1. TITLE PAGE

Vaccine Name and Compound Number:	BNT162 RNA-Based COVID-19 Vaccines, Compound Number: PF-07302048
Report Title:	Interim Report – Adolescents: 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 Date:	22 March 2021 (Phase 2/3, Visit 3 [post-Dose 2 blood draw] assay completed for participants 12 through 25 years of age)
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:	14 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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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
EU	European Union
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
HIV	human immunodeficiency virus
IA	interim analysis
ICD	informed consent document
ICH	International Council for Harmonisation
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
N-binding	SARS-CoV-2 nucleoprotein binding
NT50	neutralizing titer 50
P2 S	SARS-CoV-2 full-length, P2 mutant, prefusion spike glycoprotein
PD	protocol deviation
PT	preferred term
QA	quality assurance
QTL	quality tolerance limit

Abbreviation	Definition
RBD	receptor-binding domain
RCDC	reverse cumulative distribution curve
RDC	remote data capture
RNA	ribonucleic acid
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
TME	targeted medical event
US	United States
VE	vaccine efficacy
VOC	variant of concern

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 SE 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).

Phase 3 participants ≥16 years of age were enrolled at sites in the US, Brazil, Argentina, Turkey, South Africa, and Germany. Participants 12-15 years of age were enrolled at sites in the US.

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 (data cutoff date: 04 November 2020), and the final analysis was conducted on an accrued 170 evaluable COVID 19 cases (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, 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 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, participants 16 through 91 years of age were analyzed for the first 37,706 participants for safety. Individuals 12 through 15 years of age were later permitted to enroll in the study.

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 were originally randomized to BNT162b2, are continuing to be followed for safety as specified in the protocol. The safety data for participants originally randomized to placebo prior to disclosure of vaccine assignment are standard blinded data that contribute to controlled assessment of safety compared to individuals 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 originally 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 displays rates of AEs adjusted for exposure time.

In this report, interim data are presented up to 1 month after Dose 2 and up to the data cutoff date for blinded follow-up only (13 March 2021) and summarizes the following participant age groups:

- Adolescents (12-15 years of age): immunobridging and safety (median ≥2 months follow-up); descriptive efficacy analyses during blinded placebo-controlled follow-up period conducted on all confirmed COVID-19 cases accrued up to the data cutoff date of 13 March 2021
- Young adults (16-25 years of age): reference group for 12-15 years immunogenicity and descriptive safety analysis comparisons
- Adults (16-55 years of age): protocol specified 'younger adult' age stratum, to provide reference safety data from analyses of participants with longer-term follow-up. Note, these data are for comparative purposes and do not include a full independent safety evaluation.

A full independent safety evaluation for Phase 2/3 participants ≥16 years of age will be reported separately at a later time.

8. STUDY OBJECTIVES AND ENDPOINTS

8.1. Phase 1

Phase 1 results are not presented in this report. Refer to Appendix 16.1.1, Protocol Section 3.1 for the study objectives, estimands, and endpoints.

8.2. Phase 2/3

The study objective, estimands, and endpoints presented in Table 1 are from Appendix 16.1.1, Protocol Amendment 14. Those previously reported in the final analysis interim C4591001 CSR dated 03 December 2020, Section 8, are based on Appendix 16.1.1, Protocol Amendment 9.

Final efficacy analyses were completed and reported in the final analysis interim CSR dated 03 December 2020 along with safety and immunogenicity data available at that time (data cutoff date 14 November 2020). This CSR reported prespecified efficacy (event-driven) in participants ≥12 years of age 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.

This CSR presents safety, efficacy, and immunogenicity data for adolescents 12 through 15 years of age up to the data cutoff date (13 March 2021). Data are included from young adults 16 through 25 years of age for immunobridging analyses and descriptive safety analysis comparisons. Longer-term reference safety data are also presented from the adult 16 through 55 years of age stratum up to the date of participant unblinding. Note, these data are for comparative purposes and do not include a full independent safety evaluation.

This study is ongoing; results for objectives outside of the scope of this CSR, including full independent safety evaluation for participants ≥16 years of age, will be reported separately at a later time (Table 1).

Table 1. 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 for participants 12 through 15 years of age only 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 for participants 12 through 15 years of age only 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 1. 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. 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 Dose 2 and to the unblinding 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 from Dose 1 to 1 month after Dose 2 are reported in this CSR. 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 Dose 2 and to the cutoff date are reported in this CSR.
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 1. 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 1. 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 for participants 12 through 15 years of age 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 for participants 12 through 15 years of age 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 1. 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 are reported in this CSR.
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 1. 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 1. 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	Data will be reported at a later time.
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	GMTs and GMFRs of SARS-CoV-2 neutralizing titers up to 1 month after Dose 2 in participants 12 through 15 and 16 through 25 are reported in this CSR.

Table 1. 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	Data will be reported at a later time.
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 1. 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.

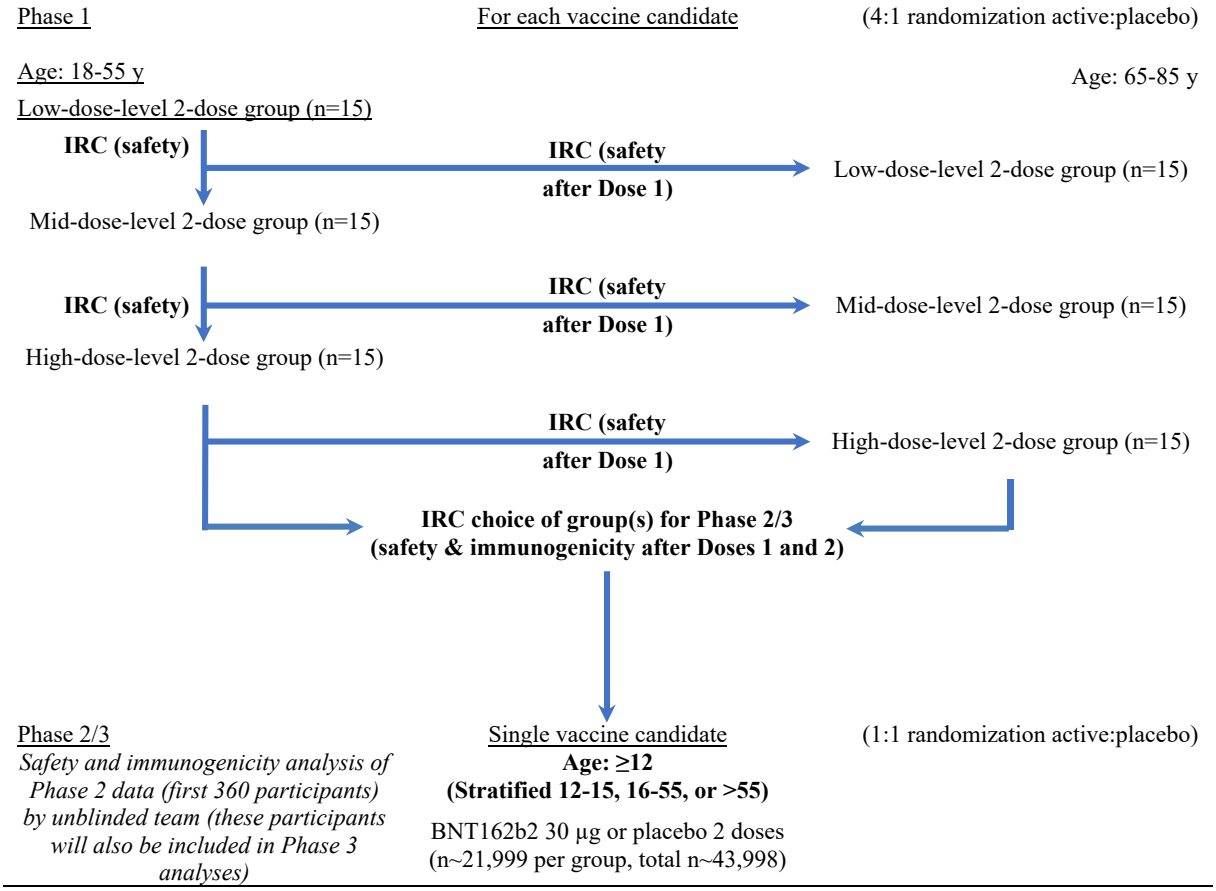
9. INVESTIGATIONAL PLAN

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 4.1.2 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.

Adolescents 12 through 15 years of age remain blinded in this study, as BNT162b2 vaccination eligibility in all markets/regions is currently for 16 years of age and older. Note that a few participants in the 12 through 15 years of age group turned 16 years of age after study enrollment

and thus became eligible for unblinding to treatment assignment and vaccination under the emergency use or conditional authorization in their country/region.

9.1.1. Phase 1

Phase 1 safety follow-up is ongoing, and participants were expected to participate for up to a maximum of approximately 26 months. This interim report only describes Phase 2/3 adolescents 12 through 15 years of age, with reference comparison to young adults 16 through 25 years of age and adults 16 through 55 years of age. 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 2200 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 (data cutoff date: 04 November 2020), and the final analysis was conducted on an accrued 170 evaluable COVID-19 cases (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, few participants 12 through 15 years of age had enrolled in the study, and no COVID-19 cases reported in this age group accrued at that time. Updated efficacy analyses during blinded placebo-controlled follow-up period were conducted on cases accrued in the 12 through 15 years of age group 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 for participants 12 through 15 years of age.

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 were assessed based on the GMR of SARS-CoV-2 neutralizing titers 1 month after Dose 2 using a 1.5-fold margin.

Safety data are included for adolescents 12 through 15 years of age through 1 month after Dose 2 and to the data cutoff date (13 March 2021) and include descriptive comparisons to participants (reactogenicity subset) in the group 16 through 25 years of age. Safety data from participants 16 through 55 years of age are included for comparative purposes, and a full independent safety evaluation of this age group along with participants >55 years of age will be reported separately at a later time.

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 at a later time.

- 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). Boostability will also be assessed (reported at a later time).

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. The study evaluated a 2-dose (separated by 21 days) schedule of the following for active immunization against COVID-19 or saline placebo in participants 12 through 15 years of age and reference groups (16 through 25 and 16 through 55 years of age):

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

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.

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 2 below.

Table 2. Investigational Product Lot Numbers – Interim – Adolescents

Investigational Product	Phase	Manufacturer	Vendor Lot Number (Manufacturer)	Lot Number[a] (Pfizer)
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
			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	

Table 2. Investigational Product Lot Numbers – Interim – Adolescents

			EE3813	PA2077905/P220395-0026L
			EE3813	NC2075485/P220395-0068L
			EE3813	NC2075485/P220395-0074L
			EJ0553Z	NC2075485/P220395-0077L
				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	PA2067775/P220395-0030L
			DK2074;20 - 002108	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
			DK2074;20 - 002221	PA2069407OTH/E220395-0049L

Note: C4591001 End of Study Information and Quality Control (QC) Record for Study Drug Appendix (Section D) dated 07Apr2021 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 – Adolescents, Final, Version 2.0, 09Apr2021.

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 Appendix 16.1.1, Protocol Section 8.2.3).

- 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 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 a 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).

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.

Adolescents 12 through 15 years of age remain blinded in this study, as BNT162b2 vaccination eligibility in all markets/regions is currently for 16 years of age and older. Note that a few participants in the 12 through 15 years of age group turned 16 years of age after study enrollment and thus became eligible for unblinding to treatment assignment and vaccination under the emergency use or conditional authorization in their country/region.

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 (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 few participants 12-15 years of age enrolled in the study and no COVID-19 cases reported in this age group accrued at that time (14 November 2020). In this report, efficacy was assessed based on all cases in participants 12 through 15 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 participants 12 through 15 years of age:

- SARS-CoV-2 neutralization assay (reference strain)

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. Electronic Diary

All participants 12 through 15 years of age and a subset of participants 16 through 55 years of age (including the young adults 16 through 25 years of age) were asked to monitor and record local reactions, systemic events, and antipyretic/pain medication usage for 7 days, following administration of study intervention using an e-diary. All other participants 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 9.5.2.3).

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 9.5.2.3).

Refer to Appendix 16.1.1, Protocol Section 8.2.2 for additional details on use of the e-diary. 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.

9.5.2.2. 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).

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.

9.5.2.3. 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 3 for Phase 2/3 participants).

Acute reactions (immediate AEs) were collected within the first 30 minutes after administration of the study intervention.

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

Refer to Appendix 16.1.1, Protocol Section 8.3 for additional details for collecting AEs and SAEs.

9.5.2.4. 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 12.4.4).

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 3.

Refer to Appendix 16.1.9, SAP Section 4 for details of all other planned analysis sets.

Table 3. 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 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 blood collection within an appropriate window after Dose 2 (28-42 days after Dose 2 for Phase 2/3), and had no other important protocol deviations as determined by the clinician.
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 (at least 164 cases) vaccine efficacy with respect to all efficacy endpoints was assessed on an accrued 170 evaluable COVID-19 cases (data cutoff date: 14 November 2020) for both 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 efficacy analyses during blinded placebo-controlled follow-up were conducted for participants 12 through 15 years of age based on the data cutoff date of 13 March 2021. 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. In addition to the protocol definition of severe COVID-19, supportive analyses using the CDC definition of severe COVID-19 was also performed.

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 participants randomized to the BNT162b2 groups with no serological or virological evidence (up to 1 month after receipt of the second dose) of past SARS-CoV-2 infection, the GMR of SARS-CoV-2 50% neutralizing titers in participants 12 to 15 years of age to those in participants 16 to 25 years of age and 2-sided 95% CIs were provided at 1 month after Dose 2 for noninferiority assessment. The GMR and its 2-sided 95% CI were derived by calculating differences in means and CIs on the natural log scale of the titers based on the Student's t-distribution and then exponentiating the results. The difference in means on the natural log scale were 12 to 15 years minus 16 to 25 years. Noninferiority was declared if the lower bound of the 2-sided 95% CI for the GMR was greater than 0.67, using 1.5-fold noninferiority margin. In addition, the difference in percentages of participants (12 to 15 years – 16 to 25 years) achieving a ≥4-fold rise in SARS-CoV-2 neutralizing titers from before vaccination to 1 month after Dose 2 were provided. The associated 2-sided 95% CI for the difference in percentage was calculated using the Miettinen and Nurminen method.

For immunogenicity results of SARS-CoV-2 neutralizing titers concentrations, the GMT was computed along with associated 95% CIs. The GMT was 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 exact 95% CIs for binary endpoints were computed using the F distribution (Clopper-Pearson method).

Titers 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 9.4.1and Appendix 16.1.9, SAP Section 6.2.1.4 and SAP Section 6.3.2 .

9.7.5. Safety Analysis

The primary safety objective was evaluated by descriptive summary statistics for local reactions, systemic events, and AEs/SAEs 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.

9.7.6. Other Analyses

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 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 greater than 62 cases (94 cases), and the final analysis of efficacy was conducted after accrual of at least 164 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.

- One IA for efficacy after accrual of at least 62 cases (performed at 94 cases).

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

- 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. Safety data for participants 16 through

55 years of age are included for comparative purposes and do not include a full independent safety evaluation (these will be reported separately).

- Updated efficacy analysis for participants 12 through 15 years of age based on the data cutoff date of 13 March 2021

Statistical analyses will be carried out as the following data become available and reported at a later time:

- Complete safety analysis up to approximately 6 months after Dose 2 for all 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.

- 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 complete 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:

- Ad hoc 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.

10. STUDY PARTICIPANTS

10.1. Disposition of Participants

10.1.1. Participants 12 Through 15 Years of Age

The disposition of adolescents (12-15 years of age) and young adults (16-25 years of age) was similar in BNT162b2 and placebo groups through 1 month after Dose 2 (Table 4). Most participants randomized in both age groups (≥97.4%) received Dose 1 and Dose 2. Among adolescents, 7 participants (0.6%) in the BNT162b2 group and 17 participants (1.5%) in the placebo group discontinued from the vaccination period and are continuing in the study for safety follow-up. Most participants across age groups completed the visit at 1 month after Dose 2 (≥94.5%).

Among adolescents who discontinued from vaccination period but continued in the study up to the 1 month post Dose 2 visit, 2 participants discontinued due to AEs, both in the BNT162b2 group (pyrexia considered by the investigator as related to study intervention, and unrelated anxiety/depression; refer to Section 12.4.3.1) and none in the placebo group.

No adolescents in the BNT162b2 and 2 participants in the placebo group withdrew from the study before the 1 month post Dose 2 visit.

A total of 49 adolescent participants withdrew from the vaccination period when they turned 16 years of age after entering the study and became eligible to be unblinded to receive BNT162b2 vaccination; of these, 19/49 received Dose 3 and Dose 4 (BNT162b2) (Appendix 16.1.7.2.1). Participants originally randomized to placebo who received Dose 3 of BNT162b2 (per protocol; refer to Section 9.1) continued in open-label follow-up in the study, but their data were censored at the time of unblinding with regard to analyses in this report. Information for these participants are provided for SAEs (refer to Section 12.4.2.1) or other significant AEs (refer to Section 12.4.4).

