(0.0, 0.3)
Injection site swelling	65	2.7	(2.1, 3.5)
Injection site urticaria	1	0.0	(0.0, 0.2)
Injection site warmth	3	0.1	(0.0, 0.4)
Malaise	83	3.5	(2.8, 4.3)
Non-cardiac chest pain	1	0.0	(0.0, 0.2)
Oedema peripheral	2	0.1	(0.0, 0.3)
Pain	393	16.5	(14.9, 18.2)
Peripheral swelling	5	0.2	(0.1, 0.5)
Pyrexia	905	38.0	(35.6, 40.6)
Swelling	2	0.1	(0.0, 0.3)
Swelling face	2	0.1	(0.0, 0.3)
Vaccination site pain	3	0.1	(0.0, 0.4)
Vaccination site reaction	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	2	0.1	(0.0, 0.3)
Allergy to vaccine	1	0.0	(0.0, 0.2)
Anaphylactoid reaction	1	0.0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	6	0.3	(0.1, 0.5)
Conjunctivitis	1	0.0	(0.0, 0.2)
Herpes zoster	1	0.0	(0.0, 0.2)
Oral herpes	1	0.0	(0.0, 0.2)
Rhinitis	1	0.0	(0.0, 0.2)
Tonsillitis	1	0.0	(0.0, 0.2)
Urinary tract infection	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3	0.1	(0.0, 0.4)

14.158. Incidence Rates of at Least 1 Related Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Contusion	1	0.0	(0.0, 0.2)
Injection related reaction	1	0.0	(0.0, 0.2)
Procedural pain	1	0.0	(0.0, 0.2)
INVESTIGATIONS	94	4.0	(3.2, 4.8)
Blood cholesterol increased	1	0.0	(0.0, 0.2)
Blood pressure increased	1	0.0	(0.0, 0.2)
Body temperature increased	91	3.8	(3.1, 4.7)
Heart rate increased	1	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	16	0.7	(0.4, 1.1)
Decreased appetite	14	0.6	(0.3, 1.0)
Hyperglycaemia	2	0.1	(0.0, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1169	49.1	(46.4, 52.0)
Arthralgia	134	5.6	(4.7, 6.7)
Back pain	15	0.6	(0.4, 1.0)
Flank pain	2	0.1	(0.0, 0.3)
Groin pain	1	0.0	(0.0, 0.2)
Joint range of motion decreased	2	0.1	(0.0, 0.3)
Joint swelling	1	0.0	(0.0, 0.2)
Limb discomfort	1	0.0	(0.0, 0.2)
Muscle fatigue	2	0.1	(0.0, 0.3)
Muscular weakness	4	0.2	(0.0, 0.4)
Musculoskeletal chest pain	1	0.0	(0.0, 0.2)
Musculoskeletal pain	1	0.0	(0.0, 0.2)
Musculoskeletal stiffness	6	0.3	(0.1, 0.5)
Myalgia	920	38.7	(36.2, 41.3)
Neck pain	7	0.3	(0.1, 0.6)
Pain in extremity	148	6.2	(5.3, 7.3)
NERVOUS SYSTEM DISORDERS	1152	48.4	(45.7, 51.3)
Balance disorder	1	0.0	(0.0, 0.2)
Cognitive disorder	1	0.0	(0.0, 0.2)
Disturbance in attention	4	0.2	(0.0, 0.4)
Dizziness	35	1.5	(1.0, 2.0)

14.158. Incidence Rates of at Least 1 Related Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dysgeusia	2	0.1	(0.0, 0.3)
Facial paralysis	3	0.1	(0.0, 0.4)
Head discomfort	1	0.0	(0.0, 0.2)
Headache	1093	45.9	(43.3, 48.8)
Hyperaesthesia	2	0.1	(0.0, 0.3)
Hypoaesthesia	1	0.0	(0.0, 0.2)
Hypogeusia	1	0.0	(0.0, 0.2)
Lethargy	9	0.4	(0.2, 0.7)
Mental impairment	2	0.1	(0.0, 0.3)
Migraine	2	0.1	(0.0, 0.3)
Paraesthesia	11	0.5	(0.2, 0.8)
Parosmia	1	0.0	(0.0, 0.2)
Radiculopathy	1	0.0	(0.0, 0.2)
Somnolence	13	0.5	(0.3, 0.9)
Syncope	1	0.0	(0.0, 0.2)
Tremor	2	0.1	(0.0, 0.3)
PSYCHIATRIC DISORDERS	15	0.6	(0.4, 1.0)
Anxiety	1	0.0	(0.0, 0.2)
Insomnia	8	0.3	(0.1, 0.7)
Irritability	2	0.1	(0.0, 0.3)
Mental fatigue	1	0.0	(0.0, 0.2)
Restlessness	2	0.1	(0.0, 0.3)
Sleep disorder	1	0.0	(0.0, 0.2)
Thinking abnormal	1	0.0	(0.0, 0.2)
RENAL AND URINARY DISORDERS	2	0.1	(0.0, 0.3)
Dysuria	1	0.0	(0.0, 0.2)
Urinary hesitation	1	0.0	(0.0, 0.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2	0.1	(0.0, 0.3)
Metrorrhagia	1	0.0	(0.0, 0.2)
Testicular pain	1	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	16	0.7	(0.4, 1.1)
Cough	2	0.1	(0.0, 0.3)

14.158. Incidence Rates of at Least 1 Related Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Epistaxis	1	0.0	(0.0, 0.2)
Immune-mediated pneumonitis	1	0.0	(0.0, 0.2)
Nasal congestion	3	0.1	(0.0, 0.4)
Oropharyngeal pain	1	0.0	(0.0, 0.2)
Paranasal sinus discomfort	1	0.0	(0.0, 0.2)
Rhinorrhoea	5	0.2	(0.1, 0.5)
Sinus congestion	1	0.0	(0.0, 0.2)
Upper respiratory tract congestion	1	0.0	(0.0, 0.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	52	2.2	(1.6, 2.9)
Angioedema	1	0.0	(0.0, 0.2)
Cold sweat	1	0.0	(0.0, 0.2)
Dermatitis	1	0.0	(0.0, 0.2)
Ecchymosis	1	0.0	(0.0, 0.2)
Erythema nodosum	1	0.0	(0.0, 0.2)
Hyperhidrosis	15	0.6	(0.4, 1.0)
Night sweats	7	0.3	(0.1, 0.6)
Petechiae	1	0.0	(0.0, 0.2)
Pruritus	4	0.2	(0.0, 0.4)
Rash	12	0.5	(0.3, 0.9)
Rash erythematous	2	0.1	(0.0, 0.3)
Rash pruritic	1	0.0	(0.0, 0.2)
Skin lesion	2	0.1	(0.0, 0.3)
Urticaria	6	0.3	(0.1, 0.5)
SURGICAL AND MEDICAL PROCEDURES	1	0.0	(0.0, 0.2)
Injection	1	0.0	(0.0, 0.2)
VASCULAR DISORDERS	8	0.3	(0.1, 0.7)
Flushing	4	0.2	(0.0, 0.4)
Haematoma	1	0.0	(0.0, 0.2)
Hot flush	2	0.1	(0.0, 0.3)
Peripheral coldness	1	0.0	(0.0, 0.2)

14.158. Incidence Rates of at Least 1 Related Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (14:06)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 rel exp p3x saf

14.159. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Vaccination (Dose 3/4), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=19525)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	113 (0.6)	(0.5, 0.7)
ENDOCRINE DISORDERS	1 (0.0)	(0.0, 0.0)
Thyroid disorder	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.0)
Dacryostenosis acquired	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	6 (0.0)	(0.0, 0.1)
Nausea	3 (0.0)	(0.0, 0.0)
Dyspepsia	1 (0.0)	(0.0, 0.0)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)
Oedema mouth	1 (0.0)	(0.0, 0.0)
Tongue oedema	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	90 (0.5)	(0.4, 0.6)
Injection site pain	72 (0.4)	(0.3, 0.5)
Fatigue	10 (0.1)	(0.0, 0.1)
Injection site swelling	3 (0.0)	(0.0, 0.0)
Chills	2 (0.0)	(0.0, 0.0)
Injection site erythema	2 (0.0)	(0.0, 0.0)
Injection site pruritus	2 (0.0)	(0.0, 0.0)
Crying	1 (0.0)	(0.0, 0.0)
Discomfort	1 (0.0)	(0.0, 0.0)
Injection site bruising	1 (0.0)	(0.0, 0.0)
Injection site hypoaesthesia	1 (0.0)	(0.0, 0.0)
Injection site reaction	1 (0.0)	(0.0, 0.0)
Malaise	1 (0.0)	(0.0, 0.0)
Pain	1 (0.0)	(0.0, 0.0)
Pyrexia	1 (0.0)	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)
Allergy to vaccine	1 (0.0)	(0.0, 0.0)

14.159. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Vaccination (Dose 3/4), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=19525)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (0.0)	(0.0, 0.1)
Myalgia	4 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	14 (0.1)	(0.0, 0.1)
Headache	10 (0.1)	(0.0, 0.1)
Dizziness	3 (0.0)	(0.0, 0.0)
Dysgeusia	1 (0.0)	(0.0, 0.0)
Paraesthesia	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.0)
Anxiety	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.0)	(0.0, 0.0)
Rhinorrhoea	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	3 (0.0)	(0.0, 0.0)
Flushing	1 (0.0)	(0.0, 0.0)
Hot flush	1 (0.0)	(0.0, 0.0)
Hypertension	1 (0.0)	(0.0, 0.0)

Note: Dose 3 = first dose of BNT162b2 (30 µg), Dose 4 = second dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
Note: Immediate AE refers to an AE reported in the 30-minute observation period after vaccination.
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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 immd vax1 all p3 saf

14.160. Incidence Rates of at Least 1 Severe Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	142	6.0	(5.0, 7.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1	0.0	(0.0, 0.2)
Anaemia	1	0.0	(0.0, 0.2)
CARDIAC DISORDERS	4	0.2	(0.0, 0.4)
Arteriospasm coronary	1	0.0	(0.0, 0.2)
Cardiac failure congestive	1	0.0	(0.0, 0.2)
Cardiovascular disorder	1	0.0	(0.0, 0.2)
Ischaemic cardiomyopathy	1	0.0	(0.0, 0.2)
Myocardial infarction	1	0.0	(0.0, 0.2)
EAR AND LABYRINTH DISORDERS	1	0.0	(0.0, 0.2)
Vertigo	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	16	0.7	(0.4, 1.1)
Abdominal pain	1	0.0	(0.0, 0.2)
Abdominal pain upper	1	0.0	(0.0, 0.2)
Anal prolapse	1	0.0	(0.0, 0.2)
Constipation	1	0.0	(0.0, 0.2)
Dyspepsia	1	0.0	(0.0, 0.2)
Gastrooesophageal reflux disease	1	0.0	(0.0, 0.2)
Intestinal obstruction	1	0.0	(0.0, 0.2)
Intestinal ulcer perforation	1	0.0	(0.0, 0.2)
Nausea	7	0.3	(0.1, 0.6)
Pancreatitis acute	1	0.0	(0.0, 0.2)
Small intestinal obstruction	1	0.0	(0.0, 0.2)
Vomiting	3	0.1	(0.0, 0.4)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	67	2.8	(2.2, 3.6)
Chills	15	0.6	(0.4, 1.0)
Drug withdrawal syndrome	1	0.0	(0.0, 0.2)
Fatigue	22	0.9	(0.6, 1.4)
Injection site erythema	1	0.0	(0.0, 0.2)
Injection site pain	19	0.8	(0.5, 1.2)

14.160. Incidence Rates of at Least 1 Severe Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pain	5	0.2	(0.1, 0.5)
Peripheral swelling	1	0.0	(0.0, 0.2)
Pyrexia	18	0.8	(0.4, 1.2)
Swelling face	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	1	0.0	(0.0, 0.2)
Hypersensitivity	1	0.0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	5	0.2	(0.1, 0.5)
COVID-19 pneumonia	1	0.0	(0.0, 0.2)
Diverticulitis	1	0.0	(0.0, 0.2)
Pneumonia	1	0.0	(0.0, 0.2)
Tooth abscess	1	0.0	(0.0, 0.2)
Urosepsis	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	11	0.5	(0.2, 0.8)
Ankle fracture	1	0.0	(0.0, 0.2)
Contusion	1	0.0	(0.0, 0.2)
Fall	5	0.2	(0.1, 0.5)
Lower limb fracture	1	0.0	(0.0, 0.2)
Postoperative ileus	1	0.0	(0.0, 0.2)
Procedural pain	1	0.0	(0.0, 0.2)
Scapula fracture	1	0.0	(0.0, 0.2)
Skin laceration	1	0.0	(0.0, 0.2)
Spinal fracture	1	0.0	(0.0, 0.2)
Subdural haematoma	1	0.0	(0.0, 0.2)
Tendon rupture	1	0.0	(0.0, 0.2)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.2)
INVESTIGATIONS	1	0.0	(0.0, 0.2)
Body temperature increased	1	0.0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	28	1.2	(0.8, 1.7)
Arthralgia	6	0.3	(0.1, 0.5)
Intervertebral disc protrusion	1	0.0	(0.0, 0.2)
Muscle fatigue	1	0.0	(0.0, 0.2)
Muscular weakness	1	0.0	(0.0, 0.2)

14.160. Incidence Rates of at Least 1 Severe Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Myalgia	15	0.6	(0.4, 1.0)
Osteoarthritis	4	0.2	(0.0, 0.4)
Pain in extremity	2	0.1	(0.0, 0.3)
Rotator cuff syndrome	1	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	4	0.2	(0.0, 0.4)
Breast cancer	1	0.0	(0.0, 0.2)
Breast cancer stage II	1	0.0	(0.0, 0.2)
Hepatic cancer	1	0.0	(0.0, 0.2)
Non-small cell lung cancer stage III	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	24	1.0	(0.6, 1.5)
Brachial plexopathy	1	0.0	(0.0, 0.2)
Cerebrovascular accident	1	0.0	(0.0, 0.2)
Dizziness	2	0.1	(0.0, 0.3)
Facial paralysis	1	0.0	(0.0, 0.2)
Headache	18	0.8	(0.4, 1.2)
Loss of consciousness	1	0.0	(0.0, 0.2)
Syncope	2	0.1	(0.0, 0.3)
PSYCHIATRIC DISORDERS	3	0.1	(0.0, 0.4)
Anxiety	1	0.0	(0.0, 0.2)
Bipolar disorder	1	0.0	(0.0, 0.2)
Major depression	1	0.0	(0.0, 0.2)
Suicidal ideation	1	0.0	(0.0, 0.2)
Suicide attempt	1	0.0	(0.0, 0.2)
RENAL AND URINARY DISORDERS	2	0.1	(0.0, 0.3)
Nephrolithiasis	1	0.0	(0.0, 0.2)
Urinary tract obstruction	1	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	4	0.2	(0.0, 0.4)
Acute respiratory failure	1	0.0	(0.0, 0.2)
Dyspnoea	1	0.0	(0.0, 0.2)
Pulmonary embolism	2	0.1	(0.0, 0.3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3	0.1	(0.0, 0.4)

14.160. Incidence Rates of at Least 1 Severe Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hyperhidrosis	1	0.0	(0.0, 0.2)
Rash pruritic	1	0.0	(0.0, 0.2)
Urticaria	1	0.0	(0.0, 0.2)
SURGICAL AND MEDICAL PROCEDURES	1	0.0	(0.0, 0.2)
Spinal fusion surgery	1	0.0	(0.0, 0.2)
VASCULAR DISORDERS	4	0.2	(0.0, 0.4)
Aortic stenosis	1	0.0	(0.0, 0.2)
Hypertension	2	0.1	(0.0, 0.3)
Thrombosis	1	0.0	(0.0, 0.2)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 30MAR2021 (00:50)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA1/adae_s131_sev_exp_p3x_saf

14.161. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	11	0.5	(0.2, 0.8)
CARDIAC DISORDERS	1	0.0	(0.0, 0.2)
Cardio-respiratory arrest	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	2	0.1	(0.0, 0.3)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.2)
Gastrointestinal necrosis	1	0.0	(0.0, 0.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1	0.0	(0.0, 0.2)
Fatigue	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	1	0.0	(0.0, 0.2)
Anaphylactoid reaction	1	0.0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	1	0.0	(0.0, 0.2)
Appendicitis perforated	1	0.0	(0.0, 0.2)
Focal peritonitis	1	0.0	(0.0, 0.2)
Pelvic abscess	1	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	1	0.0	(0.0, 0.2)
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1	0.0	(0.0, 0.2)
Brain neoplasm	1	0.0	(0.0, 0.2)
PSYCHIATRIC DISORDERS	2	0.1	(0.0, 0.3)
Completed suicide	1	0.0	(0.0, 0.2)
Depression	1	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1	0.0	(0.0, 0.2)
Pulmonary embolism	1	0.0	(0.0, 0.2)
VASCULAR DISORDERS	1	0.0	(0.0, 0.2)
Deep vein thrombosis	1	0.0	(0.0, 0.2)

14.161. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 30MAR2021 (00:50)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA1/adae s131 lif exp p3x saf

14.162. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021) – Open-Label Follow-up Period – Subjects Who Originally Received Placebo, had COVID-19 Occurrence After Dose 1 and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=853, TE[b]=0.9)		
Adverse Event	**n[c]**	**IR (/100 PY)[d]**	**(95% CI[e])**
Any event	225	256.8	(224.4, 292.7)
Related[f]	211	240.9	(209.5, 275.6)
Severe	4	4.6	(1.2, 11.7)
Life-threatening	0	0.0	(0.0, 4.2)
Any serious adverse event	3	3.4	(0.7, 10.0)
Related[f]	0	0.0	(0.0, 4.2)
Severe	3	3.4	(0.7, 10.0)
Life-threatening	0	0.0	(0.0, 4.2)
Any adverse event leading to withdrawal	3	3.4	(0.7, 10.0)
Related[f]	3	3.4	(0.7, 10.0)
Severe	1	1.1	(0.0, 6.4)
Life-threatening	0	0.0	(0.0, 4.2)
Death	0	0.0	(0.0, 4.2)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s092 cr cut p3x covid

14.163. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo, had COVID-19 Occurrence After Dose 1 and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=853, TE[b]=0.9)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	225	256.8	(224.4, 292.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	6	6.8	(2.5, 14.9)
Lymphadenopathy	6	6.8	(2.5, 14.9)
CARDIAC DISORDERS	1	1.1	(0.0, 6.4)
Myocardial infarction	1	1.1	(0.0, 6.4)
GASTROINTESTINAL DISORDERS	15	17.1	(9.6, 28.2)
Abdominal pain	1	1.1	(0.0, 6.4)
Diarrhoea	5	5.7	(1.9, 13.3)
Nausea	6	6.8	(2.5, 14.9)
Vomiting	4	4.6	(1.2, 11.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	207	236.3	(205.2, 270.8)
Asthenia	2	2.3	(0.3, 8.2)
Chills	49	55.9	(41.4, 73.9)
Fatigue	64	73.1	(56.3, 93.3)
Inflammation	1	1.1	(0.0, 6.4)
Influenza like illness	1	1.1	(0.0, 6.4)
Injection site bruising	1	1.1	(0.0, 6.4)
Injection site erythema	2	2.3	(0.3, 8.2)
Injection site pain	144	164.4	(138.6, 193.5)
Injection site pruritus	2	2.3	(0.3, 8.2)
Injection site reaction	1	1.1	(0.0, 6.4)
Injection site swelling	3	3.4	(0.7, 10.0)
Malaise	5	5.7	(1.9, 13.3)
Pain	28	32.0	(21.2, 46.2)
Pyrexia	49	55.9	(41.4, 73.9)
Swelling face	1	1.1	(0.0, 6.4)
IMMUNE SYSTEM DISORDERS	1	1.1	(0.0, 6.4)
Allergy to vaccine	1	1.1	(0.0, 6.4)
INFECTIONS AND INFESTATIONS	5	5.7	(1.9, 13.3)
Clostridium difficile infection	1	1.1	(0.0, 6.4)

14.163. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo, had COVID-19 Occurrence After Dose 1 and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=853, TE[b]=0.9)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Otitis externa	1	1.1	(0.0, 6.4)
Tooth infection	1	1.1	(0.0, 6.4)
Urinary tract infection	2	2.3	(0.3, 8.2)
Urosepsis	1	1.1	(0.0, 6.4)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2	2.3	(0.3, 8.2)
Foot fracture	1	1.1	(0.0, 6.4)
Limb injury	1	1.1	(0.0, 6.4)
INVESTIGATIONS	7	8.0	(3.2, 16.5)
Body temperature increased	7	8.0	(3.2, 16.5)
METABOLISM AND NUTRITION DISORDERS	1	1.1	(0.0, 6.4)
Insulin resistance	1	1.1	(0.0, 6.4)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	42	47.9	(34.6, 64.8)
Arthralgia	3	3.4	(0.7, 10.0)
Back pain	2	2.3	(0.3, 8.2)
Myalgia	33	37.7	(25.9, 52.9)
Pain in extremity	5	5.7	(1.9, 13.3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1	1.1	(0.0, 6.4)
Non-small cell lung cancer stage III	1	1.1	(0.0, 6.4)
NERVOUS SYSTEM DISORDERS	58	66.2	(50.3, 85.6)
Dizziness	3	3.4	(0.7, 10.0)
Headache	52	59.4	(44.3, 77.8)
Lethargy	1	1.1	(0.0, 6.4)
Somnolence	2	2.3	(0.3, 8.2)
PSYCHIATRIC DISORDERS	2	2.3	(0.3, 8.2)
Anxiety	1	1.1	(0.0, 6.4)
Attention deficit hyperactivity disorder	1	1.1	(0.0, 6.4)
RENAL AND URINARY DISORDERS	1	1.1	(0.0, 6.4)
Chronic kidney disease	1	1.1	(0.0, 6.4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2	2.3	(0.3, 8.2)
Acute respiratory failure	1	1.1	(0.0, 6.4)

14.163. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo, had COVID-19 Occurrence After Dose 1 and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=853, TE[b]=0.9)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pleuritic pain	1	1.1	(0.0, 6.4)
Pulmonary embolism	1	1.1	(0.0, 6.4)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	5	5.7	(1.9, 13.3)
Actinic keratosis	1	1.1	(0.0, 6.4)
Ecchymosis	1	1.1	(0.0, 6.4)
Rash	1	1.1	(0.0, 6.4)
Urticaria	2	2.3	(0.3, 8.2)
SURGICAL AND MEDICAL PROCEDURES	1	1.1	(0.0, 6.4)
Chondroplasty	1	1.1	(0.0, 6.4)
VASCULAR DISORDERS	1	1.1	(0.0, 6.4)
Flushing	1	1.1	(0.0, 6.4)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 cr cut p3x covid

14.164. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	52 (0.4)	(0.3, 0.5)	49 (0.4)	(0.3, 0.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	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)
Neutropenia	0	(0.0, 0.0)	0	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	8 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.0)	0	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	0	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac arrest	0	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure congestive	0	(0.0, 0.0)	0	(0.0, 0.0)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina pectoris	0	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	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)
Cardiac failure acute	0	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	0	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Junctional ectopic tachycardia	0	(0.0, 0.0)	1 (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)	0	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	0	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular arrhythmia	0	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	(0.0, 0.0)	0	(0.0, 0.0)
Congenital bladder neck obstruction	0	(0.0, 0.0)	0	(0.0, 0.0)

14.164. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Heart disease congenital	0	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	0	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplopia	0	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Small intestinal obstruction	0	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal adhesions	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	0	(0.0, 0.0)	0	(0.0, 0.0)
Colitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Diarrhoea	0	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal mucosa hyperaemia	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)
Inguinal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	0	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal varices haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	0	(0.0, 0.0)
Umbilical hernia	0	(0.0, 0.0)	0	(0.0, 0.0)
Volvulus	0	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chest pain	0	(0.0, 0.0)	0	(0.0, 0.0)

14.164. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	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	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cholecystitis acute	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholelithiasis	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)
Cholecystitis	0	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	0	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	13 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Appendicitis	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pneumonia	0	(0.0, 0.0)	0	(0.0, 0.0)
Cellulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Urinary tract infection	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Appendicitis perforated	0	(0.0, 0.0)	0	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Peritonsillar abscess	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	0	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	0	(0.0, 0.0)	0	(0.0, 0.0)
Anal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial sepsis	0	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Empyema	0	(0.0, 0.0)	0	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.164. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Osteomyelitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis acute	0	(0.0, 0.0)	0	(0.0, 0.0)
Shigella sepsis	0	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Subacute endocarditis	0	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	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)
Upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Overdose	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial bones fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Road traffic accident	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alcohol poisoning	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)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fall	0	(0.0, 0.0)	0	(0.0, 0.0)
Femur fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Spinal column injury	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)
Subdural haematoma	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)

14.164. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Traumatic haemothorax	0	(0.0, 0.0)	0	(0.0, 0.0)
Traumatic intracranial haemorrhage	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)	0	(0.0, 0.0)
Blood glucose abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	0	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Osteoarthritis	0	(0.0, 0.0)	0	(0.0, 0.0)
Arthralgia	0	(0.0, 0.0)	0	(0.0, 0.0)
Back pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscular weakness	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)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Prostate cancer	0	(0.0, 0.0)	0	(0.0, 0.0)
Malignant melanoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma pancreas	0	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	0	(0.0, 0.0)	0	(0.0, 0.0)
Biliary cancer metastatic	0	(0.0, 0.0)	0	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	0	(0.0, 0.0)
Invasive ductal breast carcinoma	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)

14.164. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
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)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to liver	0	(0.0, 0.0)	0	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatic carcinoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Penile neoplasm	0	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer metastatic	0	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cancer	0	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cerebrovascular accident	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ischaemic stroke	0	(0.0, 0.0)	0	(0.0, 0.0)
Transient ischaemic attack	0	(0.0, 0.0)	0	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amyotrophic lateral sclerosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	0	(0.0, 0.0)
Cervicogenic headache	0	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	0	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord compression	0	(0.0, 0.0)	0	(0.0, 0.0)
Transient global amnesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	0	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abortion spontaneous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.0)	4 (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)	0	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.164. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Disorientation	0	(0.0, 0.0)	0	(0.0, 0.0)
Mental disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Nephrolithiasis	0	(0.0, 0.0)	0	(0.0, 0.0)
Acute kidney injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	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 bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian cyst	0	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	0	(0.0, 0.0)
Uterine prolapse	0	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pulmonary embolism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute respiratory failure	0	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonia aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	0	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Deep vein thrombosis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertension	0	(0.0, 0.0)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	0	(0.0, 0.0)
Aortic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arteriosclerosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive crisis	0	(0.0, 0.0)	0	(0.0, 0.0)

14.164. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 ser age pd2 p3 saf

14.165. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	75 (0.8)	(0.7, 1.1)	67 (0.8)	(0.6, 1.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lymphadenopathy	0	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	12 (0.1)	(0.1, 0.2)	15 (0.2)	(0.1, 0.3)
Atrial fibrillation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute coronary syndrome	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Coronary artery disease	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Aortic valve incompetence	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bradycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cardiac arrest	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Acute left ventricular failure	0	(0.0, 0.0)	0	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Angina unstable	0	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	0	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure acute	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)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Junctional ectopic tachycardia	0	(0.0, 0.0)	0	(0.0, 0.0)
Myocardial ischaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
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)
Congenital bladder neck obstruction	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)

14.165. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
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	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Choroidal neovascularisation	0	(0.0, 0.0)	0	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Visual impairment	0	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	5 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.2)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pancreatitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Abdominal adhesions	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain upper	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Colitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gastrointestinal mucosa hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Incarcerated inguinal hernia	0	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia	0	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Obstructive pancreatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal varices haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Umbilical hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Volvulus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	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)	0	(0.0, 0.0)
Chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Death	0	(0.0, 0.0)	0	(0.0, 0.0)

14.165. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Influenza like illness	0	(0.0, 0.0)	0	(0.0, 0.0)
Shoulder injury related to vaccine administration	0	(0.0, 0.0)	0	(0.0, 0.0)
Vascular stent occlusion	0	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cholelithiasis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bile duct stone	0	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Anaphylactic reaction	0	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Drug hypersensitivity	0	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	14 (0.2)	(0.1, 0.3)	15 (0.2)	(0.1, 0.3)
Appendicitis	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Pneumonia	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Cellulitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Urinary tract infection	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
COVID-19	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diverticulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Postoperative wound infection	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anal abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Complicated appendicitis	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)
Meningitis bacterial	0	(0.0, 0.0)	0	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.165. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Peritoneal abscess	0	(0.0, 0.0)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pyelonephritis acute	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
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)
Subacute endocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Suspected COVID-19	0	(0.0, 0.0)	0	(0.0, 0.0)
Upper respiratory tract infection	0	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (0.1)	(0.0, 0.1)	6 (0.1)	(0.0, 0.1)
Overdose	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Facial bones fracture	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Road traffic accident	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Alcohol poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cervical vertebral fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	0	(0.0, 0.0)
Fall	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)
Flail chest	0	(0.0, 0.0)	0	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Head injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hip fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
Humerus fracture	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)
Multiple injuries	0	(0.0, 0.0)	0	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spinal column injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Spinal cord injury cervical	0	(0.0, 0.0)	0	(0.0, 0.0)
Subdural haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Toxicity to various agents	0	(0.0, 0.0)	0	(0.0, 0.0)
Traumatic haemothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.165. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blood glucose abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diabetic ketoacidosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Osteoarthritis	2 (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)
Back pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Muscular weakness	0	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondritis	0	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	8 (0.1)	(0.0, 0.2)	6 (0.1)	(0.0, 0.1)
Prostate cancer	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Malignant melanoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Uterine leiomyoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma gastric	0	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma pancreas	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)
Biliary cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Chronic myeloid leukaemia	0	(0.0, 0.0)	0	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Leydig cell tumour of the testis	0	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	0	(0.0, 0.0)	0	(0.0, 0.0)

14.165. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Metastases to central nervous system	0	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to liver	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pancreatic carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Penile neoplasm	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Prostate cancer metastatic	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thyroid cancer	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	9 (0.1)	(0.0, 0.2)	10 (0.1)	(0.1, 0.2)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Syncope	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Amyotrophic lateral sclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cervicogenic headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Hemiplegic migraine	0	(0.0, 0.0)	0	(0.0, 0.0)
Idiopathic intracranial hypertension	0	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord compression	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)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	0	(0.0, 0.0)
Abortion spontaneous	0	(0.0, 0.0)	0	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	0	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Depression suicidal	0	(0.0, 0.0)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.165. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Mental disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Psychotic disorder	0	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	0	(0.0, 0.0)
RENAL AND URINARY DISORDERS	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acute kidney injury	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Renal colic	0	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	0	(0.0, 0.0)	0	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Breast hyperplasia	0	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ovarian mass	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	6 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Pulmonary embolism	1 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Acute respiratory failure	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	0	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Respiratory arrest	0	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Deep vein thrombosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hypertension	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Aortic stenosis	0	(0.0, 0.0)	0	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive crisis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hypertensive urgency	0	(0.0, 0.0)	0	(0.0, 0.0)

14.165. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 ser age pd2 p3 saf

14.166. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	268	3.2	(2.8, 3.6)	268	3.3	(2.9, 3.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Anaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Microcytic anaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Neutropenia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Thrombocytopenia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
CARDIAC DISORDERS	42	0.5	(0.4, 0.7)	39	0.5	(0.3, 0.6)
Acute coronary syndrome	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Acute left ventricular failure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Acute myocardial infarction	6	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Angina pectoris	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Angina unstable	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic valve incompetence	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Arrhythmia supraventricular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Arteriosclerosis coronary artery	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Arteriospasm coronary	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Atrial fibrillation	5	0.1	(0.0, 0.1)	9	0.1	(0.1, 0.2)
Atrioventricular block complete	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bradycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac arrest	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Cardiac failure acute	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coronary artery disease	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Coronary artery dissection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Coronary artery occlusion	0	0.0	(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, 0.0)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Myocardial infarction	4	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Myocardial ischaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pericarditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tachyarrhythmia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tachycardia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.166. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Ventricular arrhythmia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ventricular tachycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Congenital bladder neck obstruction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Congenital ureteropelvic junction obstruction	0	0.0	(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, 0.0)
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	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Choroidal neovascularisation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diplopia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eye haemorrhage	0	0.0	(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, 0.0)
Retinal artery occlusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Visual impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	23	0.3	(0.2, 0.4)	21	0.3	(0.2, 0.4)
Abdominal adhesions	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abdominal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abdominal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abdominal pain upper	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Colitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Colitis ischaemic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Constipation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diarrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diverticular perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diverticulum intestinal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Duodenal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Enterocolitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Food poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastrointestinal haemorrhage	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal mucosa hyperaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haemorrhoids	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hiatus hernia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ileus	0	0.0	(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, 0.0)

14.166. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Incarcerated inguinal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Inguinal hernia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Intestinal obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal perforation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intestinal strangulation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Large intestine perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Obstructive pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oesophageal food impaction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oesophageal varices haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pancreatic cyst	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pancreatitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis acute	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Retroperitoneal haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Salivary gland calculus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Small intestinal obstruction	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Umbilical hernia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Volvulus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	10	0.1	(0.1, 0.2)	4	0.0	(0.0, 0.1)
Asthenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chest pain	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Drug withdrawal syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Influenza like illness	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Non-cardiac chest pain	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sudden cardiac death	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vascular stent occlusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	12	0.1	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Bile duct stone	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary colic	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cholecystitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholecystitis acute	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Cholecystitis chronic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cholelithiasis	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatocellular injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.166. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anaphylactic shock	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Drug hypersensitivity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	50	0.6	(0.4, 0.8)	57	0.7	(0.5, 0.9)
Abdominal abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abscess intestinal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Appendicitis	14	0.2	(0.1, 0.3)	9	0.1	(0.1, 0.2)
Appendicitis perforated	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arthritis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bacterial sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Brain abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.0)	13	0.2	(0.1, 0.3)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cellulitis	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Complicated appendicitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Device related infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diabetic foot infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diverticulitis	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Emphysematous cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Empyema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Escherichia urinary tract infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Extradural abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gangrene	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastroenteritis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meningitis bacterial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Osteomyelitis	0	0.0	(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, 0.0)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peritonitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritonsillar abscess	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonia	4	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Post procedural infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Postoperative wound infection	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pyelonephritis	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pyelonephritis acute	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Renal abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.166. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Respiratory tract infection viral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sepsis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Septic shock	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Shigella sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Staphylococcal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Staphylococcal sepsis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subacute endocarditis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subcutaneous abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tooth infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Upper respiratory tract infection	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Urinary tract infection	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Urosepsis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	19	0.2	(0.1, 0.4)	26	0.3	(0.2, 0.5)
Alcohol poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ankle fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Brain contusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cervical vertebral fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Colon injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Concussion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Craniocerebral injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Delayed recovery from anaesthesia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Facial bones fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fall	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Femur fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Flail chest	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Foot fracture	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Forearm fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Head injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hip fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Humerus fracture	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Ligament rupture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lower limb fracture	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Lumbar vertebral fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Meniscus injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Multiple injuries	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Overdose	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Patella fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.166. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pelvic fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post procedural haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Post-traumatic pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Procedural haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Radius fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rib fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Road traffic accident	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Spinal column injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spinal cord injury cervical	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Subdural haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tibia fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Toxicity to various agents	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Traumatic haemothorax	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ulna fracture	0	0.0	(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, 0.0)
Wrist fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
INVESTIGATIONS	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Blood glucose abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood pressure increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cardiac stress test abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hepatic enzyme increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Red blood cell morphology abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	4	0.0	(0.0, 0.1)	10	0.1	(0.1, 0.2)
Diabetes mellitus inadequate control	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diabetic ketoacidosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Fluid retention	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperglycaemia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Hypoglycaemia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypokalaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyponatraemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Type 2 diabetes mellitus	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	13	0.2	(0.1, 0.3)	11	0.1	(0.1, 0.2)
Arthralgia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Arthritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Back pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intervertebral disc compression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.166. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Intervertebral disc degeneration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscular weakness	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Osteoarthritis	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Osteochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Psoriatic arthropathy	0	0.0	(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)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	39	0.5	(0.3, 0.6)	35	0.4	(0.3, 0.6)
Acute myeloid leukaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma of colon	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma pancreas	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adrenal gland cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
B-cell lymphoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Benign hydatidiform mole	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary cancer metastatic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bladder cancer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Borderline serous tumour of ovary	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Breast cancer	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Breast cancer in situ	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Breast cancer stage I	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Carcinoid tumour of the stomach	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Colon adenoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gallbladder cancer stage II	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastric cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Invasive ductal breast carcinoma	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Leydig cell tumour of the testis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lipoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lobular breast carcinoma in situ	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lung adenocarcinoma	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Malignant melanoma	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Meningioma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.166. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Metastases to liver	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Non-Hodgkin's lymphoma recurrent	0	0.0	(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, 0.0)
Oropharyngeal cancer recurrent	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oropharyngeal squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pancreatic carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Papillary serous endometrial carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Papillary thyroid cancer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Penile neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Plasma cell myeloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Polycythaemia vera	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Prostate cancer	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Prostate cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Squamous cell carcinoma of head and neck	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Teratoma	0	0.0	(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, 0.0)
Tonsil cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Transitional cell carcinoma	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Uterine cancer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Uterine leiomyoma	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	25	0.3	(0.2, 0.4)	23	0.3	(0.2, 0.4)
Amnesia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Amyotrophic lateral sclerosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Carpal tunnel syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cerebral infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebrovascular accident	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cervicogenic headache	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dementia Alzheimer's type	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dizziness	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Guillain-Barre syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haemorrhagic stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hemiplegic migraine	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Idiopathic intracranial hypertension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intraventricular haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ischaemic stroke	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.166. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Paraesthesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peripheral nerve lesion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Spinal cord compression	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subarachnoid haemorrhage	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Syncope	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Toxic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Transient global amnesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Transient ischaemic attack	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Abortion incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abortion spontaneous	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Retained products of conception	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	5	0.1	(0.0, 0.1)	9	0.1	(0.1, 0.2)
Alcohol abuse	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bipolar disorder	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Depression	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depression suicidal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Disorientation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Major depression	0	0.0	(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, 0.0)
Panic attack	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Suicidal ideation	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Suicide attempt	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	11	0.1	(0.1, 0.2)	8	0.1	(0.0, 0.2)
Acute kidney injury	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hydronephrosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nephrolithiasis	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Renal colic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Subcapsular renal haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ureterolithiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urinary bladder polyp	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)

14.166. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Adnexal torsion	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Breast hyperplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Endometriosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ovarian cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ovarian mass	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rectocele	0	0.0	(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, 0.0)
Vaginal prolapse	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	14	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.3)
Acute respiratory failure	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Asthma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Asthmatic crisis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dyspnoea	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypoxia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Interstitial lung disease	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal septum deviation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pneumonia aspiration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pneumothorax	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pulmonary embolism	5	0.1	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Pulmonary mass	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Respiratory failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Miscarriage of partner	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Finger amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
VASCULAR DISORDERS	12	0.1	(0.1, 0.3)	13	0.2	(0.1, 0.3)
Accelerated hypertension	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Aortic aneurysm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Aortic rupture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Aortic stenosis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Arteriosclerosis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Deep vein thrombosis	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Hypertension	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypertensive crisis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.166. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hypertensive emergency	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypertensive urgency	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Orthostatic hypotension	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Peripheral artery stenosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_sae_exp_p3_saf

14.167. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	103	2.1	(1.7, 2.5)	117	2.4	(2.0, 2.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Microcytic anaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
CARDIAC DISORDERS	9	0.2	(0.1, 0.3)	11	0.2	(0.1, 0.4)
Acute coronary syndrome	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Acute left ventricular failure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Acute myocardial infarction	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angina unstable	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arrhythmia supraventricular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arteriospasm coronary	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrial fibrillation	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Bradycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiac failure congestive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myocardial infarction	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Myocardial ischaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Congenital ureteropelvic junction obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EYE DISORDERS	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Choroidal neovascularisation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Visual impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	10	0.2	(0.1, 0.4)	7	0.1	(0.1, 0.3)
Abdominal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diverticular perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Food poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haemorrhoids	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.167. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Ileus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Impaired gastric emptying	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Incarcerated inguinal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Inguinal hernia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intestinal perforation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Obstructive pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oesophageal food impaction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oesophageal varices haemorrhage	0	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, 0.1)
Pancreatitis acute	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Influenza like illness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Non-cardiac chest pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Shoulder injury related to vaccine administration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vascular stent occlusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	6	0.1	(0.0, 0.3)	5	0.1	(0.0, 0.2)
Bile duct stone	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary colic	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cholecystitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholecystitis acute	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cholecystitis chronic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholelithiasis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatocellular injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Drug hypersensitivity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	26	0.5	(0.3, 0.8)	23	0.5	(0.3, 0.7)
Abdominal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Appendicitis	12	0.2	(0.1, 0.4)	7	0.1	(0.1, 0.3)