Table 4. Disposition of All Randomized Subjects Through 1 Month After Dose 2 – Subjects 12 Through 15 and 16 Through 25 Years of Age

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N^a=1134) n^b (%)	16-25 Years (N^a=1875) n^b (%)	12-15 Years (N^a=1130) n^b (%)	16-25 Years (N^a=1913) n^b (%)
Randomized	1134 (100.0)	1875 (100.0)	1130 (100.0)	1913 (100.0)

Table 4. Disposition of All Randomized Subjects Through 1 Month After Dose 2 – Subjects 12 Through 15 and 16 Through 25 Years of Age

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1134) n[b] (%)	16-25 Years (N[a]=1875) n[b] (%)	12-15 Years (N[a]=1130) n[b] (%)	16-25 Years (N[a]=1913) n[b] (%)
Not vaccinated	3 (0.3)	6 (0.3)	1 (0.1)	7 (0.4)
Vaccinated				
Dose 1	1131 (99.7)	1869 (99.7)	1129 (99.9)	1906 (99.6)
Dose 2	1124 (99.1)	1826 (97.4)	1117 (98.8)	1836 (96.0)
Completed 1-month post–Dose 2 visit (vaccination period)	1118 (98.6)	1803 (96.2)	1102 (97.5)	1807 (94.5)
Discontinued from vaccination period but continue in the study up to 1-month post–Dose 2 visit	7 (0.6)	13 (0.7)	17 (1.5)	42 (2.2)
Discontinued after Dose 1 and before Dose 2	7 (0.6)	12 (0.6)	10 (0.9)	36 (1.9)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	1 (0.1)	7 (0.6)	6 (0.3)
Reason for discontinuation from vaccination period				
No longer meets eligibility criteria	3 (0.3)	4 (0.2)	10 (0.9)	26 (1.4)
Withdrawal by subject	0	6 (0.3)	1 (0.1)	1 (0.1)
Pregnancy	0	1 (0.1)	0	3 (0.2)
Adverse event	2 (0.2)	1 (0.1)	0	0
Physician decision	1 (0.1)	0	0	2 (0.1)
Protocol deviation	0	0	1 (0.1)	2 (0.1)
Lost to follow-up	0	0	0	1 (0.1)
Other	1 (0.1)	1 (0.1)	5 (0.4)	7 (0.4)
Withdrawn from the study before 1-month post–Dose 2 visit	0	45 (2.4)	2 (0.2)	56 (2.9)
Withdrawn after Dose 1 and before Dose 2	0	25 (1.3)	1 (0.1)	34 (1.8)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	0	20 (1.1)	1 (0.1)	22 (1.2)
Reason for withdrawal from the study				
Lost to follow-up	0	29 (1.5)	0	32 (1.7)
Withdrawal by subject	0	14 (0.7)	0	19 (1.0)
Protocol deviation	0	0	1 (0.1)	1 (0.1)
Withdrawal by parent/guardian	0	1 (0.1)	1 (0.1)	0
Adverse event	0	0	0	1 (0.1)
Physician decision	0	0	0	1 (0.1)
Other	0	1 (0.1)	0	2 (0.1)

Table 4. Disposition of All Randomized Subjects Through 1 Month After Dose 2 – Subjects 12 Through 15 and 16 Through 25 Years of Age

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N^a=1134) n^b (%)	16-25 Years (N^a=1875) n^b (%)	12-15 Years (N^a=1130) n^b (%)	16-25 Years (N^a=1913) n^b (%)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Subjects randomized but did not sign informed consent or had a significant quality event due to lack of PI oversight are not included in any analysis population.
a. N = number of randomized subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 27MAR2021 (06:06) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adds_s002_ped_rand

10.1.2. Participants 16 Through 55 Years of Age

The disposition of randomized adult participants (16-55 years of age) was similar in the BNT162b2 and placebo groups during the blinded follow-up period (Table 5). Most participants randomized (97.7%) received Dose 1 and Dose 2. There were 278 (2.1%) participants in the BNT162b2 group and 388 (3.0%) participants in the placebo group who discontinued from the vaccination period. Most participants (95.8%) completed the 1 month post Dose 2 visit and 25.5% of the BNT162b2 group participants completed the 6 months post Dose 2 (25.5%) visit as of the data cutoff date. There were 608 participants in the BNT162b2 and placebo groups who were withdrawn from the study (2.0% and 2.7%, respectively), mostly due to lost to follow-up (1.2%) or withdrawn by subject (0.9%).

Open-label data for participants who were unblinded, including original placebo participant who received open-label BNT162b2 30 µg as Dose 3/Dose 4, are shown in Table 5 for reference but not discussed further for safety analyses.

Table 5. Disposition of All Randomized Subjects – Phase 2/3 Subjects 16-55 Years of Age

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=13104) n^b (%)	Placebo (N^a=13132) n^b (%)	Total (N^a=26236) n^b (%)

Table 5. Disposition of All Randomized Subjects – Phase 2/3 Subjects 16-55 Years of Age

	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)
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)

Table 5. Disposition of All Randomized Subjects – Phase 2/3 Subjects 16-55 Years of Age

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=13104) n[b] (%)	Placebo (N[a]=13132) n[b] (%)	Total (N[a]=26236) 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	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)	
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)	

Table 5. Disposition of All Randomized Subjects – Phase 2/3 Subjects 16-55 Years of Age

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=13104) n[b] (%)	Placebo (N[a]=13132) n[b] (%)	Total (N[a]=26236) 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		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, Subject C4591001 1088 10881077 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: 31MAR2021 (18:10) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adds_s002_all_1655_rand

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 16.2.2.1 and Appendix 16.2.2.2 list important PDs in participants 12 through 25 years of age and participants 16 through 55 years of age, respectively, 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. Participants 12 Through 15 Years of Age

For the adolescent and young adult groups, almost all participants were administered study intervention as randomized (Table 6). 100% received Dose 1. In the adolescent group, 99.4% and 98.9% received Dose 2 of BNT162b2 and placebo, respectively. In the young adult group, 97.6% and 95.2% received Dose 2 of BNT162b2 and placebo, respectively.

The majority of participants received Dose 2 between 21 to 27 days after Dose 1 in the BNT162b2 (65.2% for the adolescent group and 60.3% for the young adult group) and placebo (64.6% for the adolescent group and 58.2% for the young adult group), followed by 14 to 20 days after Dose 1 in the BNT162b2 (31.7% for adolescent group and 34.1% for the young adult group) and placebo (32.2% for the adolescent group and 34.0% for the young adult group) (Table 7).

Table 6. Vaccine as Administered, by Vaccine Group – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset)

Vaccine (as Administered)	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N^a=1131) n^b (%)	16-25 Years (N^a=539) n^b (%)	12-15 Years (N^a=1129) n^b (%)	16-25 Years (N^a=564) n^b (%)
Vaccinated	1131 (100.0)	539 (100.0)	1129 (100.0)	564 (100.0)
Not vaccinated	0	0	0	0
Dose 1				
BNT162b2 (30 µg)	1131 (100.0)	539 (100.0)	0	0
Placebo	0	0	1129 (100.0)	564 (100.0)
Dose 2				
BNT162b2 (30 µg)	1124 (99.4)	526 (97.6)	0	0
Placebo	0	0	1117 (98.9)	537 (95.2)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (02:54) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/advx_s002_adm_ped_rand

Table 7. Vaccine Administration Timing – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset)

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N^a=1131) n^b (%)	16-25 Years (N^a=539) n^b (%)	12-15 Years (N^a=1129) n^b (%)	16-25 Years (N^a=564) n^b (%)
Randomized	1131 (100.0)	539 (100.0)	1129 (100.0)	564 (100.0)
Not vaccinated	0	0	0	0
Dose 1	1131 (100.0)	539 (100.0)	1129 (100.0)	564 (100.0)
Dose 2[c]	1124 (99.4)	526 (97.6)	1117 (98.9)	537 (95.2)
<14 Days	0	0	0	0
14 to 20 Days	358 (31.7)	184 (34.1)	364 (32.2)	192 (34.0)
21 to 27 Days	737 (65.2)	325 (60.3)	729 (64.6)	328 (58.2)
28 to 34 Days	23 (2.0)	7 (1.3)	15 (1.3)	6 (1.1)
35 to 41 Days	4 (0.4)	5 (0.9)	4 (0.4)	4 (0.7)
42 to 48 Days	1 (0.1)	1 (0.2)	1 (0.1)	1 (0.2)
49 to 55 Days	1 (0.1)	0	3 (0.3)	2 (0.4)
>55 Days	0	4 (0.7)	1 (0.1)	4 (0.7)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Days calculated since Dose 1.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (02:11) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/advx_s002_time_ped_rand

10.3.2. Participants 16 Through 55 Years of Age

For the adult group, almost all participants were administered study intervention as randomized (Table 8). 99.7% received Dose 1 and 98.1% received Dose 2 of BNT162b2 in the BNT162b2 group. In participants originally randomized to placebo, 99.7% received Dose 1 and 97.7% received Dose 2 of placebo, and 86.8% received Dose 3 and 65.4% received Dose 4 of BNT162b2 after unblinding.

For Dose 1, 2 participants randomized to the placebo group received BNT162b2, 1 participant randomized to the BNT162b2 group received placebo, and vaccination for 1 participant randomized to the BNT162b2 group could not be determined. For Dose 2, 1 participant randomized to the placebo group received BNT162b2, and 2 participants randomized to the BNT162b2 group received placebo.

The majority of participants received Dose 2 between 21 to 27 days after Dose 1 in the BNT162b2 (62.7%) and placebo (62.7%), followed by 14 to 20 days after Dose 1 in the BNT162b2 (32.7%) and placebo (32.3%) (Table 9). In participants originally randomized to placebo, 86.8% received BNT162b2 after unblinding (Dose 3) and the majority of participants received Dose 4 between 21 to 27 days after Dose 3 (44.1%), followed by 14 to 20 days after Dose 3 (19.5%).

Table 8. Vaccine as Administered by Vaccine Group – Phase 2/3 Subjects 16-55 Years of Age – All Randomized Subjects

Vaccine (as Administered)	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=13104) n[b] (%)	Placebo (N[a]=13132) n[b] (%)
Vaccinated	13073 (99.8)	13100 (99.8)
Not vaccinated	31 (0.2)	32 (0.2)
Dose 1		
BNT162b2 (30 µg)	13071 (99.7)	2 (0.0)
Placebo	1 (0.0)	13098 (99.7)
Indeterminate vaccine[c]	1 (0.0)	0
Dose 2		
BNT162b2 (30 µg)	12860 (98.1)	1 (0.0)
Placebo	2 (0.0)	12824 (97.7)
Indeterminate vaccine[c]	0	0
Dose 3		
First dose BNT162b2 (30 µg)		11405 (86.8)
Indeterminate vaccine[c]		0
Dose 4		
Second dose BNT162b2 (30 µg)		8586 (65.4)
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.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 28MAR2021 (12:39) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 EUA 1655/advx s002 adm 1655 rand

Table 9. Vaccine Administration Timing – Phase 2/3 Subjects 16-55 Years of Age – All Randomized Subjects

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=13104) n[b] (%)	**Placebo (N[a]=13132) n[b] (%)**
Randomized	13104 (100.0)	13132 (100.0)
Not vaccinated	31 (0.2)	32 (0.2)
Dose 1	13073 (99.8)	13100 (99.8)
Dose 2[c]	12862 (98.2)	12825 (97.7)
<14 Days	0	1 (0.0)
14 to 20 Days	4280 (32.7)	4245 (32.3)
21 to 27 Days	8221 (62.7)	8239 (62.7)
28 to 34 Days	158 (1.2)	200 (1.5)
35 to 41 Days	62 (0.5)	61 (0.5)
42 to 48 Days	43 (0.3)	34 (0.3)
49 to 55 Days	23 (0.2)	20 (0.2)
>55 Days	75 (0.6)	25 (0.2)
Dose 3 (first dose of BNT162b2 [30 µg])		11405 (86.8)
Dose 4 (second dose of BNT162b2 [30 µg])[d]		8586 (65.4)
<14 Days		1 (0.0)
14 to 20 Days		2564 (19.5)
21 to 27 Days		5788 (44.1)
28 to 34 Days		152 (1.2)
35 to 41 Days		56 (0.4)
42 to 48 Days		18 (0.1)
49 to 55 Days		6 (0.0)
>55 Days		1 (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: 28MAR2021 (14:23) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/advx_s002_time_1655_rand

10.4. Data Sets Analyzed

10.4.1. Participants 12 Through 15 Years of Age

10.4.1.1. Safety Population

The safety populations, including subsets and exclusions, the adolescent and young adult groups were similar in the corresponding BNT162b2 and placebo groups (Table 10). Safety analysis results hereafter are presented for adolescent and young adult safety population (including the reactogenicity subset) up to 1 month after Dose 2 and for all available data up to the data cutoff date (13 March 2021).

Table 10. Safety Population – Subjects 12 Through 15 and 16 Through 25 Years of Age

	Vaccine Group (as Administered)					
	12-15 Years			16-25 Years		
	BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a]	BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a]
Randomized[b]			2264			3788
Vaccinated	1131	1129	2260 (99.8)	1869	1906	3775 (99.7)
Safety population	1131	1129	2260 (99.8)	1867	1903	3770 (99.5)
Reactogenicity subset	1131	1129	2260 (99.8)	537	561	1098 (29.0)
HIV-positive	0	0	0	1	0	1 (0.0)
Excluded from safety population			4 (0.2)			18 (0.5)
Reason for exclusion						
Subject did not receive study vaccine			4 (0.2)			13 (0.3)
Unreliable data due to lack of PI oversight			0			5 (0.1)

Note: Human immunodeficiency virus (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, or the total sample.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (04:09) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adsl s003 saf pop ped

10.4.1.2. Duration of Follow-Up

The median duration of follow-up for adolescents was >2 months after Dose 2. Almost all (98.3%) of adolescent participants had at least 1 month of follow-up after Dose 2, and 1308 out of 2260 enrolled adolescents (57.9%) had at least 2 months of follow-up after Dose 2 (Table 11).

Table 11. Follow-up Time After Dose 2 – Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Placebo (N[a]=1129) n[b] (%)	Total (N[a]=2260) n[b] (%)
Subjects (%) with length of follow-up of:			
Total exposure from Dose 2 to cutoff date			
<1 Month	13 (1.1)	25 (2.2)	38 (1.7)
≥1 Month to <2 months	458 (40.5)	456 (40.4)	914 (40.4)
≥2 Months to <3 months	612 (54.1)	599 (53.1)	1211 (53.6)
≥3 Months	48 (4.2)	49 (4.3)	97 (4.3)

Note: Follow-up time was calculated to the cutoff date or the date of unblinding, whichever date was earlier.
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 (00:54) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_fu_d2_ped_saf

10.4.1.3. Immunogenicity Populations

For immunogenicity analyses, it was planned to select a random sample of 280 participants in the BNT162b2 group for each of the two age groups as an immunogenicity subset for the NI assessment. The immunogenicity subset was chosen to reflect the population tested which received BNT162b2 or placebo.

The Dose 2 evaluable immunogenicity population for adolescents 12-15 years of age included 209 participants in the BNT162b2 group and 36 participants in the placebo group), and for young adults 16-25 years of age included 186 participants in the BNT162b2 group and 32 participants in the placebo group. Reasons for participant exclusion from the evaluable immunogenicity populations are shown in Table 12. The majority of exclusions were due to participants not having at least 1 valid and determinate immunogenicity result after Dose 2, mostly as the result of testing laboratory supply limitation of the qualified viral lot and were generally balanced across age and vaccine groups.

Table 12. Immunogenicity Populations – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset)

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years n[a] (%)	16-25 Years n[a] (%)	12-15 Years n[a] (%)	16-25 Years n[a] (%)
Randomized[b]	280 (100.0)	280 (100.0)	50 (100.0)	50 (100.0)
Dose 2 all-available immunogenicity population	210 (75.0)	191 (68.2)	36 (72.0)	34 (68.0)
Subjects excluded from Dose 2 all-available immunogenicity population	70 (25.0)	89 (31.8)	14 (28.0)	16 (32.0)
Reason for exclusion				
Did not receive Dose 2	1 (0.4)	0	0	0
Did not have at least 1 valid and determinate immunogenicity result after Dose 2	69 (24.6)	89 (31.8)	14 (28.0)	16 (32.0)
Dose 2 evaluable immunogenicity population	209 (74.6)	186 (66.4)	36 (72.0)	32 (64.0)
Subjects excluded from Dose 2 evaluable immunogenicity population	71 (25.4)	94 (33.6)	14 (28.0)	18 (36.0)
Reason for exclusion[c]				
Did not receive 2 doses of the vaccine to which they were randomly assigned	1 (0.4)	0	0	0
Did not receive Dose 2 within 19-42 days after Dose 1	1 (0.4)	2 (0.7)	0	2 (4.0)
Did not have at least 1 valid and determinate immunogenicity result after Dose 2	69 (24.6)	89 (31.8)	14 (28.0)	16 (32.0)
Did not have blood collection within 28-42 days after Dose 2	3 (1.1)	16 (5.7)	0	3 (6.0)
Had important protocol deviation(s) as determined by the clinician	0	0	0	1 (2.0)

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.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (00:54) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adva_s008_imm_pop_ped

10.4.1.4. Efficacy Populations

The protocol prespecified final analysis of efficacy was completed with a data cutoff date of 14 November 2020. At that time, few adolescents (12-15 years of age) had enrolled in the study, precluding a meaningful efficacy evaluation. An analysis was performed with all accrued cases during blinded follow-up to a data cutoff date of 13 March 2021, for efficacy in adolescents.

In the efficacy analyses, adolescents in the efficacy populations included:

- Evaluable efficacy population without evidence of SARS-CoV-2 infection prior to 7 days after Dose 2: N=1005 in the BNT162b2 group and N=978 in the placebo group (Table 17).

- Evaluable efficacy population with or without evidence of SARS-CoV-2 infection prior to 7 days after Dose 2: N=1119 in the BNT162b2 group and N=1110 in the placebo group (Table 18).

- Dose 1 all-available efficacy population: N=1131 in the BNT162b2 group and N=1129 in the placebo group (Table 19).

Since the efficacy populations include nearly the same number of participants in each group as in the safety population (Table 10), the demographics of the efficacy populations are essentially the same as the safety population.

10.4.2. Participants 16 Through 55 Years of Age

The safety population age group of adults (16-55 years of age) included 13,069 participants in the BNT162b2 group and 13,095 participants in the placebo group (Table 13).

Duration of follow-up was ≥4 months after Dose 2 for 57.8% of adult participants (16-55 years of age) during the blinded placebo-controlled follow-up period (Table 13). As of the data cutoff date, the proportion of participants in the age group with blinded follow-up to at least 6 months after Dose 2 included 10.4% in the BNT162b2 group and 8.2% in the placebo group. When the total exposure time from Dose 2 to the data cutoff date is considered, 6666 participants 16-55 years of age (51.0%) had ≥6 months of follow-up time.

Table 13. Follow-up Time After Dose 2 – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

	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)		

Table 13. Follow-up Time After Dose 2 – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=13069) n^b (%)	Placebo (N^a=13095) n^b (%)	Total (N^a=26164) n^b (%)

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: 31MAR2021 (17:26) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adsl_fu_d2_1655_saf

10.5. Demographic and Other Baseline Characteristics

10.5.1. Participants 12 Through 15 Years of Age

10.5.1.1. Safety Population – Participants 12 Through 15 Years of Age

Demographic characteristics for adolescents (12-15 years of age) and young adults (16-25 years of age) were similar in the corresponding BNT162b2 and placebo groups in the safety population (Table 14). Overall, most adolescent participants in the BNT162b2 group were White (85.9%), with 4.6% Black participants and 6.4% Asian participants, and other racial groups were <3.0%. There were 11.7% Hispanic/Latino participants. The median age of adolescents in the BNT162b2 group was 14.0 years and 50.1% were male. Obese adolescents (based on age- and sex-specific body mass index) made up 11.3% (placebo group) to 12.6% (BNT162b2 group) of this age group in the safety population.