14.167. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Arthritis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Cellulitis	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Diabetic foot infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Escherichia urinary tract infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gangrene	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastroenteritis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meningitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peritonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumonia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Postoperative wound infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pyelonephritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Renal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Upper respiratory tract infection	0	0.0	(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)
Urosepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	8	0.2	(0.1, 0.3)	12	0.2	(0.1, 0.4)
Ankle fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cervical vertebral fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colon injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Craniocerebral injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial bones fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Flail chest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foot fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Forearm fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hip fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Humerus fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ligament rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meniscus injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Multiple injuries	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Overdose	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.167. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Procedural haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Road traffic accident	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Spinal cord injury cervical	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tibia fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Toxicity to various agents	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ulna fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper limb fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Wrist fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INVESTIGATIONS	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Red blood cell morphology abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	3	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Diabetic ketoacidosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoglycaemia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypokalaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Type 2 diabetes mellitus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Back pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intervertebral disc degeneration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscular weakness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Psoriatic arthropathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spondylolisthesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	10	0.2	(0.1, 0.4)	12	0.2	(0.1, 0.4)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
B-cell lymphoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Benign hydatidiform mole	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cancer	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Invasive ductal breast carcinoma	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.167. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Leydig cell tumour of the testis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lipoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Malignant melanoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meningioma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papillary thyroid cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Plasma cell myeloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Teratoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uterine leiomyoma	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	11	0.2	(0.1, 0.4)	8	0.2	(0.1, 0.3)
Amnesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Carpal tunnel syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cerebrovascular accident	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Guillain-Barre syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hemiplegic migraine	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Idiopathic intracranial hypertension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ischaemic stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paraesthesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peripheral nerve lesion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Subarachnoid haemorrhage	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Syncope	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Transient ischaemic attack	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.3)
Abortion incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abortion spontaneous	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retained products of conception	0	0.0	(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, 0.3)
Alcohol abuse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depression	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.167. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Depression suicidal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Major depression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Suicidal ideation	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Suicide attempt	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	6	0.1	(0.0, 0.3)	6	0.1	(0.0, 0.3)
Nephrolithiasis	3	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Renal colic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Subcapsular renal haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ureterolithiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urinary bladder polyp	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Adnexal torsion	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Breast hyperplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Endometriosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectocele	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaginal prolapse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Asthmatic crisis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoxia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal septum deviation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumonia aspiration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pulmonary embolism	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Miscarriage of partner	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
VASCULAR DISORDERS	5	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Accelerated hypertension	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deep vein thrombosis	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Hypertensive urgency	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.167. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sae age p3 saf

14.168. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	165	4.9	(4.2, 5.7)	151	4.6	(3.9, 5.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.3)
Anaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Neutropenia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Thrombocytopenia	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
CARDIAC DISORDERS	33	1.0	(0.7, 1.4)	28	0.8	(0.6, 1.2)
Acute coronary syndrome	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Acute myocardial infarction	4	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Angina pectoris	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Angina unstable	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Aortic valve incompetence	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Arteriosclerosis coronary artery	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Atrial fibrillation	5	0.1	(0.0, 0.3)	6	0.2	(0.1, 0.4)
Atrioventricular block complete	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Bradycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cardiac arrest	6	0.2	(0.1, 0.4)	2	0.1	(0.0, 0.2)
Cardiac failure acute	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cardiac failure congestive	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Coronary artery disease	3	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Coronary artery dissection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Coronary artery occlusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Hypertensive heart disease	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Myocardial infarction	4	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Pericarditis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Tachyarrhythmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Tachycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Ventricular arrhythmia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ventricular tachycardia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Congenital bladder neck obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Heart disease congenital	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.168. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Vertigo	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
EYE DISORDERS	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Diplopia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Eye haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Retinal artery occlusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	13	0.4	(0.2, 0.7)	14	0.4	(0.2, 0.7)
Abdominal adhesions	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Abdominal hernia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Abdominal pain upper	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Colitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Colitis ischaemic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Constipation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Diarrhoea	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Diverticulum intestinal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Duodenal obstruction	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Enterocolitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastritis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastrointestinal haemorrhage	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Gastrointestinal mucosa hyperaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Hiatus hernia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Intestinal obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Intestinal strangulation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Large intestine perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pancreatic cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pancreatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pancreatitis acute	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Retroperitoneal haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Salivary gland calculus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Small intestinal obstruction	4	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Umbilical hernia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Volvulus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	7	0.2	(0.1, 0.4)	2	0.1	(0.0, 0.2)

14.168. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Asthenia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Chest pain	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Drug withdrawal syndrome	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Non-cardiac chest pain	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Sudden cardiac death	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	6	0.2	(0.1, 0.4)	2	0.1	(0.0, 0.2)
Cholecystitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Cholecystitis acute	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Cholelithiasis	5	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Anaphylactic shock	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	24	0.7	(0.5, 1.1)	34	1.0	(0.7, 1.4)
Abscess intestinal	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Appendicitis	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Appendicitis perforated	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Bacterial sepsis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Brain abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
COVID-19	0	0.0	(0.0, 0.1)	8	0.2	(0.1, 0.5)
COVID-19 pneumonia	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Cellulitis	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Complicated appendicitis	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Device related infection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Diverticulitis	4	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Emphysematous cholecystitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Empyema	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Extradural abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Osteomyelitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Penile infection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Peritonitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Peritonsillar abscess	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pneumonia	3	0.1	(0.0, 0.3)	8	0.2	(0.1, 0.5)
Post procedural infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Postoperative wound infection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.168. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pyelonephritis	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pyelonephritis acute	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Respiratory tract infection viral	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Sepsis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Septic shock	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Shigella sepsis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Staphylococcal infection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Staphylococcal sepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Subacute endocarditis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Subcutaneous abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Tooth infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Upper respiratory tract infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Urinary tract infection	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	11	0.3	(0.2, 0.6)	14	0.4	(0.2, 0.7)
Alcohol poisoning	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Brain contusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Concussion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Craniocerebral injury	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Delayed recovery from anaesthesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Facial bones fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Fall	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Femur fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Foot fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Head injury	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hip fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Humerus fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Lower limb fracture	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Lumbar vertebral fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Overdose	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Patella fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pelvic fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Post procedural haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Post-traumatic pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Radius fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

14.168. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Rib fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Road traffic accident	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Spinal column injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Subdural haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Traumatic haemothorax	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Wrist fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
INVESTIGATIONS	1	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Blood glucose abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Blood pressure increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cardiac stress test abnormal	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hepatic enzyme increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	1	0.0	(0.0, 0.2)	5	0.2	(0.0, 0.4)
Diabetes mellitus inadequate control	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Fluid retention	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hyperglycaemia	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Hyponatraemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Type 2 diabetes mellitus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	9	0.3	(0.1, 0.5)	5	0.2	(0.0, 0.4)
Arthralgia	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Arthritis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Intervertebral disc compression	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Intervertebral disc degeneration	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Intervertebral disc protrusion	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Osteoarthritis	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Spondylolisthesis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	29	0.9	(0.6, 1.2)	23	0.7	(0.4, 1.0)
Acute myeloid leukaemia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Adenocarcinoma of colon	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Adenocarcinoma pancreas	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Adrenal gland cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Biliary cancer metastatic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

14.168. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Bladder cancer	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Borderline serous tumour of ovary	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Breast cancer	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Breast cancer in situ	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Breast cancer stage I	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Carcinoid tumour of the stomach	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Colon adenoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gallbladder cancer stage II	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Gastric cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Invasive ductal breast carcinoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Lobular breast carcinoma in situ	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Lung adenocarcinoma	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Lymphoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Malignant melanoma	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Metastases to liver	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Metastases to lymph nodes	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Non-Hodgkin's lymphoma recurrent	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Non-small cell lung cancer stage IV	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Oropharyngeal cancer recurrent	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Oropharyngeal squamous cell carcinoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pancreatic carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Papillary serous endometrial carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Penile neoplasm	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Polycythaemia vera	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Prostate cancer	3	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Prostate cancer metastatic	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Skin cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Squamous cell carcinoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Squamous cell carcinoma of head and neck	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Thyroid cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Tonsil cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Transitional cell carcinoma	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Uterine cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Uterine leiomyoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

14.168. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
NERVOUS SYSTEM DISORDERS	14	0.4	(0.2, 0.7)	15	0.5	(0.3, 0.7)
Amyotrophic lateral sclerosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cerebral infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cerebrovascular accident	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Cervicogenic headache	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Dementia Alzheimer's type	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Dizziness	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Haemorrhagic stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Intraventricular haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Ischaemic stroke	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Spinal cord compression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Subarachnoid haemorrhage	2	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Syncope	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Toxic encephalopathy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Transient global amnesia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Transient ischaemic attack	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Uraemic encephalopathy	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	3	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
Bipolar disorder	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Disorientation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Mental disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Panic attack	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Suicide attempt	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	5	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.2)
Acute kidney injury	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hydronephrosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Nephrolithiasis	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Ovarian cyst	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ovarian mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Uterine prolapse	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	10	0.3	(0.1, 0.5)	10	0.3	(0.1, 0.6)

14.168. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Acute respiratory failure	2	0.1	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Asthma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Dyspnoea	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Interstitial lung disease	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pneumonia aspiration	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pneumonitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pneumothorax	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pulmonary embolism	2	0.1	(0.0, 0.2)	5	0.2	(0.0, 0.4)
Pulmonary mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Respiratory failure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
SURGICAL AND MEDICAL PROCEDURES	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Finger amputation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
VASCULAR DISORDERS	7	0.2	(0.1, 0.4)	8	0.2	(0.1, 0.5)
Aortic aneurysm	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Aortic rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Aortic stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Arteriosclerosis	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Deep vein thrombosis	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Hypertension	3	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.1)
Hypertensive crisis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypertensive emergency	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Orthostatic hypotension	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Peripheral artery stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sae age p3 saf

14.169. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=674, TE[b]=2.5)			Placebo (N[a]=705, TE[b]=2.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	10	4.0	(1.9, 7.3)	5	1.9	(0.6, 4.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Microcytic anaemia	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
CARDIAC DISORDERS	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Acute left ventricular failure	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Cardiac failure congestive	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
GASTROINTESTINAL DISORDERS	1	0.4	(0.0, 2.2)	1	0.4	(0.0, 2.1)
Intestinal perforation	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Oesophageal varices haemorrhage	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
HEPATOBILIARY DISORDERS	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Cholecystitis acute	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
INFECTIONS AND INFESTATIONS	2	0.8	(0.1, 2.9)	0	0.0	(0.0, 1.4)
Appendicitis	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Pneumonia	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Overdose	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
INVESTIGATIONS	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Red blood cell morphology abnormal	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Adenocarcinoma of colon	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	0.0	(0.0, 1.5)	2	0.8	(0.1, 2.7)
Abortion spontaneous incomplete	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
Retained products of conception	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
PSYCHIATRIC DISORDERS	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Depression	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)

14.169. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=674, TE[b]=2.5)			Placebo (N[a]=705, TE[b]=2.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Endometriosis	0	0.0	(0.0, 1.5)	1	0.4	(0.0, 2.1)
VASCULAR DISORDERS	3	1.2	(0.2, 3.5)	0	0.0	(0.0, 1.4)
Arteriosclerosis	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Deep vein thrombosis	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)
Hypertension	1	0.4	(0.0, 2.2)	0	0.0	(0.0, 1.4)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_sae_base_p3_saf

14.170. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	256	3.2	(2.8, 3.6)	262	3.3	(2.9, 3.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Anaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Neutropenia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Thrombocytopenia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
CARDIAC DISORDERS	41	0.5	(0.4, 0.7)	39	0.5	(0.4, 0.7)
Acute coronary syndrome	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Acute myocardial infarction	6	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Angina pectoris	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Angina unstable	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic valve incompetence	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Arrhythmia supraventricular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Arteriosclerosis coronary artery	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Arteriospasm coronary	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Atrial fibrillation	5	0.1	(0.0, 0.1)	9	0.1	(0.1, 0.2)
Atrioventricular block complete	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bradycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac arrest	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Cardiac failure acute	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coronary artery disease	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Coronary artery dissection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Coronary artery occlusion	0	0.0	(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, 0.0)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Myocardial infarction	4	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Myocardial ischaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pericarditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tachyarrhythmia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tachycardia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.170. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Ventricular arrhythmia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ventricular tachycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Congenital bladder neck obstruction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Congenital ureteropelvic junction obstruction	0	0.0	(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, 0.0)
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	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Choroidal neovascularisation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diplopia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eye haemorrhage	0	0.0	(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, 0.0)
Retinal artery occlusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Visual impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	22	0.3	(0.2, 0.4)	20	0.3	(0.2, 0.4)
Abdominal adhesions	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abdominal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abdominal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abdominal pain upper	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Colitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Colitis ischaemic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Constipation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diarrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diverticular perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diverticulum intestinal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Duodenal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Enterocolitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Food poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastrointestinal haemorrhage	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.170. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Gastrointestinal mucosa hyperaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haemorrhoids	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hiatus hernia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ileus	0	0.0	(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, 0.0)
Incarcerated inguinal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Inguinal hernia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Intestinal obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal strangulation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Large intestine perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Obstructive pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oesophageal food impaction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pancreatic cyst	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pancreatitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis acute	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Retroperitoneal haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Salivary gland calculus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Small intestinal obstruction	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Umbilical hernia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Volvulus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	10	0.1	(0.1, 0.2)	4	0.1	(0.0, 0.1)
Asthenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chest pain	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Drug withdrawal syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Influenza like illness	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Non-cardiac chest pain	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sudden cardiac death	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vascular stent occlusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	11	0.1	(0.1, 0.2)	6	0.1	(0.0, 0.2)
Bile duct stone	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.170. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Biliary colic	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cholecystitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholecystitis acute	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Cholelithiasis	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatocellular injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anaphylactic shock	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Drug hypersensitivity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	48	0.6	(0.4, 0.8)	57	0.7	(0.5, 0.9)
Abdominal abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abscess intestinal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Appendicitis	13	0.2	(0.1, 0.3)	9	0.1	(0.1, 0.2)
Appendicitis perforated	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arthritis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bacterial sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Brain abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.0)	13	0.2	(0.1, 0.3)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cellulitis	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Complicated appendicitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Device related infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diabetic foot infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diverticulitis	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Emphysematous cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Empyema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Escherichia urinary tract infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Extradural abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gangrene	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastroenteritis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meningitis bacterial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.170. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Osteomyelitis	0	0.0	(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, 0.0)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peritonitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritonsillar abscess	1	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)
Post procedural infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Postoperative wound infection	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pyelonephritis	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pyelonephritis acute	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Renal abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Respiratory tract infection viral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sepsis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Septic shock	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Shigella sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Staphylococcal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Staphylococcal sepsis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subacute endocarditis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subcutaneous abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tooth infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Upper respiratory tract infection	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Urinary tract infection	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Urosepsis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	18	0.2	(0.1, 0.4)	26	0.3	(0.2, 0.5)
Alcohol poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ankle fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Brain contusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cervical vertebral fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Colon injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Concussion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Craniocerebral injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Delayed recovery from anaesthesia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.170. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Facial bones fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fall	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Femur fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Flail chest	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Foot fracture	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Forearm fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Head injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hip fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Humerus fracture	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Ligament rupture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lower limb fracture	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Lumbar vertebral fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Meniscus injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Multiple injuries	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Overdose	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Patella fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pelvic fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post procedural haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Post-traumatic pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Procedural haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Radius fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rib fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Road traffic accident	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Spinal column injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spinal cord injury cervical	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Subdural haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tibia fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Toxicity to various agents	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Traumatic haemothorax	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ulna fracture	0	0.0	(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, 0.0)
Wrist fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
INVESTIGATIONS	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)

14.170. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Blood glucose abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood pressure increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cardiac stress test abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hepatic enzyme increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	4	0.0	(0.0, 0.1)	10	0.1	(0.1, 0.2)
Diabetes mellitus inadequate control	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diabetic ketoacidosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Fluid retention	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperglycaemia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Hypoglycaemia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypokalaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyponatraemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Type 2 diabetes mellitus	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	12	0.1	(0.1, 0.3)	11	0.1	(0.1, 0.2)
Arthralgia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Arthritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Back pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intervertebral disc compression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intervertebral disc degeneration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscular weakness	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Osteoarthritis	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Osteochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Psoriatic arthropathy	0	0.0	(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)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	38	0.5	(0.3, 0.6)	35	0.4	(0.3, 0.6)
Acute myeloid leukaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma pancreas	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adrenal gland cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
B-cell lymphoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Benign hydatidiform mole	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.170. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Biliary cancer metastatic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bladder cancer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Borderline serous tumour of ovary	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Breast cancer	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Breast cancer in situ	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Breast cancer stage I	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Carcinoid tumour of the stomach	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Colon adenoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gallbladder cancer stage II	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastric cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Invasive ductal breast carcinoma	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Leydig cell tumour of the testis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lipoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lobular breast carcinoma in situ	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lung adenocarcinoma	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Malignant melanoma	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Meningioma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to liver	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Non-Hodgkin's lymphoma recurrent	0	0.0	(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, 0.0)
Oropharyngeal cancer recurrent	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oropharyngeal squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pancreatic carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Papillary serous endometrial carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Papillary thyroid cancer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Penile neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Plasma cell myeloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.170. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Polycythaemia vera	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Prostate cancer	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Prostate cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Squamous cell carcinoma of head and neck	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Teratoma	0	0.0	(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, 0.0)
Tonsil cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Transitional cell carcinoma	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Uterine cancer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Uterine leiomyoma	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	24	0.3	(0.2, 0.4)	23	0.3	(0.2, 0.4)
Amnesia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Amyotrophic lateral sclerosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Carpal tunnel syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cerebral infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebrovascular accident	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cervicogenic headache	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dementia Alzheimer's type	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dizziness	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Guillain-Barre syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haemorrhagic stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hemiplegic migraine	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Idiopathic intracranial hypertension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intraventricular haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ischaemic stroke	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Paraesthesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peripheral nerve lesion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Spinal cord compression	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subarachnoid haemorrhage	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Syncope	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Transient global amnesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.170. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Transient ischaemic attack	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Abortion incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abortion spontaneous	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	4	0.0	(0.0, 0.1)	9	0.1	(0.1, 0.2)
Alcohol abuse	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bipolar disorder	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Depression	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Depression suicidal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Disorientation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Major depression	0	0.0	(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, 0.0)
Panic attack	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Suicidal ideation	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Suicide attempt	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	11	0.1	(0.1, 0.2)	8	0.1	(0.0, 0.2)
Acute kidney injury	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hydronephrosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nephrolithiasis	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Renal colic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Subcapsular renal haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ureterolithiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urinary bladder polyp	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.1)
Adnexal torsion	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Breast hyperplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ovarian cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ovarian mass	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rectocele	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.170. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Uterine prolapse	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vaginal prolapse	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	14	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.3)
Acute respiratory failure	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Asthma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Asthmatic crisis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dyspnoea	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypoxia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Interstitial lung disease	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal septum deviation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pneumonia aspiration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pneumothorax	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pulmonary embolism	5	0.1	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Pulmonary mass	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Respiratory failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Miscarriage of partner	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Finger amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
VASCULAR DISORDERS	9	0.1	(0.1, 0.2)	13	0.2	(0.1, 0.3)
Accelerated hypertension	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Aortic aneurysm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Aortic rupture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Aortic stenosis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Arteriosclerosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Deep vein thrombosis	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Hypertension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypertensive crisis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypertensive emergency	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.170. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21102, TE[b]=80.4)			Placebo (N[a]=21092, TE[b]=79.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hypertensive urgency	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Orthostatic hypotension	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Peripheral artery stenosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_sae_base_p3_saf

14.171. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	82	3.5	(2.8, 4.3)	85	3.6	(2.9, 4.5)
CARDIAC DISORDERS	8	0.3	(0.1, 0.7)	6	0.3	(0.1, 0.6)
Acute coronary syndrome	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Acute myocardial infarction	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Angina pectoris	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Angina unstable	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Aortic valve incompetence	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Arrhythmia supraventricular	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Arteriosclerosis coronary artery	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Cardio-respiratory arrest	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Coronary artery disease	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pericarditis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Congenital bladder neck obstruction	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
EYE DISORDERS	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Choroidal neovascularisation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	6	0.3	(0.1, 0.6)	4	0.2	(0.0, 0.4)
Diverticular perforation	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Food poisoning	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Gastritis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Haemorrhoids	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Incarcerated inguinal hernia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Intestinal perforation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Oesophageal food impaction	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pancreatic cyst	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pancreatitis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Pancreatitis acute	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.3)

14.171. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Chest pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Influenza like illness	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Vascular stent occlusion	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	6	0.3	(0.1, 0.6)	3	0.1	(0.0, 0.4)
Bile duct stone	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Biliary colic	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Cholecystitis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Cholecystitis acute	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Cholecystitis chronic	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Cholelithiasis	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	19	0.8	(0.5, 1.3)	26	1.1	(0.7, 1.6)
Abdominal abscess	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Appendicitis	7	0.3	(0.1, 0.6)	5	0.2	(0.1, 0.5)
Arthritis bacterial	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
COVID-19	0	0.0	(0.0, 0.2)	6	0.3	(0.1, 0.6)
Cellulitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Complicated appendicitis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Emphysematous cholecystitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Extradural abscess	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Gangrene	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Gastroenteritis	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Penile infection	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Peritonitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Pneumonia	1	0.0	(0.0, 0.2)	4	0.2	(0.0, 0.4)
Postoperative wound infection	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Pyelonephritis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Renal abscess	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Sepsis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Septic shock	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Shigella sepsis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Staphylococcal sepsis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Subacute endocarditis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Urinary tract infection	2	0.1	(0.0, 0.3)	4	0.2	(0.0, 0.4)