Note that for safety endpoint analyses of adolescents that included comparative data from young adults, the young adult group analyzed was the reactogenicity subset (ie, those participants in the young adult group who completed an e-diary for reactogenicity in addition to AE reporting).

Demographic characteristics for the adolescents and young adults in the reactogenicity subset were similar to those in the safety population (Supplemental Table 14.1).

Table 14. Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131) n[b] (%)	16-25 Years (N[a]=1867) n[b] (%)	12-15 Years (N[a]=1129) n[b] (%)	16-25 Years (N[a]=1903) n[b] (%)
Sex				
Male	567 (50.1)	921 (49.3)	585 (51.8)	882 (46.3)
Female	564 (49.9)	946 (50.7)	544 (48.2)	1021 (53.7)
Race				
White	971 (85.9)	1443 (77.3)	962 (85.2)	1510 (79.3)
Black or African American	52 (4.6)	189 (10.1)	57 (5.0)	179 (9.4)
American Indian or Alaska Native	4 (0.4)	32 (1.7)	3 (0.3)	18 (0.9)
Asian	72 (6.4)	108 (5.8)	71 (6.3)	108 (5.7)
Native Hawaiian or other Pacific Islander	3 (0.3)	10 (0.5)	0	3 (0.2)
Multiracial	23 (2.0)	76 (4.1)	29 (2.6)	74 (3.9)
Not reported	6 (0.5)	9 (0.5)	7 (0.6)	11 (0.6)
Racial designation				
Japanese	5 (0.4)	3 (0.2)	2 (0.2)	6 (0.3)
Ethnicity				
Hispanic/Latino	132 (11.7)	604 (32.4)	130 (11.5)	575 (30.2)
Non-Hispanic/non-Latino	997 (88.2)	1259 (67.4)	996 (88.2)	1322 (69.5)
Not reported	2 (0.2)	4 (0.2)	3 (0.3)	6 (0.3)
Country				
Argentina	0	282 (15.1)	0	287 (15.1)
Brazil	0	160 (8.6)	0	142 (7.5)
Germany	0	11 (0.6)	0	20 (1.1)
South Africa	0	69 (3.7)	0	75 (3.9)
Turkey	0	12 (0.6)	0	15 (0.8)
USA	1131 (100.0)	1333 (71.4)	1129 (100.0)	1364 (71.7)
Age at vaccination (years)				
Mean (SD)	13.6 (1.11)	21.0 (2.99)	13.6 (1.11)	21.0 (2.98)
Median	14.0	22.0	14.0	21.0
Min, max	(12, 15)	(16, 25)	(12, 15)	(16, 25)
Baseline SARS-CoV-2 status				
Positive[c]	46 (4.1)	100 (5.4)	47 (4.2)	104 (5.5)
Negative[d]	1028 (90.9)	1754 (93.9)	1023 (90.6)	1789 (94.0)
Missing	57 (5.0)	13 (0.7)	59 (5.2)	10 (0.5)
Body mass index (BMI) Obese[e]				
Yes	143 (12.6)	353 (18.9)	128 (11.3)	385 (20.2)
No	988 (87.4)	1514 (81.1)	1001 (88.7)	1518 (79.8)

Table 14. Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131) n[b] (%)	16-25 Years (N[a]=1867) n[b] (%)	12-15 Years (N[a]=1129) n[b] (%)	16-25 Years (N[a]=1903) 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.
e. 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. For 16 through 25 years age group, obesity is defined as BMI≥30.0 kg/m^2.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 01APR2021 (22:23) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA1/adsl s005 demo ped saf

Participants in the reactogenicity subset had a diverse medical history profile consistent with that of individuals in the general population in the same age group (Supplemental Table 14.2). For adolescents in the BNT162b2 group, immune system disorders (398 [35.2%]), respiratory disorders (178 [15.7%]), skin and subcutaneous tissue disorders (169 [14.9%]), surgical and medical procedures (110 [9.7%]), and social circumstances (104 [9.2%]), and nervous system disorders (94 [8.3%]) SOCs were most frequently reported.

10.5.1.2. Immunogenicity Population – Participants 12 Through 15 Years of Age

In the Dose 2 evaluable immunogenicity population adolescent (12-15 years of age) BNT162b2 group, 50.7% of participants were male; 88.0% were White, 7.7% were Black or African American, and 2.4% were Asian; 10.5% were Hispanic/Latino; and the median age was 14 years (Table 15). Baseline SARS-CoV-2 status was positive for 4.8% of adolescent participants in the BNT162b2 group. Obese adolescents (based on age- and sex-specific body mass index) made up 8.3% (placebo group) to 11.5% (BNT162b2 group) of this age group in the evaluable immunogenicity population.

Demographics were generally similar for BNT162b2 and placebo, and in adolescents and young adults 16-25 years of age.

Demographics of the evaluable immunogenicity population were similar to those in the all-available immunogenicity population (Supplemental Table 14.3). Likewise, the immunogenicity population demographics were generally similar to those in the safety population (Table 14).

Table 15. Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=209) n[b] (%)	16-25 Years (N[a]=186) n[b] (%)	12-15 Years (N[a]=36) n[b] (%)	16-25 Years (N[a]=32) n[b] (%)
Sex				
Male	106 (50.7)	92 (49.5)	21 (58.3)	14 (43.8)
Female	103 (49.3)	94 (50.5)	15 (41.7)	18 (56.3)
Race				
White	184 (88.0)	147 (79.0)	31 (86.1)	28 (87.5)
Black or African American	16 (7.7)	15 (8.1)	3 (8.3)	2 (6.3)
American Indian or Alaska Native	1 (0.5)	3 (1.6)	0	1 (3.1)
Asian	5 (2.4)	10 (5.4)	1 (2.8)	1 (3.1)
Native Hawaiian or other Pacific Islander	0	3 (1.6)	0	0
Multiracial	3 (1.4)	6 (3.2)	1 (2.8)	0
Not reported	0	2 (1.1)	0	0
Racial designation				
Japanese	1 (0.5)	0	0	0
Ethnicity				
Hispanic/Latino	22 (10.5)	31 (16.7)	2 (5.6)	7 (21.9)
Non-Hispanic/non-Latino	187 (89.5)	154 (82.8)	34 (94.4)	25 (78.1)
Not reported	0	1 (0.5)	0	0
Country				
USA	209 (100.0)	186 (100.0)	36 (100.0)	32 (100.0)
Age at vaccination (years)				
Mean (SD)	13.5 (1.12)	20.6 (3.09)	13.4 (1.17)	20.3 (3.05)
Median	14.0	21.0	13.0	19.5
Min, max	(12, 15)	(16, 25)	(12, 15)	(16, 25)
Baseline SARS-CoV-2 status				
Positive[c]	10 (4.8)	8 (4.3)	2 (5.6)	1 (3.1)
Negative[d]	194 (92.8)	178 (95.7)	33 (91.7)	31 (96.9)
Missing	5 (2.4)	0	1 (2.8)	0
Body mass index (BMI) Obese[e]				
Yes	24 (11.5)	43 (23.1)	3 (8.3)	4 (12.5)
No	185 (88.5)	143 (76.9)	33 (91.7)	28 (87.5)

Table 15. Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N^a=209) n^b (%)	16-25 Years (N^a=186) n^b (%)	12-15 Years (N^a=36) n^b (%)	16-25 Years (N^a=32) 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.
e. 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. For 16 through 25 years age group, obesity is defined as BMI≥30.0 kg/m^2.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 02APR2021 (00:07) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA1/adsl_s005_demo_ped_d2_ei

10.5.2. Participants 16 Through 55 Years of Age

Demographic characteristics for Phase 2/3 adults in the 16-55 years of age group were similar in the BNT162b2 and placebo groups (Table 16). Overall, most adult participants were White (78.2%), with 11.0% Black participants and 5.4% Asian participants, and other racial groups were <6.0%. There were 30.8% Hispanic/Latino participants. The median age was 40.0 years and 49.9% of participants were male. Obese adults made up 33.7% of this safety population.

Table 16. Demographic Characteristics – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

	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)

Table 16. Demographic Characteristics – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Placebo (N[a]=13095) n[b] (%)	Total (N[a]=26164) n[b] (%)
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)			
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)

Table 16. Demographic Characteristics – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Placebo (N[a]=13095) n[b] (%)	Total (N[a]=26164) n[b] (%)
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: 31MAR2021 (17:35) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adsl_s005_demo_all_1655_saf

Adult participants had a diverse medical history profile consistent with that of individuals in the general population in the same age group (Supplemental Table 14.4). In the BNT162b2 group, conditions in the surgical and medical procedures (3976 [30.4%]), metabolism and nutrition disorders (2414 [18.5%]), psychiatric disorders (2695 [20.6%]), and immune system disorders (3238 [24.8%]) SOCs were most frequently reported.

10.6. Participant Compliance

10.6.1. Immunogenicity Blood Samples – Participants 12 Through 15 Years of Age

Most participants in the adolescent and young adult groups (≥90.0%) had immunogenicity blood samples taken within the protocol specified time frames from 28 to 35 days after Dose 2 (Supplemental Table 14.5).

10.6.2. E-Diary

10.6.2.1. Participants 12 Through 15 Years of Age

Overall, transmission of e-diary data for each day during the 7 days after Dose 1 of BNT162b2 was ≥87.6% (range: 87.6% to 96.3%) and ≥87.9% (range: 87.9% to 94.8%) for the adolescent and young adult groups, respectively (Supplemental Table 14.6). After Dose 2 of BNT162b2 for the adolescent group, transmission of e-diary data was 75.8% on Day 1 and ranged from 81.2% to 87.5% for each day during Day 2 through Day 7. After Dose 2 of BNT162b2 for the young adult group, transmission of e-diary data was 71.8% on Day 1 and ranged from 78.5% to 83.2% for each day during Day 2 through Day 7. Transmission rates were similar in the BNT162b2 groups and the placebo groups.

10.6.2.2. Participants 16 Through 55 Years of Age

Overall, transmission of e-diary data for adults 16-55 years of age was ≥89.1% (range: 89.1% to 94.3%) for each day during the 7 days after Dose 1 of BNT162b2 (Supplemental Table 14.7). After Dose 2 of BNT162b2, transmission of e-diary data was 76.8% on Day 1 and ranged from 82.6% to 85.9% for each day during Day 2 through Day 7. Transmission rates were similar in the BNT162b2 group and the placebo group.

10.7. Prior and Concomitant Vaccines, Medications, and Procedures

10.7.1. Participants 12 Through 15 Years of Age

A small percentage of participants 12 through 15 and 16 through 25 years of age in either group (≤3.2%) received any concomitant vaccine from after Dose 1 through 1 month after Dose 2, and most concomitant vaccines received were the influenza vaccine (Supplemental Table 14.8).

10.7.2. Participants 16 Through 55 Years of Age

A small percentage of participants 16 through 55 years of age in either group (≤9.9%) received any concomitant vaccine after Dose 1, and most concomitant vaccines received were the influenza vaccine (Supplemental Table 14.9).

11. EFFICACY AND IMMUNOGENICITY EVALUATION

11.1. Efficacy Results

11.1.1. Interim Analysis 1 and Final Analysis of Efficacy

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

Efficacy results of the first successful 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.

11.1.2. Vaccine Efficacy Against COVID-19 – Participants 12 Through 15 Years of Age

11.1.2.1. Confirmed Cases of COVID-19 at Least 7 Days after Dose 2 – Evaluable Efficacy Population – Participants 12 Through 15 Years of Age

11.1.2.1.1. Participants Without Evidence of Infection Before and During Vaccination Regimen – Participants 12 Through 15 Years of Age

As of the data cutoff date (13 March 2021), confirmed COVID-19 cases in the evaluable efficacy population adolescent group (12-15 years of age) without evidence of prior SARS-CoV-2 infection at least 7 days after Dose 2 included 0 cases in the BNT162b2 group and 16 cases in the placebo group. The observed VE was 100% (2-sided 95% CI: 75.3%, 100.0%) (Table 17).

Table 17. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and 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]=1005)		Placebo (N[a]=978)			
Efficacy Endpoint	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	0	0.154 (1001)	16	0.147 (972)	100.0	(75.3, 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: 30MAR2021 (22:23)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 peds wo eval

11.1.2.1.2. Participants With or Without Evidence of Infection Before and During Vaccination Regimen – Participants 12 Through 15 Years of Age

Confirmed COVID-19 cases in the evaluable efficacy population adolescent group (12-15 years of age) with or without evidence of prior SARS-CoV-2 infection at least 7 days after Dose 2 included 0 cases in the BNT162b2 group and 18 cases in the placebo group. The observed VE was 100.0% (2-sided 95% CI: 78.1%, 100.0%) (Table 18).

Relative to the analysis of cases in participants without prior evidence of SARS-CoV-2 infection (Table 17), 2 additional cases reported in the placebo group of the evaluable efficacy population with or without evidence of prior SARS-CoV-2 infection before and during vaccine regimen occurred in participants who were baseline negative serostatus for SARS-CoV-2, and had a negative NAAT at Visit 1 followed by a positive NAAT (confirmed by the central laboratory) at Visit 2 (Appendix 16.2.8.1.2).

Table 18. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and 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]=1119)		Placebo (N[a]=1110)			
Efficacy Endpoint	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	0	0.170 (1109)	18	0.163 (1094)	100.0	(78.1, 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: 30MAR2021 (22:24)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 peds eval

11.1.2.1.3. All Confirmed Cases of COVID-19 After Dose 1 – All-Available Efficacy Population – Participants 12 Through 15 Years of Age

As of the data cutoff date (13 March 2021), confirmed COVID-19 cases in the Dose 1 all-available efficacy (modified intention-to-treat) population adolescent group (12-15 years of age) included 3 cases in the BNT162b2 group and 35 cases in the placebo group, with an observed VE of 91.6% (2-sided 95% CI: 73.5%, 98.4%) (Table 19).

The time interval from after Dose 1 to prior to receiving Dose 2 included 3 cases in the BNT162b2 group and 12 cases in the placebo group; these 3 cases in the BNT162 group, which comprised all COVID-19 cases reported in the BNT162b2 group in this population at any time, all occurred within the period from after Dose 1 to <11 days after Dose 1. All 3 of these cases in the BNT162b2 group occurred in participants who had baseline SARS-CoV-2 negative status.

The observed VE for BNT162b2 in adolescents in the Dose 1 all-available population was 100.0% (ie, all cases were confined to the placebo group) for all time intervals starting from ≥11 days after Dose 1 to before Dose 2, through ≥2 months after Dose 2 and <4 months after Dose 2.

Table 19. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=1131)		Placebo (N[a]=1129)			
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	3	0.257 (1120)	35	0.250 (1119)	91.6	(73.5, 98.4)
After Dose 1 to before Dose 2	3		12		75.0	(7.4, 95.5)
After Dose 1 to <11 days after Dose 1	3		4		25.0	(-343.3, 89.0)
≥11 Days after Dose 1 to before Dose 2	0		8		100.0	(41.4, 100.0)
Dose 2 to 7 days after Dose 2	0		5		100.0	(-9.1, 100.0)
≥7 Days after Dose 2	0		18		100.0	(77.3, 100.0)
≥7 days after Dose 2 to <2 Months after Dose 2	0		16		100.0	(74.1, 100.0)
≥2 Months after Dose 2 to <4 Months after Dose 2	0		2		100.0	(-432.5, 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 for overall row).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 30MAR2021 (22:24)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve cov pd1 peds aai

11.1.3. Vaccine Efficacy Against Severe COVID-19 – Participants 12 Through 15 Years of Age

No severe COVID-19 cases (per protocol definition or CDC criteria) were reported in adolescents (12-15 years of age) as of the data cutoff date (13 March 2021) (Appendix 16.2.8.1.1).

11.2. Efficacy Conclusions – Participants 12 Through 15 Years of Age

Descriptive efficacy analyses were conducted for the adolescent group on cases accrued during blinded follow-up period through the data cutoff date of 13 March 2021.

In the adolescent group, in the efficacy analyses in the evaluable efficacy population based on cases reported from at least 7 days after Dose 2 through the data cutoff date, the observed VE was 100% (0 and 16 cases in the BNT162b2 and placebo group, respectively, with 2-sided 95% CI: 75.3%, 100%) for individuals without evidence of prior SARS-CoV-2 infection before and during vaccination regimen, and 100% (0 and 18 cases in the BNT162b2 and placebo group, respectively, with 2-sided 95% CI: 78.1%, 100%) for those with or without evidence of prior SARS-CoV-2 infection before and during vaccination regimen.

The efficacy analysis for the Dose 1 all-available (modified intention-to-treat) population included 3 cases in the BNT162b2 group and 35 cases in the placebo group, with an observed VE of 91.6% (2-sided 95% CI: 73.5%, 98.4%), with no cases reported in the BNT162b2 group starting from ≥11 days after Dose 1.

No severe cases were reported in the 12-15 years of age group as of the date cutoff date.

Overall, these efficacy data strongly support BNT162b2 use in adolescents 12-15 years of age.

11.3. Immunogenicity Results – Participants 12 Through 15 Years of Age

11.3.1. Noninferiority of Immune Response to Prophylactic BNT162b2 in Participants 12 Through 15 Years Compared with Participants 16 Through 25 Years of Age

Geometric Mean Ratio (GMR) in Neutralization Titers

The immune response to BNT162b2 in adolescents 12-15 years of age was noninferior to that observed in young adults 16-25 years of age, based on SARS-CoV-2 50% neutralizing titers at 1 month after Dose 2, in participants without prior evidence of SARS-COV-2 infection, and in fact greatly exceeded the response observed in young adults. The GMT ratio of adolescents to young adults was 1.76 (2-sided 95% CI: 1.47, 2.10), meeting the 1.5-fold NI criterion (ie, lower bound of the 2-sided 95% CI for GMR >0.67) (Table 20). Of note, the lower bound of the 2-sided 95% CI for the GMR is >1 which indicates a statistically greater response in the adolescents than that of young adults.

Seroresponse

Among participants without prior evidence of SARS-CoV-2 infection up to 1 month after Dose 2 of BNT162b2, high proportions (97.9% of adolescents and 100.0% of young adults) had a ≥4-fold rise (seroresponse) in SARS-CoV-2 50% neutralizing titers from before vaccination to 1 month after Dose 2. The difference in proportions of participants who had a ≥4-fold rise between the two age groups (adolescents – young adults) was -2.1% (2-sided 95% CI: -6.0%, 0.9%) (Table 21).

Table 20. Summary of Geometric Mean Ratio – NT50 – Comparison of Subjects 12 Through 15 Years of Age to Subjects 16 Through 25 Years of Age (Immunogenicity Subset) – Subjects Without Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)					
		BNT162b2 (30 µg)					
		12-15 Years		16-25 Years		12-15 Years/16-25 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	GMR[d] (95% CI[d])	Met Noninferiority Objective[e] (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	190	1239.5 (1095.5, 1402.5)	170	705.1 (621.4, 800.2)	1.76 (1.47, 2.10)	Y

Abbreviations: GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (up to 1 month after receipt of the 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 up to 1 month after Dose 2 were included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
d. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers (Group 1 [12-15 years] – Group 2 [16-25 years]) and the corresponding CI (based on the Student t distribution).
e. Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:54)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adva s001 gmr ped ev eval

Table 21. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point 1 Month After Dose 2 – NT50 – Comparison of Subjects 12 Through 15 Years of Age to Subjects 16 Through 25 Years of Age (Immunogenicity Subset) – Subjects Without Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)					
		BNT162b2 (30 µg)					
		12-15 Years		16-25 Years		Difference	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	%[e]	(95% CI[f])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	143	140 (97.9) (94.0, 99.6)	124	124 (100.0) (97.1, 100.0)	-2.1	(-6.0, 0.9)

Abbreviations: LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (up to 1 month after receipt of the 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 up to 1 month after Dose 2 were included in the analysis.
Note: Baseline assay results below the LLOQ were set to LLOQ in the analysis.
a. Protocol-specified timing for blood sample collection.
b. N = number of subjects with valid and determinate assay results for the specified assay 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.
e. Difference in proportions, expressed as a percentage (12-15 years – 16-25 years).
f. 2-Sided CI, based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (05:56)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adva s003 4fold ped eval

11.3.2. GMTs – Participants 12 Through 15 Years of Age

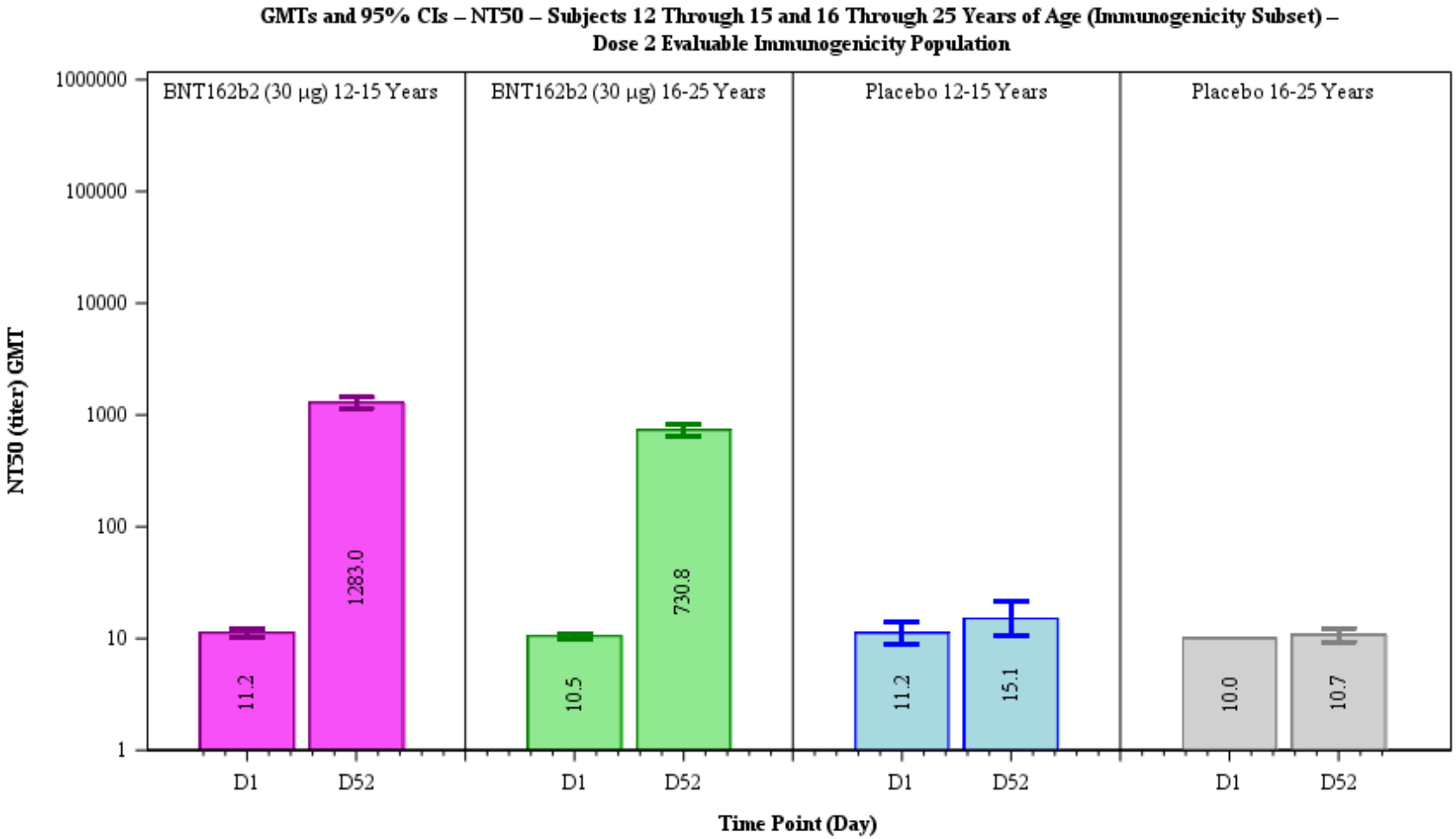
At 1 month after Dose 2 (Day 52) of BNT162b2, substantial increases above baseline in SARS-CoV-2 50% neutralizing GMTs were observed in both age groups, with a greater magnitude of increase in the adolescent group compared with the young adult group (Figure 2, Figure 3, and Supplemental Table 14.10). The neutralizing GMT in adolescents at 1 month after Dose 2 was approximately 1.76-fold that of the young adult group. As expected, the neutralizing GMTs were low in both placebo groups.

Geometric Mean Titers (GMTs) by Baseline SARS-CoV-2 Status

Vaccination with BNT162b2 induced an increased immune response (GMTs) at 1 month after Dose 2 for all participants, regardless of baseline SARS-CoV-2 positive or negative status. Adolescents who were baseline SARS-CoV-2 positive had SARS-CoV-2 50% neutralizing GMTs approximately 1.89-fold that of adolescents who were baseline negative (Supplemental Table 14.10). A similar pattern was observed for baseline SARS-CoV-2 positive versus negative young adults.

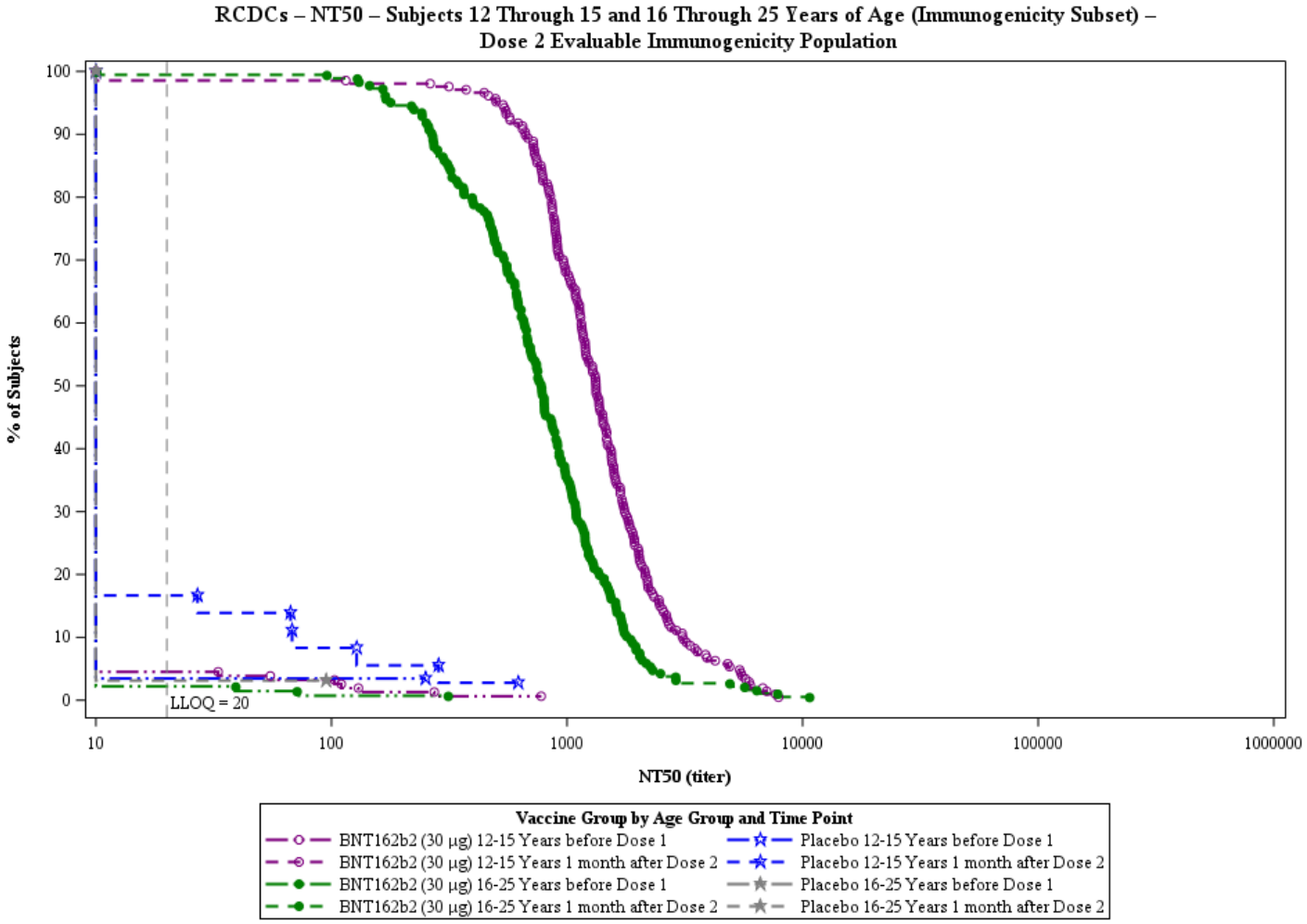
SARS-CoV-2 50% neutralizing titers for the Dose 2 all-available immunogenicity population were similar to those observed for the evaluable immunogenicity population (Supplemental Table 14.11).

Figure 2. Geometric Mean Titers: SARS-CoV-2 Neutralization Assay – NT50 – Subjects 12-15 and 16-25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population



Abbreviations: D = day; GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Number within each bar denotes geometric mean titer.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:54)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adva_f002_sars_50_ped

Figure 3. Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 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.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:54)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adva_f003_sars_50_ped

11.3.3. GMFRs – Participants 12 Through 15 Years of Age

The GMFRs of SARS-CoV-2 50% serum neutralizing titers from before vaccination to 1 month after Dose 2 of BNT162b2 were robust, with a greater magnitude of rise in the adolescent group (118.3) compared with the young adult group (71.2) (Table 22).

GMFR in Titers by Baseline SARS-CoV-2 Status

The GMFRs were higher in the adolescent compared to young adult group 1 month after the second dose. Given the limited sample size for those positive at baseline, the GMFRs were numerically higher in those who were negative at baseline (Table 22).

GMFRs of SARS-CoV-2 50% neutralizing titers for the Dose 2 all-available immunogenicity population were similar to those observed for the evaluable immunogenicity population (Supplemental Table 14.12).

Table 22. Summary of Geometric Mean Fold Rise From Before Vaccination to Each Subsequent Time Point, by Baseline SARS-CoV-2 Status – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
			12-15 Years		16-25 Years		12-15 Years		16-25 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	ALL	154	118.3 (101.4, 137.9)	135	71.2 (61.3, 82.7)	29	1.4 (1.0, 1.9)	24	1.1 (0.9, 1.3)
		POS	8	47.6 (26.4, 86.0)	5	47.1 (3.1, 721.4)	1	1.1 (NE, NE)	0	NE (NE, NE)
		NEG	145	125.0 (106.9, 146.2)	130	72.3 (62.9, 83.2)	27	1.4 (1.0, 2.0)	24	1.1 (0.9, 1.3)

Abbreviations: COVID-19 = coronavirus disease 2019; GMFR = geometric mean fold rise; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; NE = not estimable; NEG = negative; NT50 = 50% neutralizing titer; POS = positive; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

a. Protocol-specified timing for blood sample collection.

b. POS = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. NEG = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19. ALL = irrespective of baseline SARS-CoV-2 status, including missing baseline status.

c. n = Number of subjects with valid and determinate assay results for the specified assay both prevaccination time points and at the given dose/sampling time point.

d. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:54)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adva s002 gmfr ped eval

11.3.4. Seroresponse Rate – Participants 12 Through 15 Years of Age

Proportions of participants with a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers from before vaccination to 1 month after Dose 2 of BNT162b2 (seroresponse rate) were 98.1% in adolescents and 99.3% in young adults(Table 23). As expected, very few placebo participants reached a ≥4-fold rise in SARS-CoV-2 neutralizing titers from before to 1 month after Dose 2.

Seroresponse Rate by Baseline SARS-CoV-2 Status

Adolescents who were baseline SARS-CoV-2 positive or negative had similar seroresponse rates (100.0% vs 97.9%) (Table 23).

Table 23. Number (%) of Subjects Achieving a ≥4-Fold Rise From Before Vaccination to Each Subsequent Time Point, by Baseline SARS-CoV-2 Status – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
			12-15 Years		16-25 Years		12-15 Years		16-25 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	N[c]	n[d] (%) (95% CI[e])	N[c]	n[d] (%) (95% CI[e])	N[c]	n[d] (%) (95% CI[e])	N[c]	n[d] (%) (95% CI[e])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	ALL	154	151 (98.1) (94.4, 99.6)	135	134 (99.3) (95.9, 100.0)	29	1 (3.4) (0.1, 17.8)	24	1 (4.2) (0.1, 21.1)
		POS	8	8 (100.0) (63.1, 100.0)	5	4 (80.0) (28.4, 99.5)	1	0 (0.0) (0.0, 97.5)	0	0 (NE) (NE, NE)
		NEG	145	142 (97.9) (94.1, 99.6)	130	130 (100.0) (97.2, 100.0)	27	1 (3.7) (0.1, 19.0)	24	1 (4.2) (0.1, 21.1)

Abbreviations: LLOQ = lower limit of quantitation; NE = not estimable; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Baseline assay results below the LLOQ were set to LLOQ in the analysis.
a. Protocol-specified timing for blood sample collection.
b. POS = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. NEG = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19. ALL = irrespective of baseline SARS-CoV-2 status, including missing baseline status
c. 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.
d. n = Number of subjects with ≥4-fold rise from before vaccination for the given assay at the given dose/sampling time point.
e. 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 s001 4fold ped eval

11.3.5. Phase 3 Immunogenicity Conclusions – Participants 12 Through 15 Years of Age

Immune response to BNT162b2 30 µg in SARS-CoV-2 50% neutralizing titers in adolescents 12-15 years of age was noninferior to (and in fact exceeded) the immune response in young adults 16-25 years of age, which provides immunobridging for adolescents. Substantial increases over baseline in neutralizing GMTs and high seroresponse rates were observed at 1 month after Dose 2 in both age groups, which were observed for participants with baseline SARSCoV-2 positive and negative status. The vast majority of BNT162b2 recipients in both age groups achieved a ≥4-fold rises from before vaccination to 1 month after Dose 2.

12. SAFETY EVALUATION

Reactogenicity (local reactions and systemic events) was assessed via e-diary in all adolescents and a subset of young adult participants up to 7 days after each dose. Adolescent participants (12-15 years of age) with e-diary data included N=1131 in the BNT162b2 group and N=1129 in the placebo group post Dose 1, and N=1124 in the BNT162b2 group and N=1117 in the placebo group post Dose 2.

Young adult participants (16-25 years of age) in the reactogenicity subset with e-diary data included N=539 in the BNT162b2 group and N=564 in the placebo group post Dose 1, and N=526 in the BNT162b2 group and N=537 in the placebo group post Dose 2.

Reactogenicity (local reactions and systemic events) was assessed via e-diary in a subset of participants in up to 7 days after each dose. Adult participants (16-55 years of age) in the reactogenicity subset with e-diary data included N=5807 post Dose 1 and N=5366 post Dose 2.