14.171. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Urosepsis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	6	0.3	(0.1, 0.6)	9	0.4	(0.2, 0.7)
Ankle fracture	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
Cervical vertebral fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Femur fracture	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Foot fracture	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Forearm fracture	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Humerus fracture	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Ligament rupture	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Lumbar vertebral fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Meniscus injury	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Multiple injuries	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Patella fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Procedural haemorrhage	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Road traffic accident	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Spinal cord injury cervical	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Ulna fracture	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Wrist fracture	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
INVESTIGATIONS	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Blood glucose abnormal	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	1	0.0	(0.0, 0.2)	4	0.2	(0.0, 0.4)
Hyperglycaemia	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hypoglycaemia	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Hyponatraemia	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	3	0.1	(0.0, 0.4)	2	0.1	(0.0, 0.3)
Back pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Intervertebral disc protrusion	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Osteoarthritis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Osteochondritis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	15	0.6	(0.4, 1.0)	4	0.2	(0.0, 0.4)
Adenocarcinoma of colon	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)

14.171. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Benign hydatidiform mole	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Breast cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Carcinoid tumour of the stomach	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Gastric cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Invasive ductal breast carcinoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Leydig cell tumour of the testis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Malignant melanoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Metastases to central nervous system	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Non-Hodgkin's lymphoma recurrent	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Papillary thyroid cancer	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Plasma cell myeloma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Polycythaemia vera	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Prostate cancer	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Prostate cancer metastatic	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Squamous cell carcinoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Transitional cell carcinoma	2	0.1	(0.0, 0.3)	0	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	6	0.3	(0.1, 0.6)	9	0.4	(0.2, 0.7)
Amyotrophic lateral sclerosis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Carpal tunnel syndrome	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Haemorrhagic stroke	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Idiopathic intracranial hypertension	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Ischaemic stroke	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Optic neuritis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Peripheral nerve lesion	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Subarachnoid haemorrhage	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Syncope	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Transient ischaemic attack	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.1	(0.0, 0.3)	2	0.1	(0.0, 0.3)
Abortion incomplete	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Abortion spontaneous	2	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
PSYCHIATRIC DISORDERS	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Bipolar disorder	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.171. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
RENAL AND URINARY DISORDERS	4	0.2	(0.0, 0.4)	6	0.3	(0.1, 0.6)
Nephrolithiasis	1	0.0	(0.0, 0.2)	5	0.2	(0.1, 0.5)
Renal colic	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Subcapsular renal haematoma	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Ureterolithiasis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Urinary bladder polyp	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Ovarian cyst	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Rectocele	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Uterine prolapse	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Vaginal prolapse	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3	0.1	(0.0, 0.4)	5	0.2	(0.1, 0.5)
Acute respiratory failure	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Asthmatic crisis	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Pneumonitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Pulmonary embolism	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Pulmonary mass	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
SURGICAL AND MEDICAL PROCEDURES	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Finger amputation	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
VASCULAR DISORDERS	2	0.1	(0.0, 0.3)	6	0.3	(0.1, 0.6)
Aortic stenosis	0	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Deep vein thrombosis	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.3)
Hypertensive emergency	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Hypertensive urgency	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.2)
Orthostatic hypotension	0	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)

14.171. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=5684, TE[b]=23.6)			Placebo (N[a]=5683, TE[b]=23.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sae eth p3 saf

14.172. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	185	3.1	(2.7, 3.6)	182	3.1	(2.7, 3.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Anaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Microcytic anaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neutropenia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thrombocytopenia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
CARDIAC DISORDERS	34	0.6	(0.4, 0.8)	33	0.6	(0.4, 0.8)
Acute coronary syndrome	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Acute left ventricular failure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Acute myocardial infarction	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Angina pectoris	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Angina unstable	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic valve incompetence	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arteriospasm coronary	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrial fibrillation	5	0.1	(0.0, 0.2)	9	0.2	(0.1, 0.3)
Atrioventricular block complete	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bradycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac arrest	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Cardiac failure acute	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	3	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Coronary artery disease	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Coronary artery dissection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Coronary artery occlusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertensive heart disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Myocardial infarction	4	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Myocardial ischaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tachyarrhythmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tachycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ventricular arrhythmia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ventricular tachycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.172. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Congenital ureteropelvic junction obstruction	0	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, 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	0.1	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diplopia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eye haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal artery occlusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Visual impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	17	0.3	(0.2, 0.5)	17	0.3	(0.2, 0.5)
Abdominal adhesions	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abdominal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abdominal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abdominal pain upper	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colitis ischaemic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Constipation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diarrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diverticulum intestinal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Duodenal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Enterocolitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastrointestinal haemorrhage	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal mucosa hyperaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hiatus hernia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ileus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Impaired gastric emptying	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Inguinal hernia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal strangulation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.172. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Large intestine perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Obstructive pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oesophageal varices haemorrhage	0	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, 0.1)
Pancreatitis acute	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Retroperitoneal haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Salivary gland calculus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Small intestinal obstruction	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Umbilical hernia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Volvulus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	8	0.1	(0.1, 0.3)	2	0.0	(0.0, 0.1)
Asthenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chest pain	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug withdrawal syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Non-cardiac chest pain	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Shoulder injury related to vaccine administration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sudden cardiac death	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	6	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Bile duct stone	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cholecystitis acute	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Cholelithiasis	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hepatocellular injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anaphylactic shock	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug hypersensitivity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	31	0.5	(0.4, 0.7)	31	0.5	(0.4, 0.8)
Abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abscess intestinal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.172. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Appendicitis	7	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Appendicitis perforated	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bacterial sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Brain abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cellulitis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Complicated appendicitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Device related infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diabetic foot infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulitis	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Empyema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Escherichia urinary tract infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Meningitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteomyelitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peritonitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritonsillar abscess	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonia	3	0.1	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Post procedural infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pyelonephritis	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pyelonephritis acute	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Respiratory tract infection viral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Septic shock	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Staphylococcal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Subcutaneous abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tooth infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper respiratory tract infection	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Urinary tract infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	12	0.2	(0.1, 0.4)	17	0.3	(0.2, 0.5)
Alcohol poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.172. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Brain contusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colon injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Concussion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Craniocerebral injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Delayed recovery from anaesthesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial bones fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fall	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Flail chest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foot fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Head injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hip fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lower limb fracture	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Overdose	3	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Post procedural haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Post-traumatic pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Radius fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rib fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Road traffic accident	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Spinal column injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subdural haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tibia fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Toxicity to various agents	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Traumatic haemothorax	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Upper limb fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Wrist fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INVESTIGATIONS	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Blood pressure increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac stress test abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hepatic enzyme increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Red blood cell morphology abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	3	0.1	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Diabetes mellitus inadequate control	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

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	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Diabetic ketoacidosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Fluid retention	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperglycaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypokalaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Type 2 diabetes mellitus	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	10	0.2	(0.1, 0.3)	9	0.2	(0.1, 0.3)
Arthralgia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Arthritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intervertebral disc compression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intervertebral disc degeneration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscular weakness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteoarthritis	4	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Psoriatic arthropathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spondylolisthesis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	24	0.4	(0.3, 0.6)	31	0.5	(0.4, 0.8)
Acute myeloid leukaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenocarcinoma pancreas	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adrenal gland cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
B-cell lymphoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Biliary cancer metastatic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bladder cancer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Borderline serous tumour of ovary	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cancer	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Breast cancer in situ	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cancer stage I	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colon adenoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gallbladder cancer stage II	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Invasive ductal breast carcinoma	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.172. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Lipoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lobular breast carcinoma in situ	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lung adenocarcinoma	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Malignant melanoma	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Meningioma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to liver	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.1)	2	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, 0.1)
Oropharyngeal cancer recurrent	0	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, 0.1)
Pancreatic carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papillary serous endometrial carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Penile neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Prostate cancer	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Skin cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Squamous cell carcinoma of head and neck	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Teratoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thyroid cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tonsil cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Uterine cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uterine leiomyoma	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	19	0.3	(0.2, 0.5)	14	0.2	(0.1, 0.4)
Amnesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebral infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebrovascular accident	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cervicogenic headache	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dementia Alzheimer's type	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dizziness	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Guillain-Barre syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hemiplegic migraine	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Idiopathic intracranial hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intraventricular haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.172. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Ischaemic stroke	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Optic neuritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paraesthesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal cord compression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subarachnoid haemorrhage	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Syncope	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Toxic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transient global amnesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transient ischaemic attack	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Abortion spontaneous	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retained products of conception	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	5	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Alcohol abuse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bipolar disorder	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depression	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Disorientation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Major depression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mental disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Panic attack	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Suicidal ideation	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Suicide attempt	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	7	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Acute kidney injury	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hydronephrosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nephrolithiasis	5	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Adnexal torsion	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.172. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Breast hyperplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Endometriosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ovarian mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	11	0.2	(0.1, 0.3)	9	0.2	(0.1, 0.3)
Acute respiratory failure	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Asthma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dyspnoea	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoxia	0	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)
Nasal septum deviation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumonia aspiration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumothorax	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pulmonary embolism	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Respiratory arrest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory failure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Miscarriage of partner	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
VASCULAR DISORDERS	10	0.2	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Accelerated hypertension	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic aneurysm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Aortic rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arteriosclerosis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Deep vein thrombosis	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Hypertension	3	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypertensive crisis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypertensive urgency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Orthostatic hypotension	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peripheral artery stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.172. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=16131, TE[b]=59.4)			Placebo (N[a]=16125, TE[b]=58.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_sae_eth_p3_saf

14.173. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Ethnicity: Not Reported

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=111, TE[b]=0.4)			Placebo (N[a]=113, TE[b]=0.4)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	1	2.4	(0.1, 13.1)	1	2.3	(0.1, 12.7)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1	2.4	(0.1, 13.1)	0	0.0	(0.0, 8.4)
Pelvic fracture	1	2.4	(0.1, 13.1)	0	0.0	(0.0, 8.4)
PSYCHIATRIC DISORDERS	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)
Depression suicidal	0	0.0	(0.0, 8.7)	1	2.3	(0.1, 12.7)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sae eth p3 saf

14.174. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	230	3.3	(2.9, 3.8)	239	3.5	(3.1, 4.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Neutropenia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thrombocytopenia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
CARDIAC DISORDERS	36	0.5	(0.4, 0.7)	35	0.5	(0.4, 0.7)
Acute coronary syndrome	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Acute myocardial infarction	5	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Angina pectoris	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Angina unstable	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic valve incompetence	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Arrhythmia supraventricular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arteriosclerosis coronary artery	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arteriospasm coronary	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrial fibrillation	5	0.1	(0.0, 0.2)	8	0.1	(0.1, 0.2)
Atrioventricular block complete	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bradycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac arrest	6	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardio-respiratory arrest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coronary artery disease	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Coronary artery dissection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Coronary artery occlusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertensive heart disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myocardial infarction	4	0.1	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Pericarditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tachyarrhythmia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tachycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ventricular arrhythmia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ventricular tachycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.174. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Congenital bladder neck obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Congenital ureteropelvic junction obstruction	0	0.0	(0.0, 0.1)	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	5	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Choroidal neovascularisation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diplopia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eye haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Retinal artery occlusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Visual impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	21	0.3	(0.2, 0.5)	18	0.3	(0.2, 0.4)
Abdominal adhesions	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abdominal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abdominal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abdominal pain upper	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colitis ischaemic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Constipation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diarrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diverticular perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulum intestinal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Duodenal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Enterocolitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Food poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haemorrhoids	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hiatus hernia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Impaired gastric emptying	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Incarcerated inguinal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.174. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Inguinal hernia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal perforation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intestinal strangulation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Large intestine perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oesophageal food impaction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatic cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis acute	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Retroperitoneal haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Salivary gland calculus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Small intestinal obstruction	4	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Umbilical hernia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	8	0.1	(0.1, 0.2)	4	0.1	(0.0, 0.2)
Asthenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chest pain	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug withdrawal syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Influenza like illness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Non-cardiac chest pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sudden cardiac death	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vascular stent occlusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	10	0.1	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Bile duct stone	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary colic	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cholecystitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholecystitis acute	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Cholecystitis chronic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholelithiasis	5	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Hepatocellular injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.174. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Anaphylactic shock	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug hypersensitivity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	40	0.6	(0.4, 0.8)	52	0.8	(0.6, 1.0)
Abdominal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abscess intestinal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Appendicitis	12	0.2	(0.1, 0.3)	9	0.1	(0.1, 0.3)
Appendicitis perforated	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arthritis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bacterial sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Brain abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.1)	13	0.2	(0.1, 0.3)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cellulitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Complicated appendicitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Device related infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diabetic foot infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulitis	4	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Emphysematous cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Empyema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Escherichia urinary tract infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Extradural abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gangrene	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastroenteritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteomyelitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Penile infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peritonitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritonsillar abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonia	3	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Post procedural infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Postoperative wound infection	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pyelonephritis	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Renal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.174. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Sepsis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Septic shock	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Shigella sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Staphylococcal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Staphylococcal sepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subacute endocarditis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tooth infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper respiratory tract infection	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Urinary tract infection	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Urosepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	17	0.2	(0.1, 0.4)	24	0.4	(0.2, 0.5)
Alcohol poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ankle fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Brain contusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cervical vertebral fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colon injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Concussion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Craniocerebral injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Delayed recovery from anaesthesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial bones fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fall	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Femur fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Flail chest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foot fracture	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Forearm fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Head injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hip fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Humerus fracture	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Ligament rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lower limb fracture	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lumbar vertebral fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Meniscus injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Multiple injuries	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.174. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Overdose	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Patella fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pelvic fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post procedural haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Post-traumatic pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Procedural haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Radius fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Road traffic accident	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Spinal cord injury cervical	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tibia fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ulna fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper limb fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Wrist fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INVESTIGATIONS	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blood glucose abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatic enzyme increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	3	0.0	(0.0, 0.1)	9	0.1	(0.1, 0.3)
Diabetes mellitus inadequate control	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diabetic ketoacidosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Fluid retention	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hyperglycaemia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypoglycaemia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypokalaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyponatraemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Type 2 diabetes mellitus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	11	0.2	(0.1, 0.3)	10	0.1	(0.1, 0.3)
Arthralgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arthritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Back pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intervertebral disc compression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intervertebral disc degeneration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.174. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Muscular weakness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteoarthritis	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Osteochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Psoriatic arthropathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spondylolisthesis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	38	0.6	(0.4, 0.8)	30	0.4	(0.3, 0.6)
Acute myeloid leukaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenocarcinoma of colon	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenocarcinoma pancreas	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adrenal gland cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
B-cell lymphoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Benign hydatidiform mole	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary cancer metastatic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bladder cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Borderline serous tumour of ovary	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cancer	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Breast cancer in situ	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Carcinoid tumour of the stomach	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colon adenoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gallbladder cancer stage II	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastric cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Invasive ductal breast carcinoma	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Leydig cell tumour of the testis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lipoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lobular breast carcinoma in situ	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lung adenocarcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Malignant melanoma	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Meningioma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.174. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to liver	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Non-Hodgkin's lymphoma recurrent	0	0.0	(0.0, 0.1)	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, 0.1)
Oropharyngeal cancer recurrent	0	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, 0.1)
Pancreatic carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papillary serous endometrial carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papillary thyroid cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Penile neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Plasma cell myeloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Polycythaemia vera	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Prostate cancer	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Prostate cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Squamous cell carcinoma of head and neck	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Teratoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thyroid cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transitional cell carcinoma	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Uterine cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uterine leiomyoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	23	0.3	(0.2, 0.5)	21	0.3	(0.2, 0.5)
Amnesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Amyotrophic lateral sclerosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Carpal tunnel syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cerebral infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebrovascular accident	4	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cervicogenic headache	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dementia Alzheimer's type	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dizziness	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haemorrhagic stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hemiplegic migraine	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Idiopathic intracranial hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.174. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Intraventricular haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ischaemic stroke	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paraesthesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peripheral nerve lesion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Subarachnoid haemorrhage	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Syncope	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Toxic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transient global amnesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transient ischaemic attack	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Abortion incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abortion spontaneous	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	5	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Bipolar disorder	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Depression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Depression suicidal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Disorientation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Major depression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mental disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Panic attack	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Suicidal ideation	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Suicide attempt	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	11	0.2	(0.1, 0.3)	8	0.1	(0.1, 0.2)
Acute kidney injury	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hydronephrosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nephrolithiasis	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Renal colic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Subcapsular renal haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ureterolithiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urinary bladder polyp	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.174. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)
Adnexal torsion	0	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, 0.1)
Ovarian mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectocele	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uterine prolapse	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vaginal prolapse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	12	0.2	(0.1, 0.3)	12	0.2	(0.1, 0.3)
Acute respiratory failure	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Asthma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthmatic crisis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Dyspnoea	0	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)
Nasal septum deviation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumonia aspiration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pulmonary embolism	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.2)
Pulmonary mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory failure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Miscarriage of partner	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Finger amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
VASCULAR DISORDERS	7	0.1	(0.0, 0.2)	12	0.2	(0.1, 0.3)
Accelerated hypertension	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic aneurysm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Aortic rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic stenosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Arteriosclerosis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Deep vein thrombosis	0	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.2)

14.174. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=18012, TE[b]=68.9)			Placebo (N[a]=18027, TE[b]=68.0)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hypertension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypertensive crisis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypertensive emergency	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertensive urgency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Orthostatic hypotension	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Peripheral artery stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Note: MedDRA (v23.1) 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.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_sae_race_p3_saf

14.175. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=2046, TE[b]=7.9)			Placebo (N[a]=2061, TE[b]=7.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	20	2.5	(1.6, 3.9)	20	2.6	(1.6, 4.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	0.0	(0.0, 0.5)	3	0.4	(0.1, 1.1)
Anaemia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Microcytic anaemia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Thrombocytopenia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
CARDIAC DISORDERS	3	0.4	(0.1, 1.1)	3	0.4	(0.1, 1.1)
Acute left ventricular failure	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Cardiac arrest	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Cardiac failure acute	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Cardiac failure congestive	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Coronary artery disease	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Myocardial infarction	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Myocardial ischaemia	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
GASTROINTESTINAL DISORDERS	2	0.3	(0.0, 0.9)	2	0.3	(0.0, 0.9)
Gastrointestinal haemorrhage	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Gastrointestinal mucosa hyperaemia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Ileus	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Obstructive pancreatitis	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Volvulus	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Non-cardiac chest pain	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
HEPATOBILIARY DISORDERS	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Bile duct stone	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
INFECTIONS AND INFESTATIONS	3	0.4	(0.1, 1.1)	3	0.4	(0.1, 1.1)
Appendicitis	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Cellulitis	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Peritonsillar abscess	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Pneumonia	1	0.1	(0.0, 0.7)	2	0.3	(0.0, 0.9)
Subcutaneous abscess	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1	0.1	(0.0, 0.7)	2	0.3	(0.0, 0.9)
Overdose	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)

14.175. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=2046, TE[b]=7.9)			Placebo (N[a]=2061, TE[b]=7.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Rib fracture	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Road traffic accident	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Spinal column injury	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Subdural haematoma	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Toxicity to various agents	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Traumatic haemothorax	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
INVESTIGATIONS	1	0.1	(0.0, 0.7)	2	0.3	(0.0, 0.9)
Blood pressure increased	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Cardiac stress test abnormal	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Red blood cell morphology abnormal	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
METABOLISM AND NUTRITION DISORDERS	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Diabetic ketoacidosis	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Type 2 diabetes mellitus	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Arthralgia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Osteoarthritis	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	0.0	(0.0, 0.5)	3	0.4	(0.1, 1.1)
Lung adenocarcinoma	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Uterine leiomyoma	0	0.0	(0.0, 0.5)	2	0.3	(0.0, 0.9)
NERVOUS SYSTEM DISORDERS	1	0.1	(0.0, 0.7)	1	0.1	(0.0, 0.7)
Idiopathic intracranial hypertension	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Spinal cord compression	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	0.0	(0.0, 0.5)	2	0.3	(0.0, 0.9)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Retained products of conception	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
PSYCHIATRIC DISORDERS	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Suicide attempt	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Endometriosis	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)

14.175. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=2046, TE[b]=7.9)			Placebo (N[a]=2061, TE[b]=7.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2	0.3	(0.0, 0.9)	2	0.3	(0.0, 0.9)
Hypoxia	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Pneumonia aspiration	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Pneumothorax	0	0.0	(0.0, 0.5)	1	0.1	(0.0, 0.7)
Pulmonary embolism	2	0.3	(0.0, 0.9)	1	0.1	(0.0, 0.7)
VASCULAR DISORDERS	5	0.6	(0.2, 1.5)	1	0.1	(0.0, 0.7)
Deep vein thrombosis	3	0.4	(0.1, 1.1)	1	0.1	(0.0, 0.7)
Hypertension	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)
Hypertensive urgency	1	0.1	(0.0, 0.7)	0	0.0	(0.0, 0.5)

Note: MedDRA (v23.1) 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.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sae race p3 saf

14.176. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1868, TE[b]=6.6)			Placebo (N[a]=1833, TE[b]=6.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	18	2.7	(1.6, 4.3)	9	1.4	(0.6, 2.7)
CARDIAC DISORDERS	3	0.5	(0.1, 1.3)	1	0.2	(0.0, 0.9)
Acute myocardial infarction	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Angina pectoris	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Atrial fibrillation	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Cardio-respiratory arrest	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Heart disease congenital	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
GASTROINTESTINAL DISORDERS	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Oesophageal varices haemorrhage	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Shoulder injury related to vaccine administration	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
HEPATOBILIARY DISORDERS	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Cholecystitis acute	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
INFECTIONS AND INFESTATIONS	7	1.1	(0.4, 2.2)	2	0.3	(0.0, 1.1)
Appendicitis	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Appendicitis perforated	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Cellulitis	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Gastroenteritis	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Meningitis bacterial	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Pyelonephritis acute	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Respiratory tract infection viral	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Urinary tract infection	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Facial bones fracture	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Intervertebral disc protrusion	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1	0.2	(0.0, 0.8)	2	0.3	(0.0, 1.1)

14.176. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1868, TE[b]=6.6)			Placebo (N[a]=1833, TE[b]=6.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Bladder cancer	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Breast cancer stage I	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Tonsil cancer	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
NERVOUS SYSTEM DISORDERS	1	0.2	(0.0, 0.8)	1	0.2	(0.0, 0.9)
Guillain-Barre syndrome	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Subarachnoid haemorrhage	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
PSYCHIATRIC DISORDERS	0	0.0	(0.0, 0.6)	2	0.3	(0.0, 1.1)
Alcohol abuse	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
Depression	0	0.0	(0.0, 0.6)	1	0.2	(0.0, 0.9)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)
Breast hyperplasia	1	0.2	(0.0, 0.8)	0	0.0	(0.0, 0.6)

Note: MedDRA (v23.1) 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.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_sae_race_p3_saf

14.177. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	152	3.5	(3.0, 4.1)	140	3.4	(2.8, 4.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Anaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neutropenia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thrombocytopenia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
CARDIAC DISORDERS	32	0.7	(0.5, 1.0)	29	0.7	(0.5, 1.0)
Acute coronary syndrome	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Acute left ventricular failure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Acute myocardial infarction	6	0.1	(0.1, 0.3)	3	0.1	(0.0, 0.2)
Angina pectoris	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Angina unstable	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic valve incompetence	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Arrhythmia supraventricular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arteriosclerosis coronary artery	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrial fibrillation	3	0.1	(0.0, 0.2)	7	0.2	(0.1, 0.3)
Atrioventricular block complete	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bradycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardiac arrest	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coronary artery disease	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Coronary artery occlusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertensive heart disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Myocardial infarction	4	0.1	(0.0, 0.2)	6	0.1	(0.1, 0.3)
Pericarditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tachyarrhythmia	0	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	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Congenital bladder neck obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Congenital ureteropelvic junction obstruction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)

14.177. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Vertigo	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
EYE DISORDERS	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diplopia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Eye haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal artery occlusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Visual impairment	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	11	0.3	(0.1, 0.5)	8	0.2	(0.1, 0.4)
Abdominal adhesions	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abdominal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diverticular perforation	0	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, 0.1)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Haemorrhoids	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hiatus hernia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Incarcerated inguinal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Inguinal hernia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal strangulation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oesophageal varices haemorrhage	0	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, 0.1)
Pancreatitis acute	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retroperitoneal haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Small intestinal obstruction	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	6	0.1	(0.1, 0.3)	2	0.0	(0.0, 0.2)
Asthenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Chest pain	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Drug withdrawal syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Non-cardiac chest pain	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	6	0.1	(0.1, 0.3)	4	0.1	(0.0, 0.2)
Bile duct stone	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary colic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.177. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Cholecystitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholecystitis acute	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Cholelithiasis	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anaphylactic shock	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug hypersensitivity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	30	0.7	(0.5, 1.0)	32	0.8	(0.5, 1.1)
Abdominal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abscess intestinal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Anal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Appendicitis	7	0.2	(0.1, 0.3)	5	0.1	(0.0, 0.3)
Appendicitis perforated	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arthritis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Bacterial sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.1)	8	0.2	(0.1, 0.4)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cellulitis	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Device related infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diverticulitis	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Emphysematous cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Extradural abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gangrene	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastroenteritis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meningitis bacterial	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteomyelitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Penile infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peritonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peritonsillar abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumonia	2	0.0	(0.0, 0.2)	6	0.1	(0.1, 0.3)
Postoperative wound infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pyelonephritis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.177. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pyelonephritis acute	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Shigella sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Staphylococcal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Staphylococcal sepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subacute endocarditis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subcutaneous abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tooth infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper respiratory tract infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urinary tract infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urosepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	15	0.3	(0.2, 0.6)	12	0.3	(0.1, 0.5)
Alcohol poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ankle fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Brain contusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cervical vertebral fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Colon injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Concussion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Craniocerebral injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Delayed recovery from anaesthesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial bones fracture	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Fall	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foot fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Forearm fracture	0	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, 0.1)
Hip fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ligament rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lower limb fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meniscus injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Overdose	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Patella fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pelvic fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Post procedural haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.177. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Road traffic accident	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Spinal cord injury cervical	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Toxicity to various agents	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Wrist fracture	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
INVESTIGATIONS	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Blood glucose abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood pressure increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatic enzyme increased	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	1	0.0	(0.0, 0.1)	8	0.2	(0.1, 0.4)
Diabetes mellitus inadequate control	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diabetic ketoacidosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyperglycaemia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Hypoglycaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypokalaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyponatraemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Type 2 diabetes mellitus	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4	0.1	(0.0, 0.2)	6	0.1	(0.1, 0.3)
Arthralgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc degeneration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intervertebral disc protrusion	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Muscular weakness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteoarthritis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Psoriatic arthropathy	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	19	0.4	(0.3, 0.7)	13	0.3	(0.2, 0.5)
Adenocarcinoma of colon	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenocarcinoma pancreas	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Benign hydatidiform mole	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary cancer metastatic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Bladder cancer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Breast cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Carcinoid tumour of the stomach	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.177. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Chronic myeloid leukaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Leydig cell tumour of the testis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lipoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Malignant melanoma	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Metastases to liver	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Non-Hodgkin's lymphoma recurrent	0	0.0	(0.0, 0.1)	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, 0.1)
Oropharyngeal cancer recurrent	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatic carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Penile neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Polycythaemia vera	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Prostate cancer	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Prostate cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Skin cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Squamous cell carcinoma of head and neck	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Thyroid cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tonsil cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transitional cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	14	0.3	(0.2, 0.5)	11	0.3	(0.1, 0.5)
Amnesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Amyotrophic lateral sclerosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Carpal tunnel syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cerebrovascular accident	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Dizziness	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Guillain-Barre syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intraventricular haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ischaemic stroke	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Optic neuritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peripheral nerve lesion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Subarachnoid haemorrhage	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Syncope	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Transient global amnesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transient ischaemic attack	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.177. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
PSYCHIATRIC DISORDERS	3	0.1	(0.0, 0.2)	6	0.1	(0.1, 0.3)
Bipolar disorder	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Depression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Disorientation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Major depression	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Panic attack	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Suicidal ideation	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Suicide attempt	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	7	0.2	(0.1, 0.3)	3	0.1	(0.0, 0.2)
Acute kidney injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Nephrolithiasis	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Renal colic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Subcapsular renal haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ureterolithiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	10	0.2	(0.1, 0.4)	7	0.2	(0.1, 0.3)
Acute respiratory failure	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypoxia	0	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)
Nasal septum deviation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumonia aspiration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pulmonary embolism	4	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)
Respiratory arrest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory failure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Miscarriage of partner	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
VASCULAR DISORDERS	7	0.2	(0.1, 0.3)	9	0.2	(0.1, 0.4)
Accelerated hypertension	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic stenosis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Arteriosclerosis	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Deep vein thrombosis	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)

14.177. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=11253, TE[b]=43.2)			Placebo (N[a]=11032, TE[b]=41.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hypertensive crisis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypertensive emergency	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertensive urgency	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Orthostatic hypotension	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Peripheral artery stenosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sae sex p3 saf

14.178. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	116	2.9	(2.4, 3.5)	128	3.2	(2.6, 3.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Microcytic anaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
CARDIAC DISORDERS	10	0.2	(0.1, 0.5)	10	0.2	(0.1, 0.5)
Acute coronary syndrome	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angina pectoris	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Angina unstable	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Arteriospasm coronary	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrial fibrillation	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Bradycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac arrest	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cardiac failure acute	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coronary artery disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Coronary artery dissection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myocardial infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myocardial ischaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Tachycardia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ventricular arrhythmia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Heart disease congenital	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
EYE DISORDERS	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Choroidal neovascularisation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Visual impairment	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	12	0.3	(0.2, 0.5)	13	0.3	(0.2, 0.5)
Abdominal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Abdominal pain upper	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colitis	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Colitis ischaemic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Constipation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.178. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Diarrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Diverticulum intestinal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Duodenal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Enterocolitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Food poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal mucosa hyperaemia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ileus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Impaired gastric emptying	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intestinal perforation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Large intestine perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Obstructive pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Oesophageal food impaction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatic cyst	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis acute	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Salivary gland calculus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Small intestinal obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Umbilical hernia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Volvulus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4	0.1	(0.0, 0.3)	2	0.0	(0.0, 0.2)
Death	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Influenza like illness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Non-cardiac chest pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Shoulder injury related to vaccine administration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sudden cardiac death	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vascular stent occlusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	6	0.1	(0.1, 0.3)	3	0.1	(0.0, 0.2)
Bile duct stone	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Biliary colic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cholecystitis acute	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cholecystitis chronic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholelithiasis	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.178. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hepatocellular injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	20	0.5	(0.3, 0.8)	25	0.6	(0.4, 0.9)
Appendicitis	7	0.2	(0.1, 0.4)	4	0.1	(0.0, 0.3)
Appendicitis perforated	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Brain abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.3)
COVID-19 pneumonia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Complicated appendicitis	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Diabetic foot infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulitis	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Empyema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Escherichia urinary tract infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastroenteritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Peritonitis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritonsillar abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonia	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Post procedural infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Postoperative wound infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pyelonephritis	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Renal abscess	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory tract infection viral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Sepsis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Septic shock	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper respiratory tract infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Urinary tract infection	2	0.0	(0.0, 0.2)	4	0.1	(0.0, 0.3)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4	0.1	(0.0, 0.3)	14	0.3	(0.2, 0.6)
Ankle fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Craniocerebral injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Femur fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Flail chest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Foot fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Head injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hip fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Humerus fracture	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)

14.178. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Lower limb fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lumbar vertebral fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Multiple injuries	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Post-traumatic pain	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Procedural haemorrhage	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Radius fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rib fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Road traffic accident	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Spinal column injury	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Subdural haematoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tibia fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Traumatic haemothorax	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ulna fracture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper limb fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
INVESTIGATIONS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac stress test abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Red blood cell morphology abnormal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Diabetic ketoacidosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Fluid retention	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypoglycaemia	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Hypokalaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	9	0.2	(0.1, 0.4)	5	0.1	(0.0, 0.3)
Arthralgia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arthritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Back pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intervertebral disc compression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intervertebral disc degeneration	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteoarthritis	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Osteochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Spondylolisthesis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.178. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	20	0.5	(0.3, 0.8)	22	0.5	(0.3, 0.8)
Acute myeloid leukaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adenocarcinoma pancreas	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Adrenal gland cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
B-cell lymphoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Borderline serous tumour of ovary	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cancer	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Breast cancer in situ	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cancer stage I	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colon adenoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gallbladder cancer stage II	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Gastric cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Invasive ductal breast carcinoma	2	0.0	(0.0, 0.2)	2	0.0	(0.0, 0.2)
Lobular breast carcinoma in situ	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lung adenocarcinoma	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Lymphoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Malignant melanoma	1	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Meningioma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Oropharyngeal squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Papillary serous endometrial carcinoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papillary thyroid cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Plasma cell myeloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Teratoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Transitional cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Uterine cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uterine leiomyoma	0	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	11	0.3	(0.1, 0.5)	12	0.3	(0.2, 0.5)
Cerebral infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cerebrovascular accident	2	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.1)

14.178. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Cervicogenic headache	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dementia Alzheimer's type	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Haemorrhagic stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hemiplegic migraine	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Idiopathic intracranial hypertension	2	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Ischaemic stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Optic neuritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paraesthesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spinal cord compression	0	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	(0.0, 0.1)
Syncope	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Toxic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Transient ischaemic attack	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.0	(0.0, 0.2)	6	0.1	(0.1, 0.3)
Abortion incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Abortion spontaneous	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retained products of conception	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	2	0.0	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Alcohol abuse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Depression suicidal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mental disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Suicide attempt	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	4	0.1	(0.0, 0.3)	5	0.1	(0.0, 0.3)
Acute kidney injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hydronephrosis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nephrolithiasis	3	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.2)
Urinary bladder polyp	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2	0.0	(0.0, 0.2)	5	0.1	(0.0, 0.3)
Adnexal torsion	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)

14.178. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=10673, TE[b]=40.3)			Placebo (N[a]=10889, TE[b]=40.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Breast hyperplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Endometriosis	0	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	(0.0, 0.1)
Ovarian mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectocele	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uterine prolapse	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Vaginal prolapse	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	4	0.1	(0.0, 0.3)	7	0.2	(0.1, 0.4)
Acute respiratory failure	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Asthma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Asthmatic crisis	0	0.0	(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	(0.0, 0.1)
Dyspnoea	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Pneumothorax	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pulmonary embolism	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.2)
Pulmonary mass	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Finger amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
VASCULAR DISORDERS	5	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Aortic aneurysm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Deep vein thrombosis	1	0.0	(0.0, 0.1)	4	0.1	(0.0, 0.3)
Hypertension	3	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sae sex p3 saf

14.179. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=100, TE[b]=0.3)			Placebo (N[a]=100, TE[b]=0.3)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	2	6.6	(0.8, 23.9)	2	6.9	(0.8, 25.1)
INFECTIONS AND INFESTATIONS	1	3.3	(0.1, 18.4)	1	3.5	(0.1, 19.3)
COVID-19 pneumonia	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
Pneumonia	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
Road traffic accident	1	3.3	(0.1, 18.4)	0	0.0	(0.0, 12.8)
METABOLISM AND NUTRITION DISORDERS	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
Diabetes mellitus	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)
Breast cancer	0	0.0	(0.0, 12.2)	1	3.5	(0.1, 19.3)

Abbreviation: HIV = human immunodeficiency virus.
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sae ex hiv p3 saf

14.180. Incidence Rates of at Least 1 Serious Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	55	2.0	(1.5, 2.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1	0.0	(0.0, 0.2)
Pancytopenia	1	0.0	(0.0, 0.2)
CARDIAC DISORDERS	8	0.3	(0.1, 0.6)
Atrial fibrillation	1	0.0	(0.0, 0.2)
Atrial flutter	1	0.0	(0.0, 0.2)
Cardiac failure congestive	1	0.0	(0.0, 0.2)
Coronary artery occlusion	1	0.0	(0.0, 0.2)
Myocardial infarction	4	0.1	(0.0, 0.4)
EYE DISORDERS	1	0.0	(0.0, 0.2)
Retinal tear	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	3	0.1	(0.0, 0.3)
Abdominal pain upper	1	0.0	(0.0, 0.2)
Haematemesis	1	0.0	(0.0, 0.2)
Rectal haemorrhage	1	0.0	(0.0, 0.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1	0.0	(0.0, 0.2)
Impaired healing	1	0.0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	6	0.2	(0.1, 0.5)
Acute hepatic failure	1	0.0	(0.0, 0.2)
Cholecystitis	1	0.0	(0.0, 0.2)
Cholecystitis acute	2	0.1	(0.0, 0.3)
Cholelithiasis obstructive	1	0.0	(0.0, 0.2)
Portosplenomesenteric venous thrombosis	1	0.0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	10	0.4	(0.2, 0.7)
Appendicitis	1	0.0	(0.0, 0.2)
Bacteraemia	1	0.0	(0.0, 0.2)
Clostridium difficile colitis	1	0.0	(0.0, 0.2)
Endocarditis	1	0.0	(0.0, 0.2)
Herpes zoster oticus	1	0.0	(0.0, 0.2)
Meningitis bacterial	1	0.0	(0.0, 0.2)
Pneumonia	1	0.0	(0.0, 0.2)
Post procedural infection	1	0.0	(0.0, 0.2)
Postoperative abscess	1	0.0	(0.0, 0.2)
Sepsis	1	0.0	(0.0, 0.2)

14.180. Incidence Rates of at Least 1 Serious Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Subcutaneous abscess	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	8	0.3	(0.1, 0.6)
Ankle fracture	1	0.0	(0.0, 0.2)
Burns second degree	1	0.0	(0.0, 0.2)
Burns third degree	1	0.0	(0.0, 0.2)
Clavicle fracture	1	0.0	(0.0, 0.2)
Fall	1	0.0	(0.0, 0.2)
Humerus fracture	1	0.0	(0.0, 0.2)
Injury	1	0.0	(0.0, 0.2)
Procedural dizziness	1	0.0	(0.0, 0.2)
Procedural pain	1	0.0	(0.0, 0.2)
Rib fracture	1	0.0	(0.0, 0.2)
Road traffic accident	2	0.1	(0.0, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1	0.0	(0.0, 0.2)
Osteoarthritis	1	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5	0.2	(0.1, 0.4)
Adenocarcinoma pancreas	1	0.0	(0.0, 0.2)
Brain cancer metastatic	1	0.0	(0.0, 0.2)
Hormone receptor positive breast cancer	1	0.0	(0.0, 0.2)
Metastases to lung	1	0.0	(0.0, 0.2)
Pancreatic carcinoma metastatic	1	0.0	(0.0, 0.2)
Uterine cancer	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	3	0.1	(0.0, 0.3)
Dizziness	1	0.0	(0.0, 0.2)
Intracranial aneurysm	1	0.0	(0.0, 0.2)
Seizure	1	0.0	(0.0, 0.2)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	1	0.0	(0.0, 0.2)
Abortion spontaneous	1	0.0	(0.0, 0.2)
PSYCHIATRIC DISORDERS	1	0.0	(0.0, 0.2)
Bipolar I disorder	1	0.0	(0.0, 0.2)
RENAL AND URINARY DISORDERS	2	0.1	(0.0, 0.3)
Nephrolithiasis	2	0.1	(0.0, 0.3)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1	0.0	(0.0, 0.2)
Endometrial thickening	1	0.0	(0.0, 0.2)
Endometriosis	1	0.0	(0.0, 0.2)

14.180. Incidence Rates of at Least 1 Serious Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	5	0.2	(0.1, 0.4)
Asthma	1	0.0	(0.0, 0.2)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.2)
Dyspnoea	1	0.0	(0.0, 0.2)
Dyspnoea exertional	1	0.0	(0.0, 0.2)
Pulmonary embolism	1	0.0	(0.0, 0.2)
VASCULAR DISORDERS	3	0.1	(0.0, 0.3)
Aortic aneurysm	2	0.1	(0.0, 0.3)
Arterial occlusive disease	1	0.0	(0.0, 0.2)
Deep vein thrombosis	1	0.0	(0.0, 0.2)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from the unblinding date to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sae ex bnt p3 saf

14.181. 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, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	73 (1.1)	(0.9, 1.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.1)
Pancytopenia	0	(0.0, 0.1)
CARDIAC DISORDERS	5 (0.1)	(0.0, 0.2)
Acute myocardial infarction	1 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.1)
Angina pectoris	0	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.1)
Cardiac failure congestive	0	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.1)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.1)
Atrial flutter	0	(0.0, 0.1)
Bradycardia	1 (0.0)	(0.0, 0.1)
Cardiac arrest	0	(0.0, 0.1)
Coronary artery disease	0	(0.0, 0.1)
Coronary artery occlusion	0	(0.0, 0.1)
Pericarditis	0	(0.0, 0.1)
Ventricular tachycardia	0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.1)
Vertigo	0	(0.0, 0.1)
EYE DISORDERS	1 (0.0)	(0.0, 0.1)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.1)
Diplopia	0	(0.0, 0.1)
Ophthalmic vein thrombosis	0	(0.0, 0.1)
Retinal tear	0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	7 (0.1)	(0.0, 0.2)
Colitis	1 (0.0)	(0.0, 0.1)
Gastritis	1 (0.0)	(0.0, 0.1)

14.181. 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, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	(95% CI[c])
Small intestinal obstruction	0	(0.0, 0.1)
Abdominal pain upper	0	(0.0, 0.1)
Food poisoning	1 (0.0)	(0.0, 0.1)
Gastrointestinal haemorrhage	0	(0.0, 0.1)
Haematemesis	0	(0.0, 0.1)
Haemorrhoids	1 (0.0)	(0.0, 0.1)
Impaired gastric emptying	1 (0.0)	(0.0, 0.1)
Intestinal obstruction	1 (0.0)	(0.0, 0.1)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.1)
Pancreatitis	1 (0.0)	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (0.0)	(0.0, 0.1)
Chest pain	0	(0.0, 0.1)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)
Asthenia	0	(0.0, 0.1)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.1)
Vascular stent occlusion	1 (0.0)	(0.0, 0.1)
HEPATOBILIARY DISORDERS	7 (0.1)	(0.0, 0.2)
Cholecystitis acute	2 (0.0)	(0.0, 0.1)
Cholelithiasis	0	(0.0, 0.1)
Bile duct stone	2 (0.0)	(0.0, 0.1)
Biliary colic	2 (0.0)	(0.0, 0.1)
Cholecystitis	1 (0.0)	(0.0, 0.1)
Cholelithiasis obstructive	1 (0.0)	(0.0, 0.1)
Portosplenomesenteric venous thrombosis	0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)
Anaphylactic reaction	1 (0.0)	(0.0, 0.1)
Drug hypersensitivity	1 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	18 (0.3)	(0.2, 0.4)
Appendicitis	9 (0.1)	(0.1, 0.3)
Diverticulitis	0	(0.0, 0.1)
Pneumonia	0	(0.0, 0.1)