12.1. Local Reactions

12.1.1. Participants 12 Through 15 Years of Age

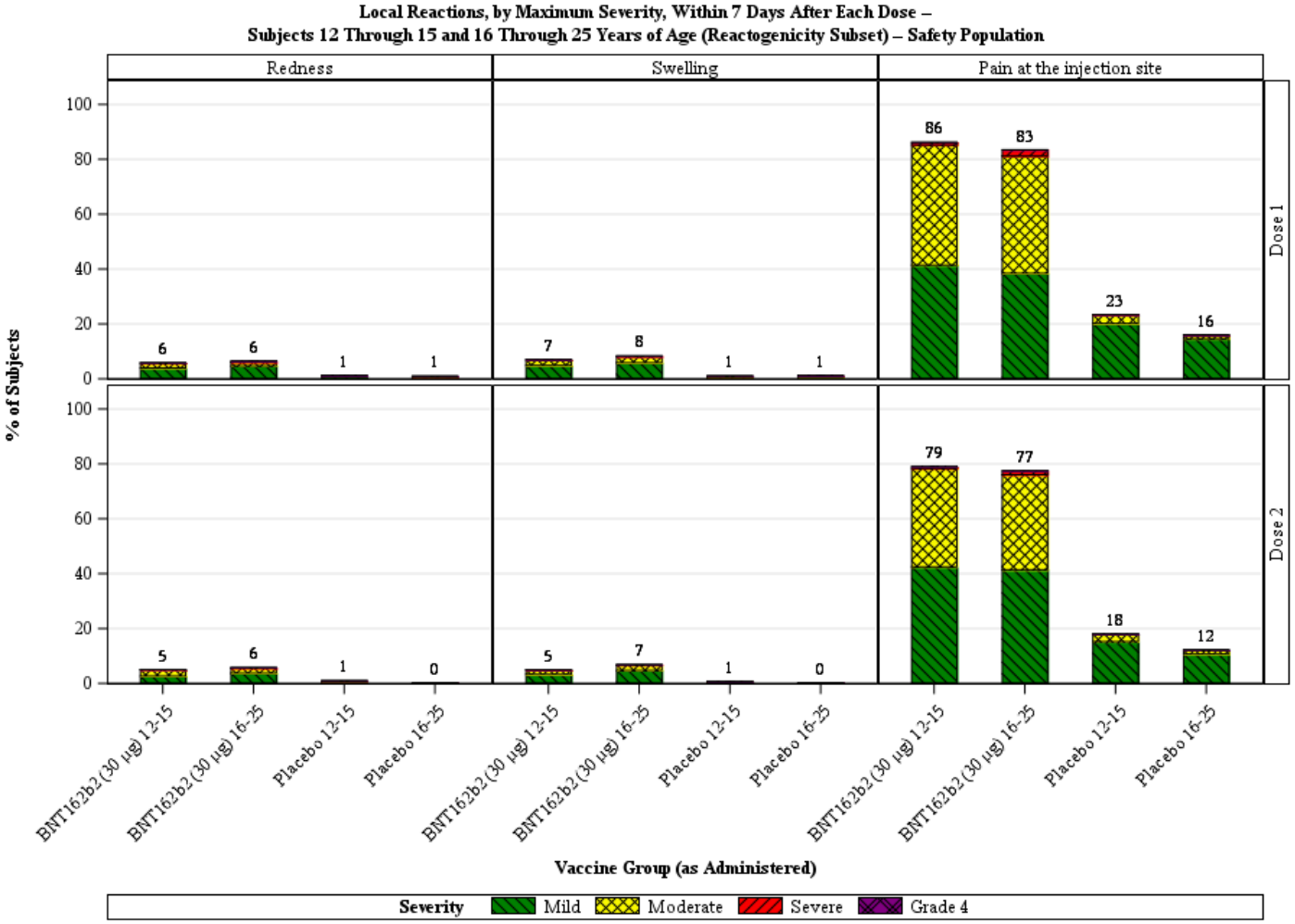
In the BNT162b2 group, pain at the injection site was most frequently reported in adolescents and young adults, and frequency was similar after Dose 1 and after Dose 2 of BNT162b2 in adolescents (86.2% vs 78.9%) and in young adults (83.4% vs 77.5%), shown in Figure 4 and presented in Supplemental Table 14.13. In the placebo group, pain at the injection site after Doses 1 and 2 was similar in adolescents (23.3% and 17.9%, respectively) and young adults (15.9% and 12.1%, respectively).

In the BNT162b2 group, frequencies of redness and swelling were similar between adolescents and young adults after Doses 1 and 2 (Figure 4). Frequencies of redness were generally low and unchanged from after Dose 1 compared with Dose 2 of BNT162b2 in adolescents (5.8% vs 5.0%) and in young adults (6.4% vs 5.7%) (Supplemental Table 14.13). Frequencies of swelling were similarly low and slightly reduced after Dose 1 compared with Dose 2 of BNT162b2 in adolescents (6.9% vs 4.9%) and in young adults (8.3% vs 6.8%). In the placebo group, redness and swelling were infrequent in the adolescent (≤1.1%) and young adult (≤1.1%) groups after Doses 1 and 2.

After the first and second dose and in both age groups, most local reactions were mild or moderate in severity. Severe local reactions were reported infrequently and at lower incidence in adolescents (≤1.5%) compared with young adults (≤3.4%) across the BNT162b2 and placebo groups after any dose. No Grade 4 local reactions were reported in either age group (Appendix 16.2.7.2.1.1).

Across age groups, median onset for all local reactions after either dose of BNT162b2 was Day 1 to Day 3 (Day 1 was the day of vaccination) (Supplemental Table 14.14) and resolved with a median duration of 1-3 days (Supplemental Table 14.15).

Figure 4. Participants Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population by Age Group: 12-15 Years and 16-25 Years



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_ped

12.1.2. Participants 16 Through 55 Years of Age

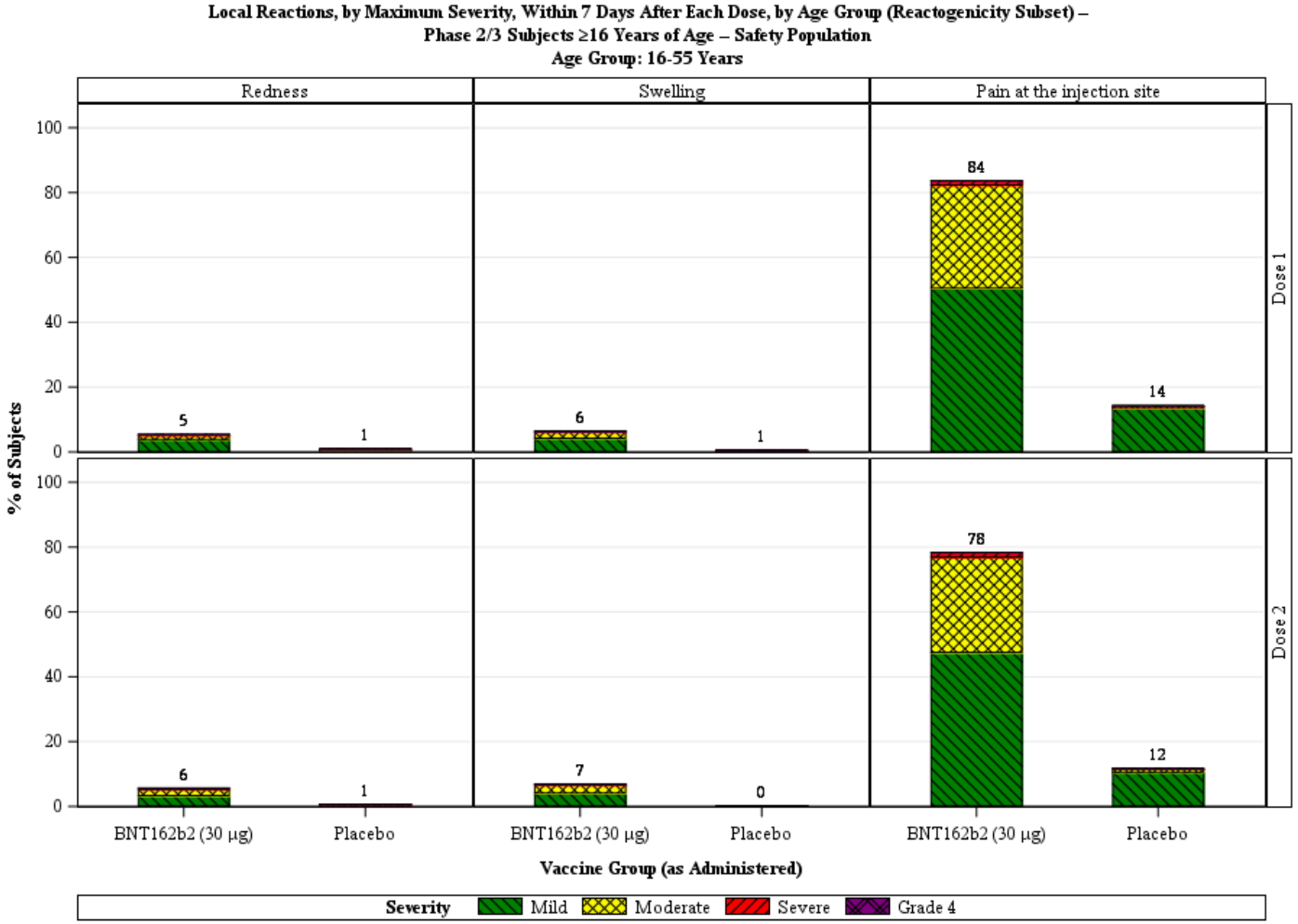
Among adults 16-55 years of age in the BNT162b2 group, pain at the injection site was the most frequently reported local reaction, with similar frequency after Dose 1 compared with Dose 2 of BNT162b2 (Figure 5).

In the BNT162b2 group, frequencies after Dose 1 and Dose 2 were similar for redness (5.4% vs 5.6%) and swelling (6.3% vs 6.8%) (Supplemental Table 14.16). In the placebo group, redness and swelling were reported infrequently (≤1.0%) after Doses 1 and 2. Pain at injection site was reported with a higher frequency in the BNT162b2 group after Dose 1 and Dose 2 than in the placebo group (Dose 1: 83.7% vs 14.2%; Dose 2: 78.3% vs 11.6%).

Overall, 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. After either dose, most local reactions were mild or moderate in severity. Severe local reactions were reported infrequently (≤2.5%) in the BNT162b2 group after either dose. No Grade 4 local reactions were reported.

Local reactions for the adult age group after either dose had a median onset day on Day 1 (Day 1 was the day of vaccination) (Supplemental Table 14.17) and resolved with a median duration of 1-2 days (Supplemental Table 14.18).

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



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_age_p3

12.2. Systemic Events

12.2.1. Participants 12 Through 15 Years of Age

Systemic events were generally similar in frequency and severity in adolescents compared with young adults (Figure 6), with frequencies and severity increasing with number of doses for most events, with the exceptions of vomiting and diarrhea which were reported infrequently and at similar incidences after each dose, and muscle and joint pain which was reported at higher frequencies in the young adults. Systemic events in the adolescent group compared with the young adult group, in decreasing order of frequency by dose (Dose 1 vs Dose 2), (Supplemental Table 14.19) were:

- fatigue: adolescents (60.1% vs 66.2%) compared to young adults (59.9% vs 65.6%)
- headache: adolescents (55.3% vs 64.5%) compared to young adults (53.9% vs 60.9%)
- chills: adolescents (27.6% vs 41.5%) compared to young adults (25.0% vs 40.0%)
- muscle pain: adolescents (24.1% vs 32.4%) compared to young adults (26.9% vs 40.8%)
- joint pain: adolescents (9.7% vs 15.8%) compared to young adults (13.2% vs 21.9%)
- fever: adolescents (10.1% vs 19.6%) compared to young adults (7.3% vs 17.2%)
- vomiting: reported infrequently in both age groups and similar after either dose
- diarrhea: reported infrequently in both age groups and similar after either dose

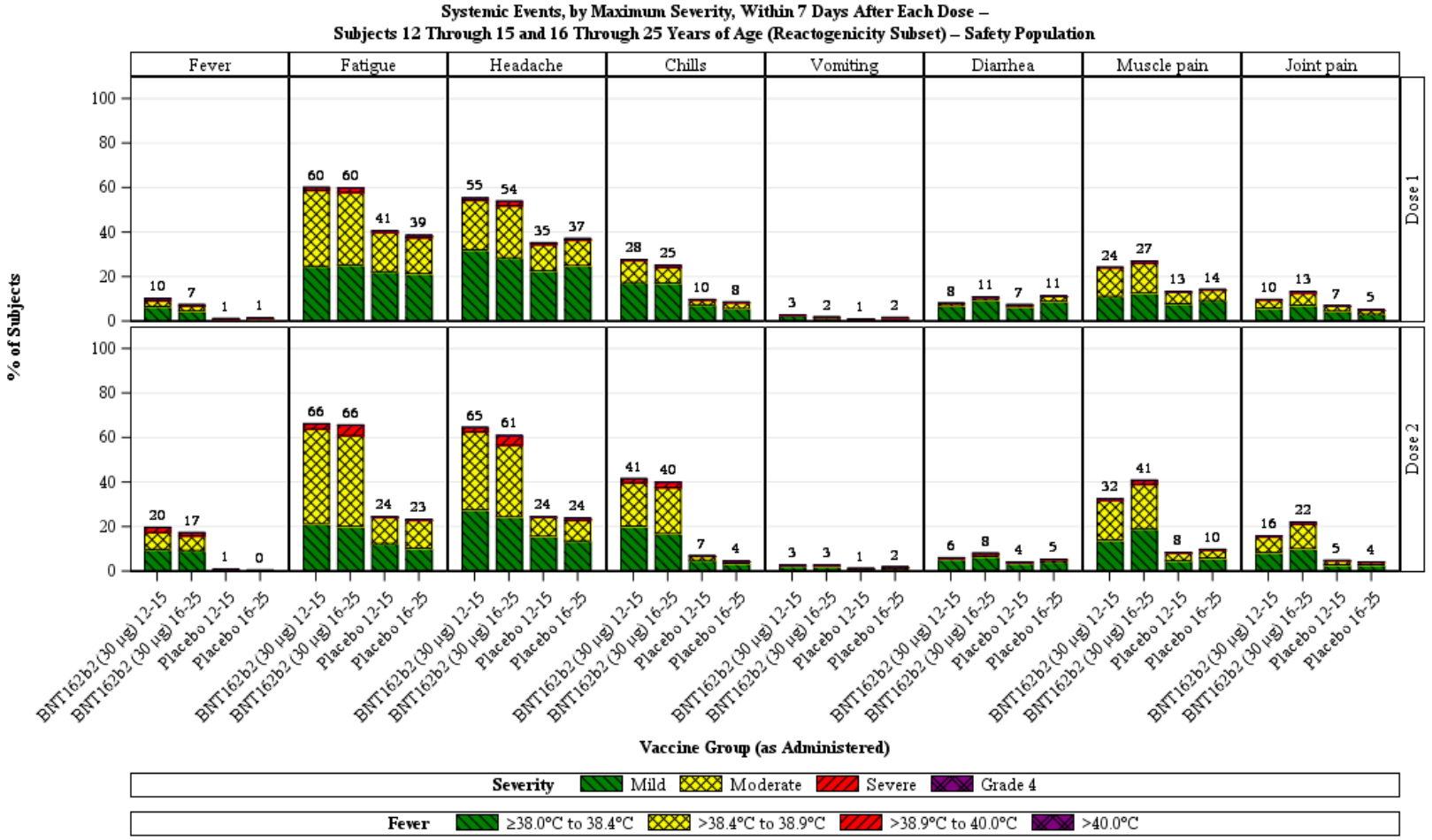
Systemic events were generally reported less frequently in placebo versus BNT162b2 groups.

Following both Dose 1 and Dose 2, use of antipyretic/pain medication was similar in adolescents (36.6% and 50.8%) and in young adults (31.5% and 45.7%), and medication use increased in both age groups after Dose 2 as compared with after Dose 1. 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 adolescent and young adult placebo groups (ranging from 8.8% to 11.9%).

After the first and second dose and in both age groups, most systemic events were mild or moderate in severity. Severe systemic events were reported infrequently and at lower incidence in adolescents (≤3.5%) compared with young adults (≤6.0%) across BNT162b2 and placebo groups after any dose. One adolescent in the BNT162b2 group had Grade 4 pyrexia (40.4°C) on Day 2 after Dose 1, with temperature returning to normal on Day 4; it was also reported as an AE (refer to analysis in Section 12.3.2.1.1.1, leading to withdrawal in Section 12.4.3.1 and Appendix 16.2.7.3.1.1).

Across age groups, median onset for all systemic events after either dose of BNT162b2 was Day 1 to Day 4 (Day 1 was the day of vaccination) (Supplemental Table 14.20). Systemic events resolved post each dose with a median duration of 1 day, except fatigue and chills which resolved within a median of 1-2 days (Supplemental Table 14.21).

Figure 6. Participants Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population by Age Group: 12-15 Years and 16-25 Years



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

Note: Subject C4591001 1077 10771278 (13 years of age) experienced systemic events, including a temperature of 40.4°C, on the day of Dose 2. Since these events were recorded as adverse events and not in the electronic diary (e-diary), they do not appear in this output.

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_ped

12.2.2. Participants 16 Through 55 Years of Age

Systemic events in the adult group (16-55 years of age) were generally increased in frequency and severity with number of doses, with the exceptions of vomiting and diarrhea which were reported infrequently and at similar incidences after each dose (Figure 7). Systemic events, in decreasing order of frequency by dose (Dose 1 vs Dose 2) (Supplemental Table 14.22), were:

- fatigue: BNT162b2 (49.4% vs 61.5%) compared to placebo (33.0% vs 22.9%)
- headache: BNT162b2 (43.5% vs 54.0%) compared to placebo (33.5% vs 24.3%)
- muscle pain: BNT162b2 (22.9% vs 39.3%) compared to placebo (11.3% vs 8.8%)
- chills: BNT162b2 (16.5% vs 37.8%) compared to placebo (6.8% vs 4.2%)
- joint pain: BNT162b2 (11.8% vs 23.8%) compared to placebo (5.8% vs 5.5%)
- fever: BNT162b2 (4.1% vs 16.4%) compared to placebo (0.9% vs 0.4%)
- vomiting: reported infrequently and similar after either dose
- diarrhea: reported infrequently and similar after either dose

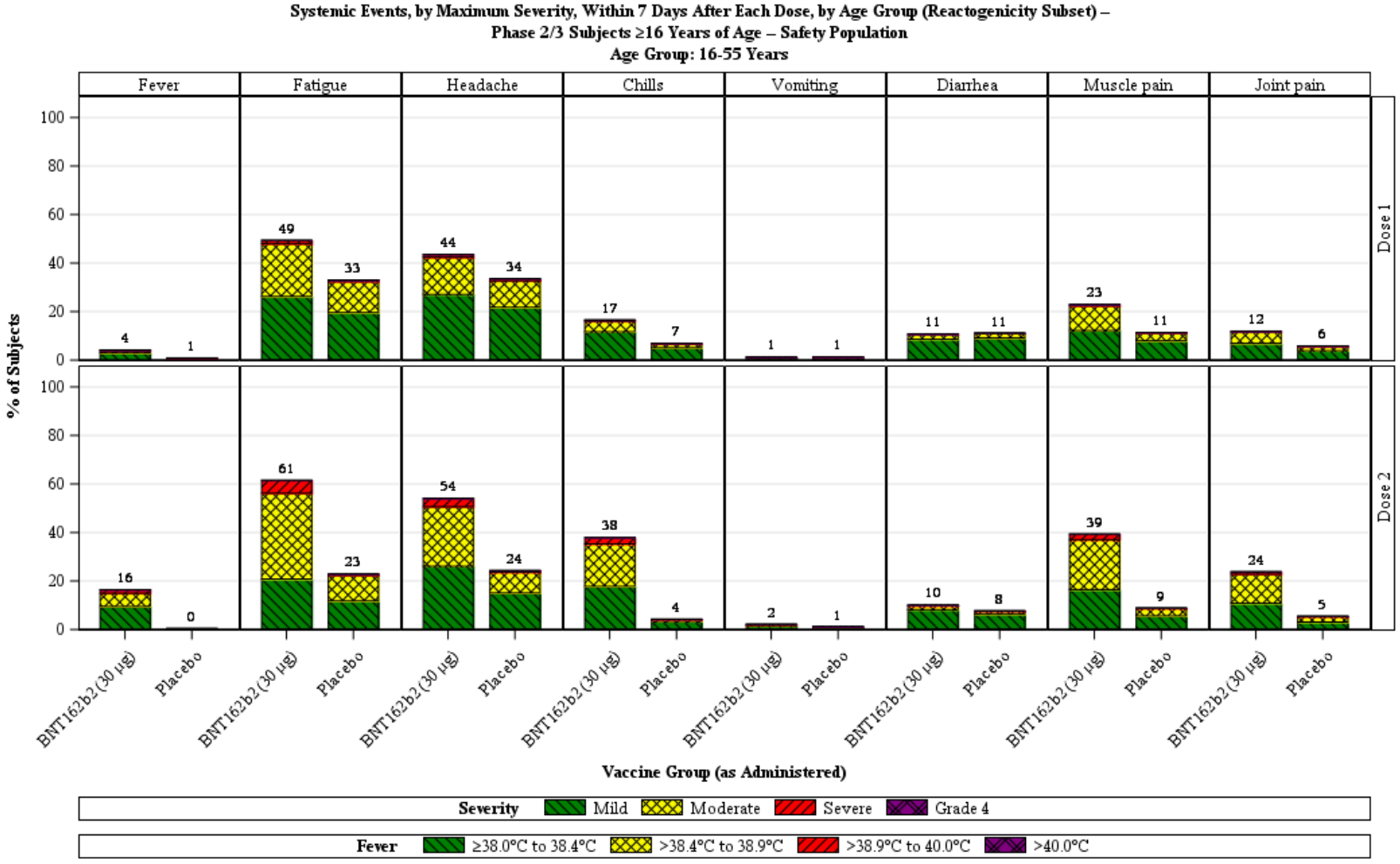
Systemic events were generally reported less frequently in the placebo group than in the BNT162b2 group, with some exceptions. Vomiting and diarrhea (after Dose 1 and Dose 2) were reported at similar frequencies in the placebo group and the BNT162b2 group (Figure 7).