14.181. 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, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	 (95% CI[c])
Cellulitis	2 (0.0)	(0.0, 0.1)
Pyelonephritis	0	(0.0, 0.1)
Abscess	1 (0.0)	(0.0, 0.1)
Appendicitis perforated	0	(0.0, 0.1)
Arthritis bacterial	1 (0.0)	(0.0, 0.1)
Bacteraemia	0	(0.0, 0.1)
Bacterial sepsis	0	(0.0, 0.1)
Clostridium difficile colitis	0	(0.0, 0.1)
Device related infection	0	(0.0, 0.1)
Empyema	0	(0.0, 0.1)
Endocarditis	0	(0.0, 0.1)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.1)
Gangrene	1 (0.0)	(0.0, 0.1)
Gastroenteritis	1 (0.0)	(0.0, 0.1)
Herpes zoster oticus	1 (0.0)	(0.0, 0.1)
Meningitis bacterial	0	(0.0, 0.1)
Penile infection	0	(0.0, 0.1)
Peritoneal abscess	1 (0.0)	(0.0, 0.1)
Peritonitis	1 (0.0)	(0.0, 0.1)
Peritonsillar abscess	0	(0.0, 0.1)
Postoperative abscess	1 (0.0)	(0.0, 0.1)
Sepsis	0	(0.0, 0.1)
Subcutaneous abscess	1 (0.0)	(0.0, 0.1)
Urinary tract infection	0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	6 (0.1)	(0.0, 0.2)
Ankle fracture	1 (0.0)	(0.0, 0.1)
Road traffic accident	1 (0.0)	(0.0, 0.1)
Wrist fracture	1 (0.0)	(0.0, 0.1)
Burns second degree	1 (0.0)	(0.0, 0.1)
Burns third degree	1 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.1)
Craniocerebral injury	0	(0.0, 0.1)

14.181. 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, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Facial bones fracture	0	(0.0, 0.1)
Fall	0	(0.0, 0.1)
Head injury	0	(0.0, 0.1)
Humerus fracture	0	(0.0, 0.1)
Patella fracture	0	(0.0, 0.1)
Pelvic fracture	0	(0.0, 0.1)
Procedural dizziness	0	(0.0, 0.1)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.1)
Tibia fracture	1 (0.0)	(0.0, 0.1)
Traumatic intracranial haemorrhage	0	(0.0, 0.1)
Upper limb fracture	1 (0.0)	(0.0, 0.1)
INVESTIGATIONS	0	(0.0, 0.1)
Cardiac stress test abnormal	0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	3 (0.0)	(0.0, 0.1)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.1)
Hypoglycaemia	1 (0.0)	(0.0, 0.1)
Hypokalaemia	1 (0.0)	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)
Osteoarthritis	0	(0.0, 0.1)
Arthritis	0	(0.0, 0.1)
Intervertebral disc compression	0	(0.0, 0.1)
Intervertebral disc degeneration	0	(0.0, 0.1)
Intervertebral disc protrusion	0	(0.0, 0.1)
Osteochondritis	1 (0.0)	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5 (0.1)	(0.0, 0.2)
Breast cancer	0	(0.0, 0.1)
Invasive ductal breast carcinoma	1 (0.0)	(0.0, 0.1)
Prostate cancer	0	(0.0, 0.1)
Acute myeloid leukaemia	0	(0.0, 0.1)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.1)

14.181. 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, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	(95% CI[c])
Adrenal gland cancer	0	(0.0, 0.1)
Benign hydatidiform mole	1 (0.0)	(0.0, 0.1)
Bladder cancer	0	(0.0, 0.1)
Borderline serous tumour of ovary	0	(0.0, 0.1)
Brain cancer metastatic	1 (0.0)	(0.0, 0.1)
Breast cancer in situ	0	(0.0, 0.1)
Carcinoid tumour of the stomach	0	(0.0, 0.1)
Colon adenoma	0	(0.0, 0.1)
Gallbladder cancer stage II	0	(0.0, 0.1)
Gastric cancer	0	(0.0, 0.1)
Malignant melanoma	1 (0.0)	(0.0, 0.1)
Non-small cell lung cancer stage IV	0	(0.0, 0.1)
Skin cancer	0	(0.0, 0.1)
Squamous cell carcinoma	0	(0.0, 0.1)
Thyroid cancer	0	(0.0, 0.1)
Transitional cell carcinoma	0	(0.0, 0.1)
Uterine cancer	0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	10 (0.2)	(0.1, 0.3)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)
Cerebrovascular accident	0	(0.0, 0.1)
Dizziness	0	(0.0, 0.1)
Optic neuritis	2 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)
Transient ischaemic attack	0	(0.0, 0.1)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.1)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.1)
Intracranial aneurysm	0	(0.0, 0.1)
Ischaemic stroke	0	(0.0, 0.1)
Paraesthesia	1 (0.0)	(0.0, 0.1)
Peripheral nerve lesion	1 (0.0)	(0.0, 0.1)
Seizure	1 (0.0)	(0.0, 0.1)
Toxic encephalopathy	0	(0.0, 0.1)

14.181. 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, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	(95% CI[c])
Transient global amnesia	0	(0.0, 0.1)
Uraemic encephalopathy	0	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2 (0.0)	(0.0, 0.1)
Abortion spontaneous	2 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	0	(0.0, 0.1)
Suicide attempt	0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	5 (0.1)	(0.0, 0.2)
Nephrolithiasis	3 (0.0)	(0.0, 0.1)
Acute kidney injury	0	(0.0, 0.1)
Renal colic	1 (0.0)	(0.0, 0.1)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.1)
Breast hyperplasia	1 (0.0)	(0.0, 0.1)
Endometrial thickening	1 (0.0)	(0.0, 0.1)
Endometriosis	1 (0.0)	(0.0, 0.1)
Ovarian cyst	0	(0.0, 0.1)
Uterine prolapse	0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (0.0)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	0	(0.0, 0.1)
Dyspnoea	1 (0.0)	(0.0, 0.1)
Dyspnoea exertional	0	(0.0, 0.1)
Interstitial lung disease	0	(0.0, 0.1)
Pneumonitis	0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	1 (0.0)	(0.0, 0.1)
Miscarriage of partner	1 (0.0)	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.1)
Finger amputation	0	(0.0, 0.1)
VASCULAR DISORDERS	1 (0.0)	(0.0, 0.1)
Aortic aneurysm	0	(0.0, 0.1)

14.181. 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, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=6666) n[b] (%)	 (95% CI[c])
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)
Arterial occlusive disease	0	(0.0, 0.1)
Hypertension	0	(0.0, 0.1)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 6m ser age p3 saf

14.182. 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, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	117 (2.2)	(1.8, 2.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)
Pancytopenia	1 (0.0)	(0.0, 0.1)
CARDIAC DISORDERS	22 (0.4)	(0.3, 0.6)
Acute myocardial infarction	3 (0.1)	(0.0, 0.2)
Atrial fibrillation	4 (0.1)	(0.0, 0.2)
Myocardial infarction	4 (0.1)	(0.0, 0.2)
Angina pectoris	3 (0.1)	(0.0, 0.2)
Angina unstable	1 (0.0)	(0.0, 0.1)
Cardiac failure congestive	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	0	(0.0, 0.1)
Arrhythmia supraventricular	0	(0.0, 0.1)
Atrial flutter	1 (0.0)	(0.0, 0.1)
Bradycardia	0	(0.0, 0.1)
Cardiac arrest	1 (0.0)	(0.0, 0.1)
Coronary artery disease	1 (0.0)	(0.0, 0.1)
Coronary artery occlusion	1 (0.0)	(0.0, 0.1)
Pericarditis	1 (0.0)	(0.0, 0.1)
Ventricular tachycardia	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 (0.1)	(0.0, 0.2)
Choroidal neovascularisation	0	(0.0, 0.1)
Diplopia	1 (0.0)	(0.0, 0.1)
Ophthalmic vein thrombosis	1 (0.0)	(0.0, 0.1)
Retinal tear	1 (0.0)	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	7 (0.1)	(0.1, 0.3)
Colitis	1 (0.0)	(0.0, 0.1)
Gastritis	1 (0.0)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)

14.182. 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, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Abdominal pain upper	1 (0.0)	(0.0, 0.1)
Food poisoning	0	(0.0, 0.1)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)
Haematemesis	1 (0.0)	(0.0, 0.1)
Haemorrhoids	0	(0.0, 0.1)
Impaired gastric emptying	0	(0.0, 0.1)
Intestinal obstruction	0	(0.0, 0.1)
Obstructive pancreatitis	0	(0.0, 0.1)
Pancreatitis	0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4 (0.1)	(0.0, 0.2)
Chest pain	2 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.1)
Asthenia	1 (0.0)	(0.0, 0.1)
Shoulder injury related to vaccine administration	0	(0.0, 0.1)
Vascular stent occlusion	0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	4 (0.1)	(0.0, 0.2)
Cholecystitis acute	1 (0.0)	(0.0, 0.1)
Cholelithiasis	3 (0.1)	(0.0, 0.2)
Bile duct stone	0	(0.0, 0.1)
Biliary colic	0	(0.0, 0.1)
Cholecystitis	0	(0.0, 0.1)
Cholelithiasis obstructive	0	(0.0, 0.1)
Portosplenomesenteric venous thrombosis	1 (0.0)	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.1)
Anaphylactic reaction	0	(0.0, 0.1)
Drug hypersensitivity	0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	18 (0.3)	(0.2, 0.5)
Appendicitis	1 (0.0)	(0.0, 0.1)
Diverticulitis	3 (0.1)	(0.0, 0.2)
Pneumonia	3 (0.1)	(0.0, 0.2)
Cellulitis	0	(0.0, 0.1)

14.182. 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, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Pyelonephritis	2 (0.0)	(0.0, 0.1)
Abscess	0	(0.0, 0.1)
Appendicitis perforated	1 (0.0)	(0.0, 0.1)
Arthritis bacterial	0	(0.0, 0.1)
Bacteraemia	1 (0.0)	(0.0, 0.1)
Bacterial sepsis	1 (0.0)	(0.0, 0.1)
Clostridium difficile colitis	1 (0.0)	(0.0, 0.1)
Device related infection	1 (0.0)	(0.0, 0.1)
Empyema	1 (0.0)	(0.0, 0.1)
Endocarditis	1 (0.0)	(0.0, 0.1)
Escherichia urinary tract infection	0	(0.0, 0.1)
Gangrene	0	(0.0, 0.1)
Gastroenteritis	0	(0.0, 0.1)
Herpes zoster oticus	0	(0.0, 0.1)
Meningitis bacterial	1 (0.0)	(0.0, 0.1)
Penile infection	1 (0.0)	(0.0, 0.1)
Peritoneal abscess	0	(0.0, 0.1)
Peritonitis	0	(0.0, 0.1)
Peritonsillar abscess	1 (0.0)	(0.0, 0.1)
Postoperative abscess	0	(0.0, 0.1)
Sepsis	1 (0.0)	(0.0, 0.1)
Subcutaneous abscess	0	(0.0, 0.1)
Urinary tract infection	1 (0.0)	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	10 (0.2)	(0.1, 0.3)
Ankle fracture	1 (0.0)	(0.0, 0.1)
Road traffic accident	1 (0.0)	(0.0, 0.1)
Wrist fracture	1 (0.0)	(0.0, 0.1)
Burns second degree	0	(0.0, 0.1)
Burns third degree	0	(0.0, 0.1)
Cervical vertebral fracture	0	(0.0, 0.1)
Craniocerebral injury	1 (0.0)	(0.0, 0.1)
Facial bones fracture	1 (0.0)	(0.0, 0.1)

14.182. 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, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Fall	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)
Patella fracture	1 (0.0)	(0.0, 0.1)
Pelvic fracture	1 (0.0)	(0.0, 0.1)
Procedural dizziness	1 (0.0)	(0.0, 0.1)
Spinal cord injury cervical	0	(0.0, 0.1)
Tibia fracture	0	(0.0, 0.1)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.1)
Upper limb fracture	0	(0.0, 0.1)
INVESTIGATIONS	1 (0.0)	(0.0, 0.1)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.1)
Diabetic ketoacidosis	0	(0.0, 0.1)
Hypoglycaemia	0	(0.0, 0.1)
Hypokalaemia	0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	8 (0.1)	(0.1, 0.3)
Osteoarthritis	4 (0.1)	(0.0, 0.2)
Arthritis	1 (0.0)	(0.0, 0.1)
Intervertebral disc compression	1 (0.0)	(0.0, 0.1)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.1)
Osteochondritis	0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	20 (0.4)	(0.2, 0.6)
Breast cancer	2 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	1 (0.0)	(0.0, 0.1)
Prostate cancer	2 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.1)
Adenocarcinoma pancreas	0	(0.0, 0.1)
Adrenal gland cancer	1 (0.0)	(0.0, 0.1)

14.182. 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, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Benign hydatidiform mole	0	(0.0, 0.1)
Bladder cancer	1 (0.0)	(0.0, 0.1)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.1)
Brain cancer metastatic	0	(0.0, 0.1)
Breast cancer in situ	1 (0.0)	(0.0, 0.1)
Carcinoid tumour of the stomach	1 (0.0)	(0.0, 0.1)
Colon adenoma	1 (0.0)	(0.0, 0.1)
Gallbladder cancer stage II	1 (0.0)	(0.0, 0.1)
Gastric cancer	1 (0.0)	(0.0, 0.1)
Malignant melanoma	0	(0.0, 0.1)
Non-small cell lung cancer stage IV	1 (0.0)	(0.0, 0.1)
Skin cancer	1 (0.0)	(0.0, 0.1)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.1)
Thyroid cancer	1 (0.0)	(0.0, 0.1)
Transitional cell carcinoma	1 (0.0)	(0.0, 0.1)
Uterine cancer	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	13 (0.2)	(0.1, 0.4)
Subarachnoid haemorrhage	1 (0.0)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)
Dizziness	2 (0.0)	(0.0, 0.1)
Optic neuritis	0	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)
Carpal tunnel syndrome	0	(0.0, 0.1)
Idiopathic intracranial hypertension	0	(0.0, 0.1)
Intracranial aneurysm	1 (0.0)	(0.0, 0.1)
Ischaemic stroke	1 (0.0)	(0.0, 0.1)
Paraesthesia	0	(0.0, 0.1)
Peripheral nerve lesion	0	(0.0, 0.1)
Seizure	0	(0.0, 0.1)
Toxic encephalopathy	1 (0.0)	(0.0, 0.1)
Transient global amnesia	1 (0.0)	(0.0, 0.1)

14.182. 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, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Uraemic encephalopathy	1 (0.0)	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.1)
Abortion spontaneous	0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.1)
Suicide attempt	1 (0.0)	(0.0, 0.1)
RENAL AND URINARY DISORDERS	4 (0.1)	(0.0, 0.2)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)
Acute kidney injury	2 (0.0)	(0.0, 0.1)
Renal colic	0	(0.0, 0.1)
Subcapsular renal haematoma	0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.0)	(0.0, 0.1)
Breast hyperplasia	0	(0.0, 0.1)
Endometrial thickening	0	(0.0, 0.1)
Endometriosis	0	(0.0, 0.1)
Ovarian cyst	1 (0.0)	(0.0, 0.1)
Uterine prolapse	1 (0.0)	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	7 (0.1)	(0.1, 0.3)
Pulmonary embolism	2 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	2 (0.0)	(0.0, 0.1)
Dyspnoea	0	(0.0, 0.1)
Dyspnoea exertional	1 (0.0)	(0.0, 0.1)
Interstitial lung disease	1 (0.0)	(0.0, 0.1)
Pneumonitis	1 (0.0)	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	0	(0.0, 0.1)
Miscarriage of partner	0	(0.0, 0.1)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.1)
Finger amputation	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	5 (0.1)	(0.0, 0.2)
Aortic aneurysm	3 (0.1)	(0.0, 0.2)
Deep vein thrombosis	1 (0.0)	(0.0, 0.1)

14.182. 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, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Arterial occlusive disease	1 (0.0)	(0.0, 0.1)
Hypertension	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 6m ser age p3 saf

14.183. 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 and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	58 (0.5)	(0.4, 0.6)	133 (1.1)	(0.9, 1.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	9 (0.1)	(0.0, 0.1)	18 (0.1)	(0.1, 0.2)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Atrial fibrillation	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Angina pectoris	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Angina unstable	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac failure congestive	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)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Atrial flutter	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)
Cardiac arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pericarditis	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)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ophthalmic vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal tear	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	4 (0.0)	(0.0, 0.1)	10 (0.1)	(0.0, 0.2)
Colitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastritis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Small intestinal obstruction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal pain upper	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Food poisoning	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.183. 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 and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gastrointestinal haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haematemesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impaired gastric emptying	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Chest pain	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	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	3 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Cholecystitis acute	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Cholelithiasis	2 (0.0)	(0.0, 0.1)	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	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Cholecystitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cholelithiasis obstructive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Portosplenomesenteric venous thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	14 (0.1)	(0.1, 0.2)	22 (0.2)	(0.1, 0.3)
Appendicitis	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Diverticulitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pneumonia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Cellulitis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arthritis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacteraemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.183. 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 and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Clostridium difficile colitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device related infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Escherichia urinary tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gangrene	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastroenteritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes zoster oticus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile infection	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)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary tract infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.0)	(0.0, 0.1)	14 (0.1)	(0.1, 0.2)
Ankle fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Road traffic accident	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wrist fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Burns second degree	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Burns third degree	0	(0.0, 0.0)	1 (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)
Facial bones fracture	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)
Head injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural dizziness	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)
Tibia fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.183. 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 and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Upper limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Osteoarthritis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Arthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	4 (0.0)	(0.0, 0.1)	21 (0.2)	(0.1, 0.3)
Breast cancer	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Prostate cancer	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign hydatidiform mole	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bladder cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Borderline serous tumour of ovary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Brain cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cancer in situ	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carcinoid tumour of the stomach	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colon adenoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gallbladder cancer stage II	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Non-small cell lung cancer stage IV	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.183. 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 and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Thyroid cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transitional cell carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	10 (0.1)	(0.0, 0.2)	13 (0.1)	(0.1, 0.2)
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Optic neuritis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Carpal tunnel syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intracranial aneurysm	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peripheral nerve lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxic encephalopathy	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	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abortion spontaneous	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	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)
RENAL AND URINARY DISORDERS	4 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Nephrolithiasis	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Acute kidney injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal colic	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	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endometrial thickening	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Endometriosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.183. 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 and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)		After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Pulmonary embolism	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dyspnoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea exertional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Miscarriage of partner	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Finger amputation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	0	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Aortic aneurysm	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Deep vein thrombosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arterial occlusive disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 15APR2021 (07:36)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA RR/adae s130 sae bnt tp p3 saf

14.184. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=582, TE[b]=0.6)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	2	3.4	(0.4, 12.2)
GASTROINTESTINAL DISORDERS	1	1.7	(0.0, 9.4)
Gastrointestinal necrosis	1	1.7	(0.0, 9.4)
Small intestinal obstruction	1	1.7	(0.0, 9.4)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1	1.7	(0.0, 9.4)
Postoperative ileus	1	1.7	(0.0, 9.4)
PSYCHIATRIC DISORDERS	1	1.7	(0.0, 9.4)
Depression	1	1.7	(0.0, 9.4)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_sae_base_p3x_covid

14.185. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	63	2.7	(2.1, 3.5)
CARDIAC DISORDERS	8	0.3	(0.1, 0.7)
Acute myocardial infarction	1	0.0	(0.0, 0.2)
Arrhythmia	1	0.0	(0.0, 0.2)
Arteriospasm coronary	1	0.0	(0.0, 0.2)
Atrial fibrillation	2	0.1	(0.0, 0.3)
Cardiac failure congestive	1	0.0	(0.0, 0.2)
Cardio-respiratory arrest	1	0.0	(0.0, 0.2)
Cardiovascular disorder	1	0.0	(0.0, 0.2)
Ischaemic cardiomyopathy	1	0.0	(0.0, 0.2)
Myocardial infarction	1	0.0	(0.0, 0.2)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.2)
Hypertrophic cardiomyopathy	1	0.0	(0.0, 0.2)
EAR AND LABYRINTH DISORDERS	1	0.0	(0.0, 0.2)
Vertigo	1	0.0	(0.0, 0.2)
EYE DISORDERS	1	0.0	(0.0, 0.2)
Diplopia	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	7	0.3	(0.1, 0.6)
Anal prolapse	1	0.0	(0.0, 0.2)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.2)
Gastrooesophageal reflux disease	1	0.0	(0.0, 0.2)
Intestinal obstruction	1	0.0	(0.0, 0.2)
Intestinal ulcer perforation	1	0.0	(0.0, 0.2)
Pancreatitis acute	2	0.1	(0.0, 0.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3	0.1	(0.0, 0.4)
Drug withdrawal syndrome	1	0.0	(0.0, 0.2)
Fatigue	1	0.0	(0.0, 0.2)
Pelvic mass	1	0.0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	2	0.1	(0.0, 0.3)
Cholecystitis	1	0.0	(0.0, 0.2)