In the BNT162b2 group, use of antipyretic/pain medication was 27.8% vs 45.2% after Dose 1 and Dose 2, respectively (Supplemental Table 14.22). Use of antipyretic/pain medication was less frequent in the placebo group after Dose 1 and Dose 2 (13.7% and 11.9%) than in the BNT162b2 group.

After the first and second dose, the majority of systemic events were mild or moderate in severity. Severe fever (>38.9 °C to 40.0 °C) was reported in the BNT162b2 group after Dose 1 for 0.3% and after Dose 2 for 1.5% of participants, and in the placebo group after Dose 1 for 0.1% and after Dose 2 for 0.1% of participants. Grade 4 fever (>40 °C) was reported for 1 participant in the BNT162b2 group and no participants in the placebo group.

Systemic events for the adult (16-55 years of age) group after either dose had a median onset day of Day 2 (Day 1 was the day of vaccination) (Supplemental Table 14.23) and resolved with a median duration of 1-2 days (Supplemental Table 14.24).

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

12.3. Adverse Events

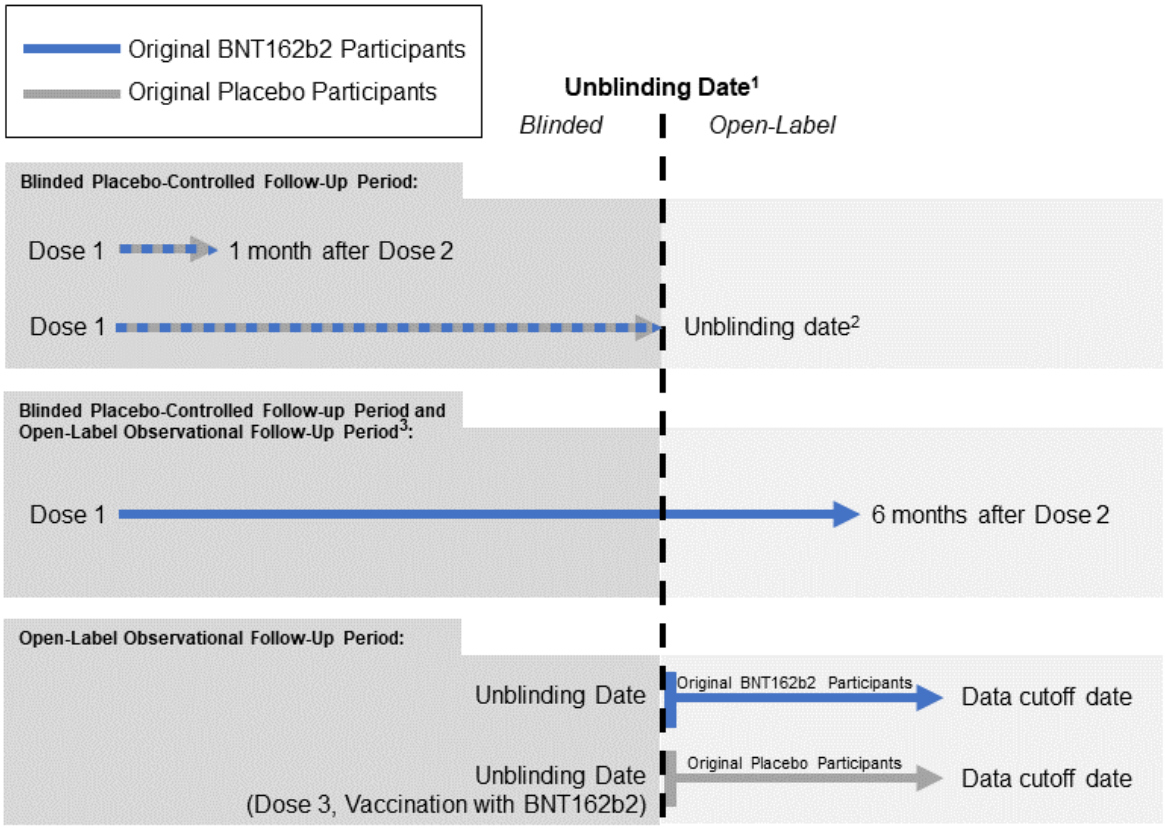
The time periods and safety analysis groups for the study are presented in Figure 8. In this clinical study report, AE results are from the blinded placebo-controlled follow-up period:

- Blinded placebo-controlled follow-up period from Dose 1 to 1 month after Dose 2 (frequencies): adolescents (12-15 years of age), young adults (16-25 years of age), and adults (16-55 years of age))
- Blinded placebo-controlled follow-up period from Dose 1 to the data cutoff date (13 March 2021): adolescents (12-15 years of age)
- Blinded placebo-controlled follow-up period from Dose 1 to the unblinding date (IRs): adults (16-55 years of age)

For AE analyses beyond 1 month after Dose 2 in adult participants, IRs are reported (as opposed to frequencies) to account for the variable exposure since unblinding began for individual participants.

Safety data from participants 16 through 55 years of age are included for comparative purposes, and a full independent safety evaluation of this age group along with participants >55 years of age will be reported separately at a later time.

Figure 8. 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.

12.3.1. Summary of Adverse Events

12.3.1.1. Participants 12 Through 15 Years of Age

AE summaries for adolescents and young adults (reactogenicity subset) are reported from Dose 1 to 1 month after Dose 2 (Section 12.3.1.1.1) and from Dose 1 until the data cutoff date (13 March 2021) (Section 12.3.1.1.2).

12.3.1.1.1. Dose 1 to 1 Month After Dose 2 – Participants 12 Through 15 Years of Age

An overview of AEs from Dose 1 to 1 month after Dose 2 for adolescents (12-15 years of age) and young adults (16-25 years of age; utilizing the reactogenicity subset) is shown in (Table 24) The number of participants with any AE were similar in the BNT162b2 and placebo groups for both age groups. Severe AEs, SAEs, and AEs leading to withdrawal were reported by ≤1.7%, ≤0.4%, and ≤0.4%, respectively, in both groups. No reported SAEs were considered by the investigator as related to study intervention. Withdrawals due to related AEs were reported in 1 adolescent participant in the BNT162b2 group and none in the placebo group; among young adults, withdrawals due to related AEs were reported in

1 participant in the BNT162b2 group and none in the placebo group. Discontinuations due to any AEs were reported in 3 participants in the BNT162b2 group and 2 participants in the placebo group, across age groups. No study participants 12 through 25 years of age died. Analysis of specific AEs reported from Dose 1 to 1 month after Dose 2 is presented in Section 12.3.2.1.1.1

Table 24. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
Adverse Event	12-15 Years (N[a]=1131) n[b] (%)	16-25 Years (N[a]=536) n[b] (%)	12-15 Years (N[a]=1129) n[b] (%)	16-25 Years (N[a]=561) n[b] (%)
Any event	68 (6.0)	58 (10.8)	67 (5.9)	45 (8.0)
Related[c]	33 (2.9)	33 (6.2)	21 (1.9)	12 (2.1)
Severe	7 (0.6)	9 (1.7)	2 (0.2)	3 (0.5)
Life-threatening	1 (0.1)	0	1 (0.1)	0
Any serious adverse event	4 (0.4)	2 (0.4)	1 (0.1)	2 (0.4)
Related[c]	0	0	0	0
Severe	2 (0.2)	2 (0.4)	0	1 (0.2)
Life-threatening	0	0	1 (0.1)	0
Any adverse event leading to withdrawal	2 (0.2)	1 (0.2)	0	2 (0.4)
Related[c]	1 (0.1)	1 (0.2)	0	0
Severe	1 (0.1)	1 (0.2)	0	0
Life-threatening	1 (0.1)	0	0	0
Death	0	0	0	0

Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.
Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).
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 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s091_pd2_ped_saf

12.3.1.1.2. Dose 1 to Data Cutoff Date – Participants 12 Through 15 Years of Age

An overview of AEs from Dose 1 to the cutoff date for 2260 adolescents (12-15 years of age) during the blinded safety follow-up is presented in (Table 25). Data for young adults are not included since they had different follow-up time up to the data cutoff date due to enrollment starting time for the age groups into the study and due to unblinding of individuals ≥16 years of age per protocol for vaccination under EUA (unlike the adolescents who remain blinded to treatment assignment) (Section 9.1).

The number of adolescents with any event was similar in the BNT162b2 and placebo groups. Severe AEs, SAEs, and AEs leading to withdrawal were reported by ≤0.8%, ≤0.4%, and ≤0.2%, respectively, in both groups. No reported SAEs were considered by the investigator as related to study intervention. Discontinuation due to related AEs was reported in 1 participant in the BNT162b2 group and none in the placebo group. As of the data cutoff date, no study participants in the adolescent group died. Analysis of specific AEs reported from Dose 1 to the data cutoff date is presented in Section 12.3.2.1.1.2.

Table 25. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Placebo (N[a]=1129) n[b] (%)
Any event	72 (6.4)	71 (6.3)
Related[c]	33 (2.9)	21 (1.9)
Severe	9 (0.8)	3 (0.3)
Life-threatening	1 (0.1)	1 (0.1)
Any serious adverse event	5 (0.4)	2 (0.2)
Related[c]	0	0
Severe	4 (0.4)	1 (0.1)
Life-threatening	0	1 (0.1)
Any adverse event leading to withdrawal	2 (0.2)	0
Related[c]	1 (0.1)	0
Severe	1 (0.1)	0
Life-threatening	1 (0.1)	0
Death	0	0

Table 25. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N^a=1131)	Placebo (N^a=1129)
Adverse Event	n^b (%)	n^b (%)

Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.
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 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s091_d1_cut_ped_saf

12.3.1.2. Participants 16 Through 55 Years of Age

AE overviews for the adult group (16-55 years of age) are reported from Dose 1 to 1 month after Dose 2 (Section 12.3.1.2.1), and from Dose 1 until the unblinding date (Section 12.3.1.2.2). Due to unblinding of individuals ≥16 years of age to treatment assignment (per protocol) to receive BNT162b2 (refer to Section 9.1), AE data analyzed up to the unblinding date were calculated as IRs using 100 person-years (PYs) of exposure as the denominator to adjust for exposure time.

12.3.1.2.1. Dose 1 to 1 Month After Dose 2 – Participants 16 Through 55 Years of Age

An overview of AEs from Dose 1 to 1 month after Dose 2 for the adults 16-55 years of age is presented in (Table 26). There was a greater frequency of participants in the BNT162b2 group compared with the placebo group who reported at least 1 AE (4233 [32.6%] vs 1871 [14.4%]) and at least 1 related AE (3480 [26.8%] vs 882 [6.8%]). Severe AEs, SAEs, and AEs leading to withdrawal were reported by ≤1.2%, ≤0.4%, and ≤0.2%, respectively, in both groups. Discontinuations due to related AEs were reported in few participants (≤0.1%) in the BNT162b2 and placebo groups.

Two adult participants (16-55 years of age) died between Dose 1 and 1 month after Dose 2, both in the placebo group (refer to Section 12.4.1).

Table 26. 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 16-55 Years of Age – Safety Population

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=12995) n[b] (%)	Placebo (N[a]=13026) 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: 31MAR2021 (17:46)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 EUA 1655/adae s091 all pd2 1655 sa

12.3.1.2.2. Dose 1 to Unblinding Date – Participants 16 Through 55 Years of Age

An overview of AEs from Dose 1 to participants' unblinding date for adults 16-55 years of age during the blinded safety follow-up is presented in (Table 27) (reported as IRs per 100 PYs adjusted for variable exposure time). The IR of at least 1 AE reported in the BNT162b2 group as compared with the placebo group was 88.4 versus 43.5 per 100 PYs, and at least 1 related AE was 70.0 versus 18.0 per 100 PYs. Severe AEs, SAEs, and AEs leading to withdrawal were reported at IRs of ≤3.9, ≤2.4, and ≤0.6 per 100 PYs, respectively, in both groups. IRs of discontinuations due to related AEs were low (0.2 per 100 PYs) in both the BNT162b2 and placebo groups.

A total of 7 adult (16-55 years of age) participants died prior to unblinding date, with an IR of 0.1 per 100 PYs in both groups: 3 participants in the BNT162b2 group and 4 participants in the placebo group (refer to Section 12.4.1).

Table 27. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

	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: 31MAR2021 (17:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adae_s092_all_unb_1655_saf

12.3.2. Analysis of Adverse Events

12.3.2.1. Adverse Events by System Organ Class and Preferred Term

12.3.2.1.1. Participants 12 Through 15 Years of Age

12.3.2.1.1.1. Dose 1 to 1 Month After Dose 2 – Participants 12 Through 15 Years of Age

AEs reported from Dose 1 to 1 month after Dose 2 for all adolescents and for young adults (in the reactogenicity subset) are presented in Table 28. AEs reported in adolescents were generally similar to young adults within the respective BNT162b2 and placebo groups.

Most of the AEs after Dose 1 up to 1 month after Dose 2 were reactogenicity events reported as AEs (ie, headache, nausea, and diarrhea). In adolescents, AE frequencies in these reactogenicity SOCs (BNT162b2 vs placebo) were:

- general disorders and administration site conditions (16 [1.4%] vs 11 [1.0%])
- musculoskeletal and connective tissue disorders (9 [0.8%] vs 8 [0.7%])
- nervous system disorders (12 [1.1%] vs 7 [0.6%])
- gastrointestinal disorders (14 [1.2%] vs 3 [0.3%])

In young adults, AE frequencies in these reactogenicity SOCs (BNT162b2 vs placebo) were:

- general disorders and administration site conditions (21 [3.9%] vs 10 [1.8%])
- musculoskeletal and connective tissue disorders (12 [2.2%] vs 8 [1.4%])
- nervous system disorders (13 [2.4%] vs 7 [1.2%])
- gastrointestinal disorders (5 [0.9%] vs 6 [1.1]%)

Overall, AEs reported in adolescents and young adults at 1 month 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.

Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N[a]=1131)		16-25 Years (N[a]=536)		12-15 Years (N[a]=1129)		16-25 Years (N[a]=561)	
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	68 (6.0)	(4.7, 7.6)	58 (10.8)	(8.3, 13.8)	67 (5.9)	(4.6, 7.5)	45 (8.0)	(5.9, 10.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	9 (0.8)	(0.4, 1.5)	1 (0.2)	(0.0, 1.0)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Lymphadenopathy	9 (0.8)	(0.4, 1.5)	1 (0.2)	(0.0, 1.0)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
CARDIAC DISORDERS	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Tachycardia	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
EAR AND LABYRINTH DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Ear pain	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Cerumen impaction	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
EYE DISORDERS	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Eye pain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Eyelid rash	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Ocular hyperaemia	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Retinal haemorrhage	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
GASTROINTESTINAL DISORDERS	14 (1.2)	(0.7, 2.1)	5 (0.9)	(0.3, 2.2)	3 (0.3)	(0.1, 0.8)	6 (1.1)	(0.4, 2.3)
Nausea	5 (0.4)	(0.1, 1.0)	2 (0.4)	(0.0, 1.3)	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)
Diarrhoea	3 (0.3)	(0.1, 0.8)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)
Abdominal pain	2 (0.2)	(0.0, 0.6)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)
Aphthous ulcer	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Lip swelling	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)

Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N[a]=1131)		16-25 Years (N[a]=536)		12-15 Years (N[a]=1129)		16-25 Years (N[a]=561)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Vomiting	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Gastritis	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Inguinal hernia	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Mouth swelling	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Oral mucosal blistering	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Rectal prolapse	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Toothache	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	16 (1.4)	(0.8, 2.3)	21 (3.9)	(2.4, 5.9)	11 (1.0)	(0.5, 1.7)	10 (1.8)	(0.9, 3.3)
Injection site pain	7 (0.6)	(0.2, 1.3)	10 (1.9)	(0.9, 3.4)	7 (0.6)	(0.2, 1.3)	2 (0.4)	(0.0, 1.3)
Fatigue	7 (0.6)	(0.2, 1.3)	7 (1.3)	(0.5, 2.7)	4 (0.4)	(0.1, 0.9)	3 (0.5)	(0.1, 1.6)
Pyrexia	5 (0.4)	(0.1, 1.0)	7 (1.3)	(0.5, 2.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Chills	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Injection site erythema	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)
Injection site swelling	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)
Oedema peripheral	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
Pain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Chest pain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Injection site bruising	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Injection site discomfort	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Injection site hyperaesthesia	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Nodule	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)

Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N[a]=1131)		16-25 Years (N[a]=536)		12-15 Years (N[a]=1129)		16-25 Years (N[a]=561)	
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])
Peripheral swelling	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Vessel puncture site pain	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Food allergy	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
INFECTIONS AND INFESTATIONS	7 (0.6)	(0.2, 1.3)	5 (0.9)	(0.3, 2.2)	7 (0.6)	(0.2, 1.3)	12 (2.1)	(1.1, 3.7)
Ear infection	3 (0.3)	(0.1, 0.8)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Appendicitis	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Conjunctivitis	0	(0.0, 0.3)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Otitis externa	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Otitis media	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Sinusitis	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)
Tonsillitis	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)
Vulvovaginal mycotic infection	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Body tinea	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Candida infection	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Cellulitis	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Cystitis	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Focal peritonitis	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Folliculitis	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Genital herpes	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Genital herpes simplex	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)

Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N[a]=1131)		16-25 Years (N[a]=536)		12-15 Years (N[a]=1129)		16-25 Years (N[a]=561)	
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])
Impetigo	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Infectious mononucleosis	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Oral fungal infection	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Pharyngitis streptococcal	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Pilonidal cyst	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Subcutaneous abscess	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Tinea capitis	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Tinea infection	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Urinary tract infection	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Vulval abscess	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	8 (0.7)	(0.3, 1.4)	3 (0.6)	(0.1, 1.6)	10 (0.9)	(0.4, 1.6)	6 (1.1)	(0.4, 2.3)
Ligament sprain	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	2 (0.4)	(0.0, 1.3)
Concussion	3 (0.3)	(0.1, 0.8)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Accident	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Clavicle fracture	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Contusion	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Exposure during pregnancy	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)
Fall	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Muscle strain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Procedural pain	0	(0.0, 0.3)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Tooth fracture	0	(0.0, 0.3)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)

Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N[a]=1131)		16-25 Years (N[a]=536)		12-15 Years (N[a]=1129)		16-25 Years (N[a]=561)	
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])
Fibula fracture	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Flail chest	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Foot fracture	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Hand fracture	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Humerus fracture	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Joint dislocation	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Lip injury	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Meniscus injury	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Patella fracture	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Radius fracture	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Road traffic accident	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
INVESTIGATIONS	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Electrocardiogram QT prolonged	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)
Decreased appetite	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	9 (0.8)	(0.4, 1.5)	12 (2.2)	(1.2, 3.9)	8 (0.7)	(0.3, 1.4)	8 (1.4)	(0.6, 2.8)
Arthralgia	2 (0.2)	(0.0, 0.6)	3 (0.6)	(0.1, 1.6)	3 (0.3)	(0.1, 0.8)	4 (0.7)	(0.2, 1.8)
Myalgia	3 (0.3)	(0.1, 0.8)	6 (1.1)	(0.4, 2.4)	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)
Back pain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Pain in extremity	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)

Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N[a]=1131)		16-25 Years (N[a]=536)		12-15 Years (N[a]=1129)		16-25 Years (N[a]=561)	
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])
Arthropathy	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Joint swelling	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Limb mass	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Mobility decreased	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Musculoskeletal chest pain	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Musculoskeletal discomfort	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Neck pain	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Osteochondrosis	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Plantar fasciitis	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Spinal disorder	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Torticollis	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.3)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Fibroadenoma of breast	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Skin papilloma	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
NERVOUS SYSTEM DISORDERS	12 (1.1)	(0.5, 1.8)	13 (2.4)	(1.3, 4.1)	7 (0.6)	(0.2, 1.3)	7 (1.2)	(0.5, 2.6)
Headache	5 (0.4)	(0.1, 1.0)	11 (2.1)	(1.0, 3.6)	4 (0.4)	(0.1, 0.9)	5 (0.9)	(0.3, 2.1)
Dizziness	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)
Migraine	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Presyncope	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Burning sensation	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)

Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N[a]=1131)		16-25 Years (N[a]=536)		12-15 Years (N[a]=1129)		16-25 Years (N[a]=561)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Neuralgia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Paraesthesia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
PSYCHIATRIC DISORDERS	7 (0.6)	(0.2, 1.3)	5 (0.9)	(0.3, 2.2)	5 (0.4)	(0.1, 1.0)	1 (0.2)	(0.0, 1.0)
Depression	3 (0.3)	(0.1, 0.8)	1 (0.2)	(0.0, 1.0)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Anxiety	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)
Attention deficit hyperactivity disorder	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Depressed mood	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Disorientation	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Generalised anxiety disorder	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Sleep terror	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Tic	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Cervical dysplasia	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)	4 (0.4)	(0.1, 0.9)	4 (0.7)	(0.2, 1.8)
Rhinorrhoea	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	4 (0.4)	(0.1, 0.9)	0	(0.0, 0.7)
Oropharyngeal pain	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	3 (0.5)	(0.1, 1.6)
Asthma	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Nasal congestion	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Reflux laryngitis	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	6 (0.5)	(0.2, 1.2)	5 (0.9)	(0.3, 2.2)	13 (1.2)	(0.6, 2.0)	2 (0.4)	(0.0, 1.3)
Rash	2 (0.2)	(0.0, 0.6)	3 (0.6)	(0.1, 1.6)	4 (0.4)	(0.1, 0.9)	0	(0.0, 0.7)

Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N[a]=1131)		16-25 Years (N[a]=536)		12-15 Years (N[a]=1129)		16-25 Years (N[a]=561)	
	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Urticaria	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	4 (0.4)	(0.1, 0.9)	0	(0.0, 0.7)
Acne	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Dermatitis contact	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Macule	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Pityriasis rosea	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Rash erythematous	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Rash maculo-papular	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Seborrhoeic dermatitis	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Sclerotherapy	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Tooth extraction	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Wisdom teeth removal	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.
Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).
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 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_1md2_soc_ped_saf

12.3.2.1.1.2. Dose 1 to Data Cutoff Date – Participants 12 Through 15 Years of Age

AEs reported from Dose 1 to the data cutoff date for adolescents (13 March 2021) are presented in Table 29. Data for young adults are not included since they had different follow-up time up to the data cutoff date (due to enrollment starting time into the study and due to unblinding of individuals ≥16 years of age per protocol, for vaccination under EUA; refer to Section 9.1.

AEs reported in adolescents through the data cutoff date were similar in the BNT162b2 and placebo groups. The most frequently reported AEs in adolescents through the data cutoff date included lymphadenopathy (9 [0.8%]), injection site pain (7 [0.6%]), fatigue (7 [0.6%]), pyrexia (5 [0.4%]), nausea (5 [0.4%]), and headache (5 [0.4%]).

Table 29. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)	
System Organ Class Preferred Term	BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Placebo (N[a]=1129) n[b] (%)
Any event	72 (6.4)	71 (6.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	9 (0.8)	2 (0.2)
Lymphadenopathy	9 (0.8)	2 (0.2)
EAR AND LABYRINTH DISORDERS	1 (0.1)	2 (0.2)
Ear pain	1 (0.1)	1 (0.1)
Cerumen impaction	0	1 (0.1)
EYE DISORDERS	1 (0.1)	1 (0.1)
Eyelid rash	1 (0.1)	0
Retinal haemorrhage	0	1 (0.1)
GASTROINTESTINAL DISORDERS	14 (1.2)	3 (0.3)
Nausea	5 (0.4)	1 (0.1)
Diarrhoea	3 (0.3)	1 (0.1)
Abdominal pain	2 (0.2)	0
Aphthous ulcer	1 (0.1)	0
Constipation	1 (0.1)	0
Gastritis	1 (0.1)	0
Lip swelling	1 (0.1)	0
Mouth swelling	1 (0.1)	0
Oral mucosal blistering	1 (0.1)	0
Rectal prolapse	1 (0.1)	0
Toothache	0	1 (0.1)
Vomiting	1 (0.1)	0

Table 29. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1131)	Placebo (N[a]=1129)
System Organ Class Preferred Term	n[b] (%)	n[b] (%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	16 (1.4)	11 (1.0)
Injection site pain	7 (0.6)	7 (0.6)
Fatigue	7 (0.6)	4 (0.4)
Pyrexia	5 (0.4)	0
Chills	1 (0.1)	1 (0.1)
Injection site swelling	1 (0.1)	0
Nodule	1 (0.1)	0
Oedema peripheral	0	1 (0.1)
Peripheral swelling	1 (0.1)	0
Vessel puncture site pain	0	1 (0.1)
IMMUNE SYSTEM DISORDERS	0	1 (0.1)
Food allergy	0	1 (0.1)
INFECTIONS AND INFESTATIONS	7 (0.6)	8 (0.7)
Ear infection	3 (0.3)	0
Appendicitis	0	2 (0.2)
Conjunctivitis	0	2 (0.2)
Body tinea	1 (0.1)	0
Candida infection	0	1 (0.1)
Focal peritonitis	0	1 (0.1)
Infectious mononucleosis	0	1 (0.1)
Otitis externa	1 (0.1)	0
Otitis media	1 (0.1)	0
Pilonidal cyst	0	1 (0.1)
Subcutaneous abscess	0	1 (0.1)
Tinea capitis	1 (0.1)	0
Vulval abscess	1 (0.1)	0
Vulvovaginal mycotic infection	1 (0.1)	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	9 (0.8)	13 (1.2)
Concussion	3 (0.3)	2 (0.2)
Ligament sprain	1 (0.1)	2 (0.2)
Accident	1 (0.1)	1 (0.1)
Clavicle fracture	1 (0.1)	1 (0.1)
Contusion	1 (0.1)	1 (0.1)
Fall	1 (0.1)	1 (0.1)
Muscle strain	1 (0.1)	1 (0.1)
Procedural pain	0	2 (0.2)
Tooth fracture	0	2 (0.2)
Foot fracture	0	1 (0.1)

Table 29. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1131)	Placebo (N[a]=1129)
System Organ Class Preferred Term	n[b] (%)	n[b] (%)
Hand fracture	1 (0.1)	0
Humerus fracture	0	1 (0.1)
Lip injury	0	1 (0.1)
Patella fracture	0	1 (0.1)
Radius fracture	1 (0.1)	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	9 (0.8)	8 (0.7)
Arthralgia	2 (0.2)	3 (0.3)
Myalgia	3 (0.3)	2 (0.2)
Joint swelling	0	1 (0.1)
Limb mass	1 (0.1)	0
Mobility decreased	1 (0.1)	0
Musculoskeletal chest pain	0	1 (0.1)
Neck pain	0	1 (0.1)
Osteochondrosis	1 (0.1)	0
Pain in extremity	1 (0.1)	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	2 (0.2)
Fibroadenoma of breast	0	1 (0.1)
Skin papilloma	0	1 (0.1)
NERVOUS SYSTEM DISORDERS	13 (1.1)	7 (0.6)
Headache	5 (0.4)	4 (0.4)
Dizziness	2 (0.2)	1 (0.1)
Presyncope	1 (0.1)	2 (0.2)
Migraine	2 (0.2)	0
Neuralgia	1 (0.1)	0
Paraesthesia	1 (0.1)	0
Syncope	1 (0.1)	0
PSYCHIATRIC DISORDERS	8 (0.7)	5 (0.4)
Depression	3 (0.3)	2 (0.2)
Anxiety	1 (0.1)	2 (0.2)
Attention deficit hyperactivity disorder	0	1 (0.1)
Disorientation	1 (0.1)	0
Generalised anxiety disorder	1 (0.1)	0
Sleep terror	1 (0.1)	0
Suicidal ideation	1 (0.1)	0
Tic	1 (0.1)	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2 (0.2)	4 (0.4)
Rhinorrhoea	1 (0.1)	4 (0.4)

Table 29. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1131)	Placebo (N[a]=1129)
System Organ Class Preferred Term	n[b] (%)	n[b] (%)
Nasal congestion	1 (0.1)	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	7 (0.6)	13 (1.2)
Rash	3 (0.3)	4 (0.4)
Urticaria	2 (0.2)	4 (0.4)
Acne	1 (0.1)	2 (0.2)
Dermatitis contact	1 (0.1)	1 (0.1)
Pityriasis rosea	0	1 (0.1)
Rash maculo-papular	0	1 (0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.
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.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (04:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_d1_cut_soc_ped_saf

12.3.2.1.2. Participants 16 Through 55 Years of Age

12.3.2.1.2.1. Dose 1 to 1 Month After Dose 2 – Participants 16 Through 55 Years of Age

Most AEs reported in adults 16-55 years of age after Dose 1 up to 1 month after Dose 2 reflected reactogenicity (Supplemental Table 14.25). AE frequencies for participants in reactogenicity SOCs (BNT162b2 vs placebo) were:

- general disorders and administration site conditions (3161 [24.3%] vs 681 [5.2%])
- musculoskeletal and connective tissue disorders (1201 [9.2%] vs 303 [2.3%])
- nervous system disorders (1067 [8.2%] vs 393 [3.0%])
- gastrointestinal disorders (440 [3.4%] vs 288 [2.2%])

Beyond participants in the Phase 2/3 reactogenicity subset (refer to Section 12.1.2 and Section 12.2.2), events related to reactogenicity are no longer reported using an e-diary but are instead reported as AEs. An analysis was planned *a priori* to evaluate if the

between-group AE imbalance from Dose 1 to 1 month after Dose 2 was attributed to reactogenicity events by examining the AEs reported within 7 days after each dose, which represents the reactogenicity reporting period. This time period was chosen because many AEs were reported in SOCs of general disorders and administration site conditions, musculoskeletal and connective tissue disorders, and nervous system disorders, which include PTs consistent with and attributable to reactogenicity only if the events occurred in this time window after each dose.

PTs commonly reported from Dose 1 to 7 days after Dose 1 (Supplemental Table 14.26) and from Dose 2 to 7 days after Dose 2 (Supplemental Table 14.27) in the SOCs of general disorders and administration site conditions (injection site pain, pyrexia, chills, and fatigue), musculoskeletal and connective tissue disorders (myalgia), and nervous system disorders (headache) represented the majority of PTs reported in those SOCs. Frequencies between BNT162b2 and placebo and from after Dose 1 to after Dose 2 were similar to patterns of reactogenicity. AE frequencies for participants in these reactogenicity SOCs reported at 7 days post each dose (BNT162b2 vs placebo) were as follows.

General disorders and administration site conditions:

- 7 days post Dose 1 (1707 [13.1%] vs 402 [3.1%])
- 7 days post Dose 2 (2390 [18.8%] vs 294 [2.3%])

Musculoskeletal and connective tissue disorders:

- 7 days post Dose 1 (357 [2.7%] vs 102 [0.8%])
- 7 days post Dose 2 (852 [6.7%] vs 78 [0.6%])

Nervous system disorders:

- 7 days post Dose 1 (360 [2.8%] vs 187 [1.4%])
- 7 days post Dose 2 (755 [5.9%] vs 134 [1.1%])

Overall, AEs reported from during the 7-day periods post each dose 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.

12.3.2.1.2.2. Dose 1 to Unblinding Date – Participants 16 Through 55 Years of Age

Most AEs reported in adult participants 16-55 years of age after Dose 1 up to the unblinding date (reported as IRs per 100 PYs adjusted for variable exposure time) were reactogenicity events, similar to the trend observed after Dose 1 to 1 month after Dose 2 (Supplemental Table 14.28). AE incidences for participants in these reactogenicity SOCs (BNT162b2 vs placebo) were:

- general disorders and administration site conditions (63.7 vs 14.1 per 100 PYs)
- musculoskeletal and connective tissue disorders (24.6 vs 7.0 per 100 PYs)
- nervous system disorders (21.8 vs 8.3 per 100 PYs)
- gastrointestinal disorders (9.5 vs 6.3 per 100 PYs)

AE analyses for adults (16-55 years of age) up through the unblinding date did not suggest any meaningful changes in the safety profile for the age group relative to that observed at 1 month after Dose 2 (refer to Section 12.3.2.1.2.1).

12.3.2.2. Related Adverse Events by System Organ Class and Preferred Term

12.3.2.2.1. Dose 1 to 1 Month After Dose 2 – Participants 12 Through 15 Years of Age

From Dose 1 to 1 month after Dose 2, AEs assessed as related by the investigator in adolescents and young adults were similar in the BNT162b2 group and in the placebo group (Table 24). Most related AEs were reactogenicity events and in the SOC of general disorders and administration site conditions, reported by 15 adolescents (1.3%) and 19 young adults (3.5%) in the BNT162b2 group compared with 9 adolescents (0.8%) and 9 young adults (1.6%) in the placebo group (Supplemental Table 14.29). Related events of lymphadenopathy were reported in the 7 adolescents in the BNT162b2 group and 1 adolescent in the placebo group, compared with 1 young adult in the BNT162b2 group and none in the placebo group (refer to other significant AEs in Section 12.4.4).

12.3.2.2.2. Dose 1 to 1 Month After Dose 2 – Participants 16 Through 55 Years of Age

From Dose 1 to 1 month after Dose 2, AEs assessed as related by the investigator during the blinded follow-up period were reported by 3480 (26.8%) adult participants 16-55 years of age in the BNT162b2 group and 882 (6.8%) participants in the placebo group (Table 26). Most related AEs were reactogenicity events and in the SOC of general disorders and administration site conditions, reported by 3118 BNT162b2 recipients (24.0%) and 608 placebo recipients (4.7%) (Supplemental Table 14.30). Among the participants who had AEs of lymphadenopathy, 52 participants (0.4%) in the BNT162b2 group and 2 participants (0.0%) in the placebo group had events assessed by the investigator as related to study intervention (discussed as events of clinical interest in Section 12.4.4).

12.3.2.3. Immediate Adverse Events – Participants 12 Through 15 Years of Age

After Dose 1, adolescents and young adults with immediate AEs were low in frequency (≤0.4%) and were reported only in the placebo groups (Supplemental Table14.31). All immediate AEs after Dose 1 were in the SOCs of general disorders and administration site

conditions (injection site pain, injection site erythema, and vessel puncture site pain) and nervous system disorders (dizziness and headache).

After Dose 2, adolescents and young adults with immediate AEs were low in frequency (≤0.4%) in BNT162b2 and placebo groups (Supplemental Table14.32). Most immediate AEs after Dose 2 were in the SOC of general disorders and administration site conditions (injection site pain, injection site bruising, injection site hyperesthesia, fatigue, chills; 1-2 participants reporting each). Other immediate AEs after Dose 2 were reported in the SOC of nervous system disorders (dizziness; 1 participant in the BNT162b2 adolescent group) or skin and subcutaneous tissue disorders (rash maculo-papular; 1 participant in the placebo adolescent group).