14.185. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hepatitis acute	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	1	0.0	(0.0, 0.2)
Anaphylactoid reaction	1	0.0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	4	0.2	(0.0, 0.4)
Appendicitis perforated	1	0.0	(0.0, 0.2)
COVID-19 pneumonia	1	0.0	(0.0, 0.2)
Clostridium difficile infection	1	0.0	(0.0, 0.2)
Focal peritonitis	1	0.0	(0.0, 0.2)
Pelvic abscess	1	0.0	(0.0, 0.2)
Pneumonia	1	0.0	(0.0, 0.2)
Urosepsis	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5	0.2	(0.1, 0.5)
Ankle fracture	1	0.0	(0.0, 0.2)
Fall	1	0.0	(0.0, 0.2)
Lower limb fracture	1	0.0	(0.0, 0.2)
Scapula fracture	1	0.0	(0.0, 0.2)
Spinal fracture	1	0.0	(0.0, 0.2)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	1	0.0	(0.0, 0.2)
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4	0.2	(0.0, 0.4)
Myalgia	1	0.0	(0.0, 0.2)
Osteoarthritis	3	0.1	(0.0, 0.4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5	0.2	(0.1, 0.5)
Brain neoplasm	1	0.0	(0.0, 0.2)
Breast cancer	1	0.0	(0.0, 0.2)
Breast cancer stage II	1	0.0	(0.0, 0.2)
Hepatic cancer	1	0.0	(0.0, 0.2)
Non-small cell lung cancer stage III	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	9	0.4	(0.2, 0.7)

14.185. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Brachial plexopathy	1	0.0	(0.0, 0.2)
Cerebrovascular accident	4	0.2	(0.0, 0.4)
Seizure	1	0.0	(0.0, 0.2)
Syncope	1	0.0	(0.0, 0.2)
Transient ischaemic attack	2	0.1	(0.0, 0.3)
PSYCHIATRIC DISORDERS	4	0.2	(0.0, 0.4)
Alcohol withdrawal syndrome	1	0.0	(0.0, 0.2)
Anxiety	1	0.0	(0.0, 0.2)
Bipolar disorder	1	0.0	(0.0, 0.2)
Completed suicide	1	0.0	(0.0, 0.2)
Major depression	1	0.0	(0.0, 0.2)
Suicide attempt	1	0.0	(0.0, 0.2)
RENAL AND URINARY DISORDERS	2	0.1	(0.0, 0.3)
Nephrolithiasis	1	0.0	(0.0, 0.2)
Urinary tract obstruction	1	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	8	0.3	(0.1, 0.7)
Acute respiratory failure	2	0.1	(0.0, 0.3)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.2)
Dyspnoea	1	0.0	(0.0, 0.2)
Pulmonary embolism	4	0.2	(0.0, 0.4)
VASCULAR DISORDERS	5	0.2	(0.1, 0.5)
Aortic stenosis	1	0.0	(0.0, 0.2)
Deep vein thrombosis	2	0.1	(0.0, 0.3)
Hypertension	1	0.0	(0.0, 0.2)
Thrombosis	1	0.0	(0.0, 0.2)

14.185. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=18832, TE[b]=23.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sae base p3x covid

14.186. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo, had COVID-19 Occurrence After Dose 1 and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=853, TE[b]=0.9)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	3	3.4	(0.7, 10.0)
CARDIAC DISORDERS	1	1.1	(0.0, 6.4)
Myocardial infarction	1	1.1	(0.0, 6.4)
INFECTIONS AND INFESTATIONS	1	1.1	(0.0, 6.4)
Clostridium difficile infection	1	1.1	(0.0, 6.4)
Urosepsis	1	1.1	(0.0, 6.4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1	1.1	(0.0, 6.4)
Non-small cell lung cancer stage III	1	1.1	(0.0, 6.4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2	2.3	(0.3, 8.2)
Acute respiratory failure	1	1.1	(0.0, 6.4)
Pulmonary embolism	1	1.1	(0.0, 6.4)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_sae_p3x_covid

14.187. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	19 (0.1)	(0.1, 0.2)	20 (0.2)	(0.1, 0.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	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	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial fibrillation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac arrest	0	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure congestive	0	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery disease	0	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	0	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	0	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	0	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Diarrhoea	0	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain upper	0	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	0	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	0	(0.0, 0.0)	0	(0.0, 0.0)
Nausea	0	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia oral	0	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chills	0	(0.0, 0.0)	0	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.187. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Facial pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Fatigue	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyrexia	0	(0.0, 0.0)	0	(0.0, 0.0)
Swelling face	0	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Drug hypersensitivity	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	0	(0.0, 0.0)	0	(0.0, 0.0)
Shigella sepsis	0	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Exposure during pregnancy	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alcohol poisoning	0	(0.0, 0.0)	0	(0.0, 0.0)
Overdose	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)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myalgia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary cancer metastatic	0	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoproliferative disorder	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 liver	0	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Headache	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)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	0	(0.0, 0.0)

14.187. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=12995)		Placebo (N[a]=13026)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parkinsonism	0	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Depression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary embolism	0	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eczema	0	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus	0	(0.0, 0.0)	0	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriosclerosis	0	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_1md2_wd_age_p3_saf

14.188. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	13 (0.1)	(0.1, 0.2)	16 (0.2)	(0.1, 0.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy	0	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Cardiac arrest	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Cardiac failure congestive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Coronary artery disease	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Tachycardia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Vertigo	0	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	0	(0.0, 0.0)	0	(0.0, 0.0)
Eye pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	0	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Diarrhoea	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Abdominal pain upper	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	0	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Dysphagia	0	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Nausea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Paraesthesia oral	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Injection site pain	0	(0.0, 0.0)	0	(0.0, 0.0)
Chills	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Death	0	(0.0, 0.0)	0	(0.0, 0.0)

14.188. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Facial pain	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)
Injection site dermatitis	0	(0.0, 0.0)	0	(0.0, 0.0)
Injection site swelling	0	(0.0, 0.0)	0	(0.0, 0.0)
Pyrexia	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	0	(0.0, 0.0)
Drug hypersensitivity	0	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Shigella sepsis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Exposure during pregnancy	0	(0.0, 0.0)	0	(0.0, 0.0)
Maternal exposure during pregnancy	0	(0.0, 0.0)	0	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Overdose	0	(0.0, 0.0)	0	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	0	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 0.0)	0	(0.0, 0.0)
Myalgia	0	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.1)
Adenocarcinoma gastric	0	(0.0, 0.0)	0	(0.0, 0.0)
Biliary cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Lymphoproliferative disorder	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metastases to central nervous system	0	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to liver	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	1 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Headache	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)
Amnesia	0	(0.0, 0.0)	0	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)

14.188. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term, by Age Group – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=8931)		Placebo (N[a]=8895)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Paraparesis	0	(0.0, 0.0)	0	(0.0, 0.0)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	0	(0.0, 0.0)	0	(0.0, 0.0)
Depression	0	(0.0, 0.0)	0	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	0	(0.0, 0.0)
Panic attack	0	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pulmonary embolism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Respiratory arrest	0	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Diabetic foot	0	(0.0, 0.0)	0	(0.0, 0.0)
Eczema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
Rash maculo-papular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.1)
VASCULAR DISORDERS	1 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Hypertension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arteriosclerosis	1 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_1md2_wd_age_p3_saf

14.189. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	45	0.5	(0.4, 0.7)	51	0.6	(0.5, 0.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
CARDIAC DISORDERS	9	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Atrial fibrillation	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Cardiac arrest	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coronary artery disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Coronary artery occlusion	0	0.0	(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, 0.0)
Myocardial infarction	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Tachycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deafness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vertigo	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
EYE DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Visual impairment	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	3	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Abdominal pain upper	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diarrhoea	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Diverticular perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dry mouth	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dysphagia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Nausea	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Paraesthesia oral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	7	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Chills	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Death	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Facial pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fatigue	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Injection site dermatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

14.189. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pyrexia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sudden cardiac death	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Swelling face	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Drug hypersensitivity	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Emphysematous cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pneumonia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Septic shock	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Shigella sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5	0.1	(0.0, 0.1)	10	0.1	(0.1, 0.2)
Alcohol poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Exposure during pregnancy	2	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Maternal exposure during pregnancy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Overdose	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
INVESTIGATIONS	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Heart rate irregular	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myalgia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary cancer metastatic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Breast cancer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphoproliferative disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Malignant melanoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to liver	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	3	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Amnesia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebral infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

14.189. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dementia Alzheimer's type	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dizziness	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Haemorrhagic stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Headache	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Paraparesis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Parkinsonism	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Depression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Depression suicidal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Panic attack	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Suicide attempt	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Acute respiratory failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pulmonary embolism	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Dermatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diabetic foot	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eczema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pruritus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rash maculo-papular	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Urticaria	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
VASCULAR DISORDERS	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Aortic rupture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Arteriosclerosis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypertension	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

14.189. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_wd_exp_p3_saf

14.190. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	22	0.4	(0.3, 0.7)	28	0.6	(0.4, 0.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
CARDIAC DISORDERS	2	0.0	(0.0, 0.1)	3	0.1	(0.0, 0.2)
Atrial fibrillation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myocardial infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vertigo	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EYE DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Visual impairment	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Diverticular perforation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dysphagia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site dermatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Injection site swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Drug hypersensitivity	0	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4	0.1	(0.0, 0.2)	10	0.2	(0.1, 0.4)
Exposure during pregnancy	2	0.0	(0.0, 0.1)	8	0.2	(0.1, 0.3)
Maternal exposure during pregnancy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Overdose	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
INVESTIGATIONS	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Heart rate irregular	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

14.190. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myalgia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	3	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Breast cancer	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Malignant melanoma	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Amnesia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dizziness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Headache	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Paraparesis	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Depression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Depression suicidal	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Panic attack	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Suicide attempt	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diabetic foot	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Urticaria	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
VASCULAR DISORDERS	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)
Hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.1)

14.190. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=12995, TE[b]=49.7)			Placebo (N[a]=13026, TE[b]=49.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 wd age p3 saf

14.191. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	23	0.7	(0.4, 1.0)	23	0.7	(0.4, 1.0)
CARDIAC DISORDERS	7	0.2	(0.1, 0.4)	5	0.2	(0.0, 0.4)
Atrial fibrillation	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Cardiac arrest	4	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Cardiac failure congestive	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Coronary artery disease	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Coronary artery occlusion	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Hypertensive heart disease	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Myocardial infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Tachycardia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Deafness unilateral	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	3	0.1	(0.0, 0.3)	4	0.1	(0.0, 0.3)
Abdominal pain upper	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Diarrhoea	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)
Dry mouth	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Nausea	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Paraesthesia oral	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3	0.1	(0.0, 0.3)	1	0.0	(0.0, 0.2)
Chills	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Facial pain	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Fatigue	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pyrexia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Sudden cardiac death	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Swelling face	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	4	0.1	(0.0, 0.3)	3	0.1	(0.0, 0.3)
COVID-19	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
COVID-19 pneumonia	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Emphysematous cholecystitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pneumonia	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Sepsis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)

14.191. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Septic shock	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Shigella sepsis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Alcohol poisoning	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1	0.0	(0.0, 0.2)	1	0.0	(0.0, 0.2)
Biliary cancer metastatic	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Lymphoproliferative disorder	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Metastases to liver	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	1	0.0	(0.0, 0.2)	5	0.2	(0.0, 0.4)
Cerebral infarction	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Dementia Alzheimer's type	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Dizziness	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Haemorrhagic stroke	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Headache	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Parkinsonism	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Acute respiratory failure	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Pulmonary embolism	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1	0.0	(0.0, 0.2)	2	0.1	(0.0, 0.2)
Dermatitis	1	0.0	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Eczema	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Pruritus	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Rash maculo-papular	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Urticaria	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
VASCULAR DISORDERS	2	0.1	(0.0, 0.2)	3	0.1	(0.0, 0.3)
Aortic rupture	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.2)
Arteriosclerosis	2	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.1)
Hypertension	0	0.0	(0.0, 0.1)	2	0.1	(0.0, 0.2)

14.191. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Phase 2/3 Subjects ≥16 Years of Age – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=8931, TE[b]=33.7)			Placebo (N[a]=8895, TE[b]=33.1)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:08)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 wd age p3 saf

14.192. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	4	0.1	(0.0, 0.4)
CARDIAC DISORDERS	1	0.0	(0.0, 0.2)
Myocardial infarction	1	0.0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	1	0.0	(0.0, 0.2)
Acute hepatic failure	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1	0.0	(0.0, 0.2)
Injury	1	0.0	(0.0, 0.2)
Road traffic accident	1	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1	0.0	(0.0, 0.2)
Metastases to lung	1	0.0	(0.0, 0.2)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from the unblinding date to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 wd exp bnt p3 saf

14.193. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: 16-55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=6666)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 0.1)
Dermatitis	0	(0.0, 0.1)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 pd2 wd age p3

14.194. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term, by Age Group – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population Age Group: >55 Years

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=5340)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	1 (0.0)	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.0)	(0.0, 0.1)
Dermatitis	1 (0.0)	(0.0, 0.1)

Note: MedDRA (v23.1) 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 event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 pd2 wd age p3

14.195. Subjects Reporting Lymphadenopathy – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=87) n[b] (%)	Placebo (N[a]=8) n[b] (%)
Severity		
Mild	60 (69.0)	7 (87.5)
Moderate	24 (27.6)	1 (12.5)
Severe	3 (3.4)	0
Onset day after Dose 1 and before Dose 2[c]		
n	26 (29.9)	2 (25.0)
Mean (SD)	10.3 (18.80)	5.0 (5.66)
Median	5.5	5.0
Min, Max	1 - 98	1 - 9
Onset day after Dose 2[c]		
n	61 (70.1)	6 (75.0)
Mean (SD)	7.5 (17.68)	23.7 (41.61)
Median	2.0	7.0
Min, Max	1 - 104	2 - 108
Duration (Days)		
n	80 (92.0)	8 (100.0)
Mean (SD)	12.7 (18.48)	16.4 (23.29)
Median	5.5	4.0
Min, Max	1 - 101	3 - 63
Unknown[d]	7 (8.0)	0

a. N = number of subjects reporting lymphadenopathy. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the event. Subjects reporting more than 1 occurrence of the event were counted by maximum severity, earliest date of onset, and longest duration.
c. Day 1 is the day of vaccination.
d. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 13APR2021 (21:33)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA1/adae_fup_lymph_saf

14.196. Incidence Rates of at Least 1 Adverse Event of Special Interest From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)			Difference	
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])	IRD (/100 PY)[f]	(95% CI[g])
BLOOD AND LYMPHATIC SYSTEM DISORDERS								
Coagulopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Thrombocytopenia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)	-0.01	(-0.05, 0.03)
CARDIAC DISORDERS								
Acute coronary syndrome	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)	-0.04	(-0.09, 0.02)
Acute myocardial infarction	6	0.1	(0.0, 0.2)	4	0.0	(0.0, 0.1)	0.02	(-0.05, 0.10)
Coronary artery occlusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Myocardial infarction	4	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)	-0.05	(-0.13, 0.03)
Myocarditis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Pericarditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
EYE DISORDERS								
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
GASTROINTESTINAL DISORDERS								
Lip swelling	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.01	(-0.03, 0.05)
Swollen tongue	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.01	(-0.03, 0.05)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS								
Death	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Swelling face	2	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)	-0.06	(-0.13, 0.01)
IMMUNE SYSTEM DISORDERS								
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Anaphylactic shock	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Hypersensitivity	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)	-0.04	(-0.10, 0.03)
INFECTIONS AND INFESTATIONS								
Appendicitis	14	0.2	(0.1, 0.3)	9	0.1	(0.1, 0.2)	0.06	(-0.06, 0.17)
Appendicitis perforated	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	-0.00	(-0.03, 0.03)
COVID-19	0	0.0	(0.0, 0.0)	13	0.2	(0.1, 0.3)	-0.16	(-0.24, -0.07)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	-0.00	(-0.03, 0.03)
Complicated appendicitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)	-0.02	(-0.06, 0.01)

14.196. Incidence Rates of at Least 1 Adverse Event of Special Interest From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)			Difference	
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])	IRD (/100 PY)[f]	(95% CI[g])
INJURY, POISONING AND PROCEDURAL COMPLICATIONS								
Exposure during pregnancy	30	0.4	(0.2, 0.5)	42	0.5	(0.4, 0.7)	-0.15	(-0.35, 0.05)
INVESTIGATIONS								
Platelet count decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS								
Arthralgia	281	3.4	(3.0, 3.8)	122	1.5	(1.2, 1.8)	1.88	(1.41, 2.36)
Arthritis	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)	-0.00	(-0.08, 0.08)
Arthritis reactive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
NERVOUS SYSTEM DISORDERS								
Cerebellar infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Cerebral infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Cerebrovascular accident	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.04	(-0.02, 0.09)
Facial paralysis	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.04	(-0.02, 0.09)
Facial paresis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Generalised tonic-clonic seizure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Guillain-Barre syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Haemorrhagic stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Intraventricular haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Ischaemic stroke	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)	-0.00	(-0.05, 0.05)
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.02	(-0.01, 0.06)
Seizure	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.01	(-0.03, 0.05)
Subarachnoid haemorrhage	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.04	(-0.02, 0.09)
Toxic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Transient ischaemic attack	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)	-0.01	(-0.07, 0.04)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS								
Abortion incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Abortion spontaneous	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)	-0.01	(-0.07, 0.04)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Retained products of conception	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS								
Penile vein thrombosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)

14.196. Incidence Rates of at Least 1 Adverse Event of Special Interest From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)			Difference	
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])	IRD (/100 PY)[f]	(95% CI[g])
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS								
Pulmonary embolism	8	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)	-0.00	(-0.10, 0.09)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS								
Angioedema	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)	0.01	(-0.04, 0.06)
Pruritus	24	0.3	(0.2, 0.4)	20	0.2	(0.1, 0.4)	0.04	(-0.11, 0.20)
Rash	62	0.7	(0.6, 1.0)	52	0.6	(0.5, 0.8)	0.11	(-0.14, 0.36)
Rash pruritic	8	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)	0.02	(-0.07, 0.11)
Urticaria	18	0.2	(0.1, 0.3)	15	0.2	(0.1, 0.3)	0.03	(-0.10, 0.17)
VASCULAR DISORDERS								
Deep vein thrombosis	7	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)	-0.00	(-0.09, 0.09)
Venous thrombosis limb	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)

Note: MedDRA (v23.1) coding dictionary applied.
Note: The 95% confidence interval quantifies the precision of the incidence rate difference estimate. Confidence intervals are not adjusted for multiplicity. They should only be used to identify potentially important adverse events.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Difference in incidence rate (BNT162b2 [30 µg] - placebo).
g. 2-sided Wald CI for the incidence rate difference.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 16APR2021 (14:02)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA1/adae_s131_aesi_p3_saf

14.197. Incidence Rates of Arthralgia Reported ≥8 Days After Either Dose 1 or Dose 2 – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)			Difference	
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])	IRD (/100 PY)[f]	(95% CI[g])
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS								
Arthralgia	53	0.6	(0.5, 0.8)	65	0.8	(0.6, 1.0)	-0.16	(-0.41, 0.10)

Note: MedDRA (v23.1) coding dictionary applied.
Note: The 95% confidence interval quantifies the precision of the incidence rate difference estimate. Confidence intervals are not adjusted for multiplicity. They should only be used to identify potentially important adverse events.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Difference in incidence rate (BNT162b2 [30 µg] - placebo).
g. 2-sided Wald CI for the incidence rate difference.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 13APR2021 (22:25)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA1/adae_s131_arth_pb_saf

Additional

14.198. Demographic Characteristics, by Age Groups – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Placebo (N[a]=22021) n[b] (%)	Total (N[a]=44047) n[b] (%)
Sex			
Male	11322 (51.4)	11098 (50.4)	22420 (50.9)
Female	10704 (48.6)	10923 (49.6)	21627 (49.1)
Race			
White	18056 (82.0)	18064 (82.0)	36120 (82.0)
Black or African American	2098 (9.5)	2118 (9.6)	4216 (9.6)
American Indian or Alaska Native	221 (1.0)	217 (1.0)	438 (1.0)
Asian	952 (4.3)	942 (4.3)	1894 (4.3)
Native Hawaiian or other Pacific Islander	58 (0.3)	32 (0.1)	90 (0.2)
Multiracial	550 (2.5)	533 (2.4)	1083 (2.5)
Not reported	91 (0.4)	115 (0.5)	206 (0.5)
Racial designation			
Japanese	78 (0.4)	78 (0.4)	156 (0.4)
Ethnicity			
Hispanic/Latino	5704 (25.9)	5695 (25.9)	11399 (25.9)
Non-Hispanic/non-Latino	16211 (73.6)	16212 (73.6)	32423 (73.6)
Not reported	111 (0.5)	114 (0.5)	225 (0.5)
Country			
Argentina	2883 (13.1)	2881 (13.1)	5764 (13.1)
Brazil	1452 (6.6)	1448 (6.6)	2900 (6.6)
Germany	249 (1.1)	250 (1.1)	499 (1.1)
South Africa	401 (1.8)	399 (1.8)	800 (1.8)
Turkey	249 (1.1)	249 (1.1)	498 (1.1)
USA	16792 (76.2)	16794 (76.3)	33586 (76.3)
Age group in years (at vaccination)			
16 to 55	13069 (59.3)	13095 (59.5)	26164 (59.4)
>55	8957 (40.7)	8926 (40.5)	17883 (40.6)
≥65	4552 (20.7)	4545 (20.6)	9097 (20.7)
16 to 17	378 (1.7)	376 (1.7)	754 (1.7)
16 to 25	1867 (8.5)	1903 (8.6)	3770 (8.6)
16 to 64	17474 (79.3)	17476 (79.4)	34950 (79.3)
18 to 64	17096 (77.6)	17100 (77.7)	34196 (77.6)
55 to 64	4873 (22.1)	4841 (22.0)	9714 (22.1)
65 to 74	3627 (16.5)	3652 (16.6)	7279 (16.5)
≥75	925 (4.2)	893 (4.1)	1818 (4.1)

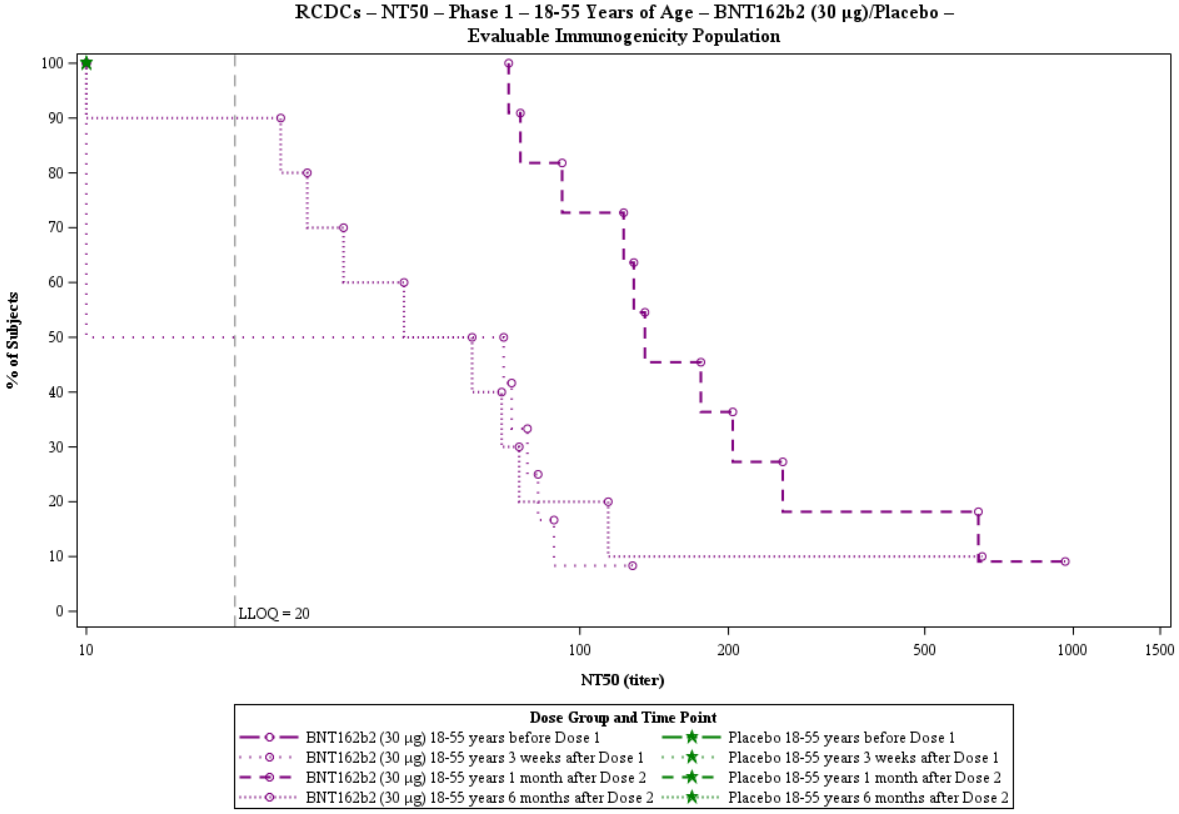
14.198. Demographic Characteristics, by Age Groups – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Placebo (N[a]=22021) n[b] (%)	Total (N[a]=44047) n[b] (%)
75 to 85	919 (4.2)	887 (4.0)	1806 (4.1)
>85	6 (0.0)	6 (0.0)	12 (0.0)
Age at vaccination (years)			
Mean (SD)	49.7 (15.99)	49.6 (16.05)	49.7 (16.02)
Median	51.0	51.0	51.0
Min, max	(16, 89)	(16, 91)	(16, 91)
Baseline SARS-CoV-2 status			
Positive[c]	689 (3.1)	716 (3.3)	1405 (3.2)
Negative[d]	21185 (96.2)	21180 (96.2)	42365 (96.2)
Missing	152 (0.7)	125 (0.6)	277 (0.6)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	271 (1.2)	304 (1.4)	575 (1.3)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	6535 (29.7)	6524 (29.6)	13059 (29.6)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	7670 (34.8)	7558 (34.3)	15228 (34.6)
Obese (≥30.0 kg/m^2)	7543 (34.2)	7629 (34.6)	15172 (34.4)
Missing	7 (0.0)	6 (0.0)	13 (0.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 20APR2021 (11:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adsl s005 demo age all p3 saf

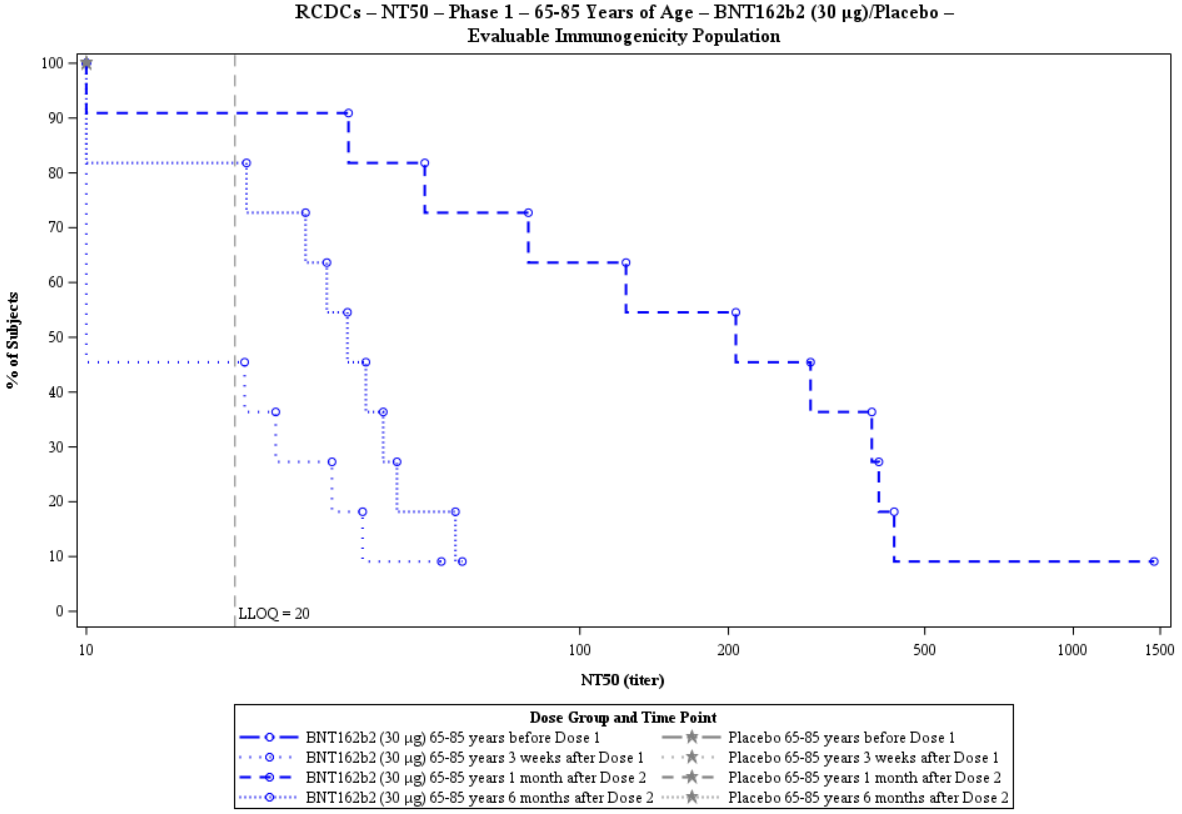
SUPPLEMENTAL FIGURES

14.1. Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay – NT50 – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population



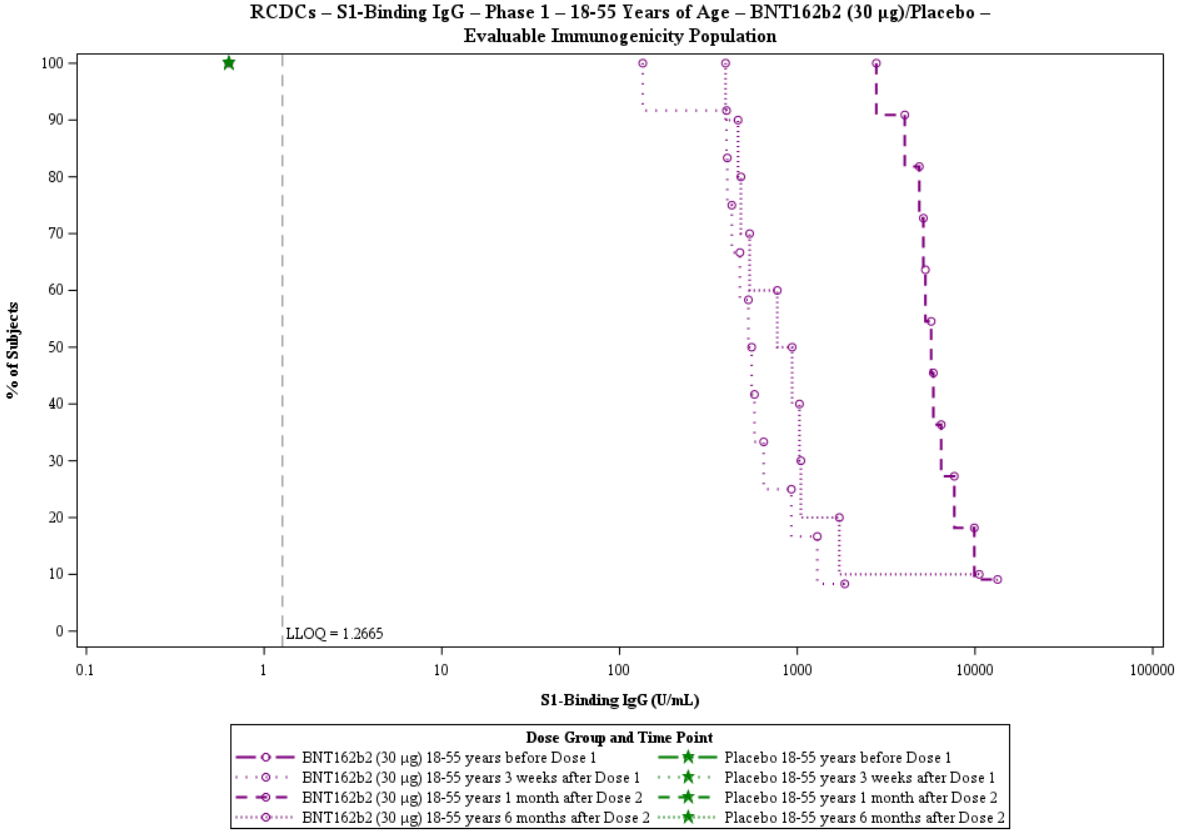
Abbreviations: LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; RCDC = reverse cumulative distribution curve; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: Blood samples from the Day 7 and Day 14 post-Dose 2 visits are not included since these samples were not retested with the 6-month post-Dose 2 samples.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:57)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adva_f003_sars_50_18_b2_p1

14.2. Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay – NT50 – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population



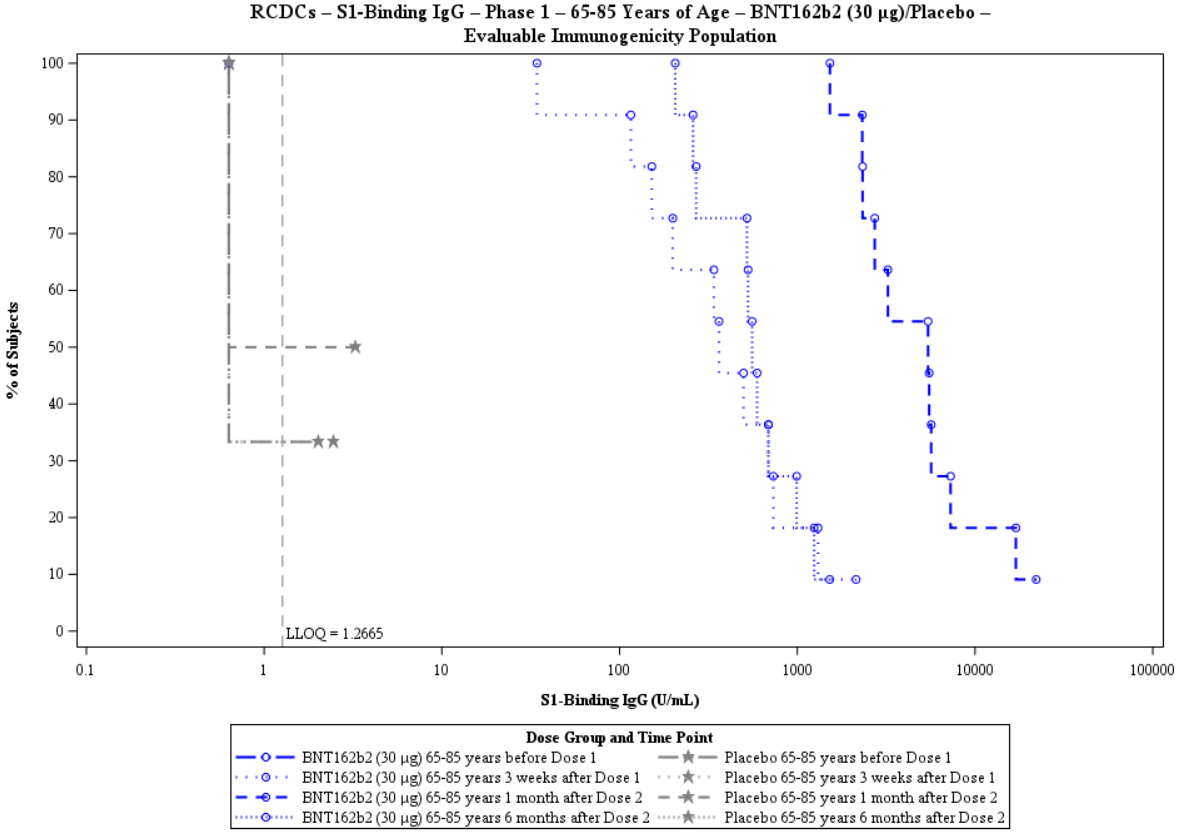
Abbreviations: LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; RCDC = reverse cumulative distribution curve; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: Blood samples from the Day 7 and Day 14 post-Dose 2 visits are not included since these samples were not retested with the 6-month post-Dose 2 samples.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:57)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2_unblinded/C4591001_BLA/adva_f003_sars_50_65_b2_p1

14.3. Reverse Cumulative Distribution Curves, S1-Binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population



Abbreviations: IgG = Immunoglobulin G; LLOQ = lower limit of quantitation; RCDC = reverse cumulative distribution curve; S1 = spike protein S1 subunit.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: Blood samples from the Day 7 and Day 14 post-Dose 2 visits are not included since these samples were not retested with the 6-month post-Dose 2 samples.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:57)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2_unblinded/C4591001_BLA/adva_f003_s1_18_b2_p1

14.4. Reverse Cumulative Distribution Curves, S1-Binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population



Abbreviations: IgG = Immunoglobulin G; LLOQ = lower limit of quantitation; RCDC = reverse cumulative distribution curve; S1 = spike protein S1 subunit.
Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: Blood samples from the Day 7 and Day 14 post-Dose 2 visits are not included since these samples were not retested with the 6-month post-Dose 2 samples.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:57)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2_unblinded/C4591001_BLA/adva_f003_s1_65_b2_p1

SUBJECT NARRATIVES

Primary Reason for Narrative	Subject Number
Death	
	Subject C4591001 1007 10071101
	Subject C4591001 1019 10191146
	Subject C4591001 1021 10211127
	Subject C4591001 1027 10271191
	Subject C4591001 1036 10361140
	Subject C4591001 1039 10391010
	Subject C4591001 1066 10661350
	Subject C4591001 1081 10811194
	Subject C4591001 1084 10841266
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	Subject C4591001 1088 10881126
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	Subject C4591001 1120 11201050
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	Subject C4591001 1127 11271112
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	Subject C4591001 1129 11291166
	Subject C4591001 1131 11311204
	Subject C4591001 1135 11351033
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	Subject C4591001 1140 11401117
	Subject C4591001 1152 11521085
	Subject C4591001 1152 11521497
	Subject C4591001 1156 11561124
	Subject C4591001 1156 11561160
	Subject C4591001 1162 11621327
	Subject C4591001 1168 11681083
	Subject C4591001 1207 12071055
	Subject C4591001 1229 12291083
	Subject C4591001 1231 12313972
	Subject C4591001 1231 12314987
	Subject C4591001 1231 12315324
	Subject C4591001 1252 12521010
Related Serious Adverse Event	
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	Subject C4591001 1015 10151047

Subject C4591001 1018 10181159
Subject C4591001 1129 11291260 (also Safety-Related Subject Withdrawal)
Subject C4591001 1142 11421247
Subject C4591001 1178 11781107 (also Safety-Related Subject Withdrawal, Lymphadenopathy)
Subject C4591001 1212 12121024

Safety-Related Subject Withdrawal

Subject C4591001 1005 10051214
Subject C4591001 1006 10061020
Subject C4591001 1007 10071347
Subject C4591001 1008 10081667
Subject C4591001 1011 10111181
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Subject C4591001 1054 10541186
Subject C4591001 1055 10551145
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Subject C4591001 1090 10901415
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Subject C4591001 4444 44442319

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Subject C4591001 1140 11401009

Bell's Palsy

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Appendicitis

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Pregnancy

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Subject C4591001 4444 44441634

Subject C4591001 4444 44441665
Subject C4591001 4444 44441748
Subject C4591001 4444 44441771
Subject C4591001 4444 44441873
Subject C4591001 4444 44442021
Subject C4591001 4444 44442041
Subject C4591001 4444 44442278

Adverse Event of Special Interest With Numerical Imbalance Between Vaccine Groups

Subject C4591001 1007 10071315
Subject C4591001 1007 10071443
Subject C4591001 1044 10441139
Subject C4591001 1048 10481104
Subject C4591001 1054 10541067
Subject C4591001 1057 10571188
Subject C4591001 1077 10771188
Subject C4591001 1083 10831023
Subject C4591001 1091 10911274
Subject C4591001 1111 11111092
Subject C4591001 1111 11111099
Subject C4591001 1117 11171121
Subject C4591001 1136 11361029
Subject C4591001 1217 12171039
Subject C4591001 1231 12311058
Subject C4591001 1231 12312787
Subject C4591001 1231 12314335
Subject C4591001 1231 12314894
Subject C4591001 1251 12511262
Subject C4591001 4444 44441035

COVID-19 Case (Severe and/or Multiple)

Subject C4591001 1007 10071306
Subject C4591001 1009 10091128
Subject C4591001 1038 10381051
Subject C4591001 1047 10471252
Subject C4591001 1072 10721037
Subject C4591001 1109 11091415
Subject C4591001 1112 11121301
Subject C4591001 1114 11141075
Subject C4591001 1116 11161160
Subject C4591001 1116 11161224
Subject C4591001 1116 11161253
Subject C4591001 1124 11241128
Subject C4591001 1125 11251014

Subject C4591001 1131 11311100
Subject C4591001 1146 11461235
Subject C4591001 1156 11561044
Subject C4591001 1171 11711212
Subject C4591001 1217 12171044
Subject C4591001 1221 12211002
Subject C4591001 1223 12231252
Subject C4591001 1226 12261599
Subject C4591001 1226 12261624
Subject C4591001 1231 12311014
Subject C4591001 1231 12312660
Subject C4591001 1231 12312679
Subject C4591001 1231 12312914
Subject C4591001 1231 12313422
Subject C4591001 1231 12313510
Subject C4591001 1231 12314681
Subject C4591001 1231 12315324
Subject C4591001 1235 12351071
Subject C4591001 1246 12461110
Subject C4591001 1247 12471066
Subject C4591001 1247 12471092
Subject C4591001 4444 44442304

15. REFERENCES

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