No allergic AEs were reported after either dose of BNT162b2 within 30 minutes after vaccination.

12.3.2.4. Severe or Life-Threatening Adverse Events

12.3.2.4.1. Dose 1 to 1 Month After Dose 2 – Participants 12 Through 15 Years of Age

From Dose 1 to 1 month after Dose 2, severe AEs reported in adolescents and young adults were overall low in number and frequency: 7 (0.6%) participants in the BNT162b2 group versus 2 (0.2%) participants in the placebo group among adolescents, and 9 (1.7%) participants in the BNT162b2 group versus 3 (0.5%) in the placebo group among young adults (Table 24). Severe AEs reported in adolescents and young adults are presented by SOC and PT in Supplemental Table 14.33.

Among adolescents, 2 participants (1 each in the BNT162b2 and placebo groups) had at least 1 life-threatening (or Grade 4) AE from Dose 1 to 1 month after Dose 2 (Supplemental Table 14.34). These included:

- Focal peritonitis and appendicitis reported in 1 adolescent in the placebo group, occurring concurrently 19 days after Dose 2 with a duration of 2 days, and considered by the investigator as not related to study intervention; both events were reported as SAEs (refer to Section 12.4.2.1.1), resolved, and the participant continued in the study

- Pyrexia (40.4°C) reported as Grade 4 in 1 adolescent in the BNT162b2 group, occurred on Day 2 after Dose 1, with temperature returning to normal on Day 4), and was considered by the investigator as related to study intervention; the event was reported by the investigator as non-serious, resolved, and the participant withdrew from the study (also recorded in the e-diary as reactogenicity systemic event in Section 12.2.1).

Additionally, 2 participants in the adolescent age group had life-threatening AEs that occurred after they turned 16 years of age during the study and were unblinded to receive BNT162b2 and were therefore not included in analyses of blinded data (per protocol; refer to Section 9.1.

- Anaphylactoid reaction reported in 1 participant originally randomized to the placebo group, 3 days after receiving the first dose of BNT162b2 (Dose 3) with a duration of

1 day, considered by the investigator as related to study intervention; the event was reported as an SAE (refer to Section 12.4.2.1), resolved, and the participant withdrew from the study (Appendix 16.2.7.5.1). The participant has ongoing medical history of drug hypersensitivity, food allergy, and seasonal allergy (Appendix 16.2.5.3.1).

- Depression reported in 1 participant originally randomized to the placebo group, 7 days after receiving the first dose of BNT162b2 (Dose 3) reported as ongoing at the time of the data cutoff date, considered by the investigator as not related to study intervention; the event was reported as an SAE due to hospitalization (refer to Section 12.4.2.1.1) and reported as resolving, and the participant continued in the study (Appendix 16.2.7.4.1.1).

Among young adults, there were no life-threatening AEs reported from Dose 1 to 1 month after Dose 2 (Table 24).

12.3.2.4.2. Dose 1 to 1 Month After Dose 2 – Participants 16 Through 55 Years of Age

From Dose 1 to 1 month after Dose 2, severe AEs reported in the adult age group (16-55 years of age) during the blinded follow-up period were low in frequency, reported in 154 [1.2%] BNT162b2 recipients and 74 [0.6%] placebo recipients (Supplemental Table 14.35). The frequency of severe events in the BNT162b2 group was primarily due to events in the SOC of general disorders and administration site conditions, reported by 75 [0.6%] BNT162b2 recipients versus 4 [0.0%] placebo recipients; the most frequently report term was pyrexia (34 [0.3%] vs 1 [0.0%]).

Life-threatening events were infrequent, reported in 8 participants (0.1%) in the BNT162b2 group and 11 participants (0.1%) in the placebo group from Dose 1 to 1 month after Dose 2 (Supplemental Table 14.36).

12.4. Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events – Phase 2/3 Participants ≥16 Years of Age

12.4.1. Deaths

No deaths were reported in adolescent (12-15 years of age) or young adult (16-25 years of age) groups evaluated in safety analyses up to the data cutoff date (13 March 2021) (Appendix 16.2.7.7.1).

A total of 7 deaths were reported among Phase 2/3 adult participants (16-55 years of age) through the unblinding date (3 in the BNT162b2 group and 4 in the placebo group) (Appendix 16.2.7.7.2). No reported deaths were assessed by the investigator as related to study intervention.

In the BNT162b2 group:

- 1 male participant 54 years of age died due to congestive cardiac failure 88 days after Dose 2
- 1 male participant 53 years of age died due to cardio-respiratory arrest 86 days after Dose 2

- 1 male participant 51 years of age died due to metastatic lung cancer 113 days after Dose 2

In the placebo group:

- 1 female participant 42 years of age died due to an undetermined cause 8 days after Dose 1
- 1 female participant 51 years of age died due to myocardial infarction 37 days after Dose 2
- 1 male participant 53 years of age died due to multiple drug overdose 32 days after Dose 2
- 1 male participant 47 years of age died due to cardio-respiratory arrest 82 days after Dose 2

Additionally, 1 participant (female, 56 years of age) in the HIV+ subset of Study C4591001 (per protocol, analyzed separately from the safety population) died due to COVID-19 pneumonia 76 days after Dose 2 of placebo. This participant was diagnosed based on a local COVID-19 test that was not protocol-approved and was not subsequently confirmed by a test result from the central laboratory. The death was not considered related to study intervention.

12.4.1.1. Death Narratives

There were no deaths in adolescent participants 12 through 15 years of age, so there are no narratives for this group. Since participants 16 through 55 years of age are presented in this report for comparative purposes only, narratives for these participants with deaths will be reported separately along with the full independent safety evaluation of these participants.

12.4.2. Serious Adverse Events

12.4.2.1. Participants 12 Through 15 Years of Age

SAE analyses for adolescents and young adults are reported from Dose 1 to 1 month after Dose 2 (Section 12.4.2.1.1), and from Dose 1 until the data cutoff date (13 March 2021) (Section 12.4.2.1.2).

12.4.2.1.1. Dose 1 to 1 Month After Dose 2 – Participants 12 Through 15 Years of Age

From Dose 1 to 1 month after Dose 2, the proportions of adolescents and young adults (in the reactogenicity subset) who reported at least 1 SAE were similar (Table 30). Overall, ≤0.4% of participants in both age groups reported any SAE after receiving BNT162b2 or placebo.

No participants in either age group had SAEs assessed by the investigator as related to study intervention.

In the adolescent group, SAEs up to 1 month after Dose 2 were reported in the BNT162b2 group in 2 participants with depression, 1 participant with concurrent events of anxiety and depression, and 1 participant with neuralgia and 1 participant in the placebo group with concurrent events of appendicitis and focal peritonitis that were both Grade 4 (refer to Section 12.3.2.4.1).

The SAE of neuralgia was reported in 1 female participant 12 years of age who had 3 emergency room visits beginning 1 day after the second dose (Appendix 16.2.7.5.1). She reported concurrent non-serious AEs of vulvar abscess, gastritis, and contact dermatitis. She subsequently had SAEs of abdominal pain and constipation. She had an extensive work-up including serial physical and laboratory examinations and was diagnosed with functional abdominal pain; she was referred to psychology and physical therapy, after which symptoms were reported as gradually improving.

In the young adult age group, SAEs up to 1 month after Dose 2 were reported by 2 participants in the BNT162b2 group (1 participant with abdominal pain and 1 participant with appendicitis) and 2 participants in the placebo group (1 participant had inguinal hernia, and 1 participant had flail chest associated with a motor vehicle accident). All SAEs in the young adult group were reported as resolved.

Table 30. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N^a=1131)		16-25 Years (N^a=536)		12-15 Years (N^a=1129)		16-25 Years (N^a=561)	
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	4 (0.4)	(0.1, 0.9)	2 (0.4)	(0.0, 1.3)	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Abdominal pain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Inguinal hernia	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
INFECTIONS AND INFESTATIONS	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Appendicitis	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Focal peritonitis	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Flail chest	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
NERVOUS SYSTEM DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Neuralgia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
PSYCHIATRIC DISORDERS	3 (0.3)	(0.1, 0.8)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Depression	3 (0.3)	(0.1, 0.8)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Anxiety	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)

Table 30. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N^a=1131)		16-25 Years (N^a=536)		12-15 Years (N^a=1129)		16-25 Years (N^a=561)	
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.
Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.
Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).
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 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_1md2_ser_ped_saf

12.4.2.1.2. Dose 1 to Data Cutoff Date – Participants 12 Through 15 Years of Age

From Dose 1 to the data cutoff date (13 March 2021), the proportions of adolescents who reported at least 1 SAE were similar in the BNT162b2 and placebo groups (Table 31). Data for young adults are not included since they had different follow-up time up to the data cutoff date (due to enrollment starting time into the study and due to unblinding of individuals ≥16 years of age per protocol, for vaccination under EUA; refer to Section 9.1).

Up to the data cutoff date, 5 adolescents (0.4%) in the BNT162b2 group and 2 adolescents (0.02%) in the placebo group reported any SAE. None of the SAEs were assessed by the investigator as related to study intervention. In addition to the SAEs that were previously reported up to 1 month after Dose 2 (refer to Section 12.4.2.1.1), SAEs reported from after 1 month post Dose 2 up to the data cutoff date included abdominal pain and constipation reported concurrently in 1 participant (who also previously reported an SAE of neuralgia) in the BNT162b2 group. This participant was ultimately diagnosed with functional abdominal pain after an extensive work-up. An SAE of suicidal ideation was reported in 1 participant in the BNT162b2 group and an SAE of appendicitis was reported in 1 participant in the placebo group. All SAEs were reported as resolved/resolving except for the events of abdominal pain and constipation which remained unresolved as of the data cutoff date.

Additionally, 2 adolescents originally randomized to the placebo group had SAEs that occurred after they turned 16 years of age during the study and were unblinded to receive BNT162b2 (per protocol; refer to Section 9.1), therefore the data are not included in the blinded analyses. These events were also considered as life-threatening (refer to Section 12.3.2.4.1): an anaphylactoid reaction reported in 1 participant 3 days after receiving the first dose of BNT162b2 (Dose 3) with a duration of 1 day, considered by the investigator as related to study intervention and leading to study withdrawal; and depression reported in 1 participant 7 days after receiving the first dose of BNT162b2 (Dose 3) reported as ongoing/resolving at the time of the data cutoff date, considered by the investigator as not related to study intervention.

Table 31. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)	
System Organ Class Preferred Term	BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Placebo (N[a]=1129) n[b] (%)
Any event	5 (0.4)	2 (0.2)
GASTROINTESTINAL DISORDERS	1 (0.1)	0
Abdominal pain	1 (0.1)	0
Constipation	1 (0.1)	0
INFECTIONS AND INFESTATIONS	0	2 (0.2)
Appendicitis	0	2 (0.2)
Focal peritonitis	0	1 (0.1)
NERVOUS SYSTEM DISORDERS	1 (0.1)	0
Neuralgia	1 (0.1)	0
PSYCHIATRIC DISORDERS	4 (0.4)	0
Depression	3 (0.3)	0
Anxiety	1 (0.1)	0
Suicidal ideation	1 (0.1)	0

Note: MedDRA (v23.1) coding dictionary applied.
Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.
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.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (04:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_d1_cut_ser_ped_saf

12.4.2.2. Participants 16 Through 55 Years of Age

12.4.2.2.1. Dose 1 to 1 Month After Dose 2 – Participants 16 Through 55 Years of Age

From Dose 1 to 1 month after Dose 2, the proportions of adult participants (16-55 years of age) who reported at least 1 SAE was similar in the BNT162b2 group (52 [0.4%]) and in the placebo group (49 [0.4%]) (Supplemental Table 14.37).

The most frequently reported SAEs in the BNT162b2 group were appendicitis (6 participants) followed by acute myocardial infarction, cellulitis, urinary tract infection, intervertebral disc protrusion, subarachnoid hemorrhage, and deep vein thrombosis (in 2 participants each). None of these events were considered by the investigator as related to study intervention.

Three SAEs (2 in the BNT162b2 group and 1 in the placebo group) were assessed by the investigator as related to study intervention:

- 1 participant in the BNT162b2 group had a related event of lymphadenopathy and was withdrawn from the study, with the event reported as resolved/recovered. This event was previously identified at the time of the EUA cutoff date of 14 November 2020.
- 1 participant in the BNT162b2 group reported shoulder injury related to vaccine administration, which was reported as resolved/recovered. This event was previously identified at the time of the EUA cutoff date of 14 November 2020.
- 1 participant in the placebo group reported related event of paresthesia and was recovering at the time of data cutoff.

12.4.2.2.2. Dose 1 to Unblinding Date – Participants 16 Through 55 Years of Age

From Dose 1 to the unblinding date, the IRs of adult participants (16-55 years of age) who reported at least 1 SAE were similar in the BNT162b2 (2.1) and placebo (2.4) groups (Supplemental Table 14.38); these were reported as IRs per 100 PYs adjusted for variable exposure time.

In addition to SAEs reported up to 1 month after Dose 2, reported events after 1 month post Dose 2 up to the unblinding date included 1 SAE in a placebo recipient that was assessed by the investigator as related to study intervention: 1 participant in the placebo group reported a related SAE of psoriatic arthropathy which was not resolved at the time of the data cutoff date (Appendix 16.2.7.5.2).

Up to the unblinding date, 12 cases of appendicitis were reported in the BNT162b2 group and 7 cases in the placebo group for similar IRs of 0.2 and 0.1 per 100 PYs, respectively. None were considered related to study intervention.

12.4.2.3. Serious Adverse Event Narratives

Narratives for the Phase 2/3 adolescent participants 12 through 15 years of age 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. Since participants 16 through 55 years of age are presented in this report for comparative purposes only, narratives in these participants with SAEs will be reported separately along with the full independent safety evaluation of these participants.

12.4.3. Safety-Related Participant Withdrawals

12.4.3.1. Participants 12 Through 15 Years of Age

From Dose 1 to 1 month after Dose 2, few adolescents and young adults in the BNT162b2 group (≤0.2%) and in the placebo group (≤0.4%) were withdrawn due to AEs (Table 32)

In the adolescent group, 1 participant in the BNT162b2 group had an AE leading to withdrawal that was considered by the investigator as related to study intervention (pyrexia; refer to Section 12.3.2.4.1), and none in the placebo group.

In the young adult group, 1 participant in the BNT162b2 group a had an AE leading to withdrawal that was considered by the investigator as related to study treatment (severe injection site pain that started 2 days after Dose 1 and resolved after 1 day) (Appendix 16.2.7.6.1), and none in the placebo group.

Table 32. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N[a]=1131)		16-25 Years (N[a]=536)		12-15 Years (N[a]=1129)		16-25 Years (N[a]=561)	
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	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Injection site pain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Pyrexia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)
Exposure during pregnancy	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Headache	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
PSYCHIATRIC DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Anxiety	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Depression	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)

Table 32. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N[a]=1131)		16-25 Years (N[a]=536)		12-15 Years (N[a]=1129)		16-25 Years (N[a]=561)	
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.
Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.
Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).
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 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_1md2_wd_ped_saf

12.4.3.2. Participants 16 Through 55 Years of Age

From Dose 1 to 1 month after Dose 2, few adult participants (16-55 years of age) in the BNT162b2 (0.1%) and placebo (0.2%) groups were withdrawn due to AEs (Supplemental Table 14.39).

In total, 19 participants in the BNT162b2 group and 20 participants in the placebo group had an AE leading to withdrawal during blinded follow-up, with 17 AEs considered by the investigator as related to study intervention (Appendix 16.2.7.6.2).

- Withdrawals due to related AEs in the BNT162b2 group included: 2 participants each with injection site pain or headache and 1 participant each with lymphadenopathy, eye pain, injection site dermatitis, injection site swelling, myalgia, or urticaria.

- Withdrawals due to related AEs in the placebo group included: 2 participants with drug hypersensitivity and 1 participant each with myalgia, urticaria, vertigo, dizziness, or irregular heart rate.

The events of urticaria (1 each in the BNT162b2 and placebo groups) were Grade 1 or 2, had on onset of 4-10 days, resolved within 4-27 days, and were considered non-serious.

In addition, 1 adult participant originally randomized to placebo who was unblinded to receive BNT162b2 had events of Grade 2 urticaria (forehead, posterior neck, bilateral posterior hands and bilateral plantar areas) and Grade 1 angioedema (forehead) with an onset of 2 days post Dose 3 and resolved after 7 days; the event was non-serious and considered by the investigator as related to study intervention; the participant was withdrawn from study intervention due to AE.

12.4.3.3. Narratives of Safety-Related Participant Withdrawals

Narratives for the adolescent participants 12 through 15 years of age with any AEs leading to withdrawal from Dose 1 through 1 month after Dose 2 are provided in Section 14. Since participants 16 through 55 years of age are presented in this report for comparative purposes only, narratives for these participants with any AEs leading to withdrawal will be reported separately along with the full independent safety evaluation of these participants.

12.4.4. Other Significant Adverse Events

Adverse Events of Clinical Interest

Adverse events of clinical interest include AESIs, such as those in the CDC list of AESIs for COVID-19 that include events potentially indicative of severe COVID-19 or autoimmune and neuroinflammatory disorders, were considered, in addition to program-defined TMEs, in the review of reported events for the adolescent group. Narratives were prepared for such events reported in adolescents (12-15 years of age). If an AE of clinical interest was not observed in the 12-15 years of age group, narratives were not provided for individuals 16 and above. AEs of clinical interest occurring in the adolescent group were reviewed along with corresponding reference information from adults and are summarized below.

Anaphylaxis

No cases of anaphylaxis or anaphylactoid reactions were reported during blinded follow-up in the adolescent (12-15 years of age) or young adult (16-25 years of age) groups as of the data cutoff date (13 March 2021).

One young adult participant (reported with both the 16-25 years of age and 16-55 years of age group data) who was originally randomized to the placebo group and unblinded to receive BNT162b2 had an anaphylactoid reaction (specific symptoms not specified) assessed as related, 3 days post Dose 3 (first dose of BNT162b2), with an event duration of 1 day; the event was reported as an SAE (refer to Section 12.4.2.1.2), reported as resolved, and the participant withdrew from the study (this participant has an ongoing medical history of drug hypersensitivity, food allergy, and seasonal allergy [Appendix 16.2.5.3.1]). Note that this event was not counted in the summary safety tables which only included blinded follow-up data.

In adults (16-55 years of age), 1 other participant had an SAE of anaphylaxis caused by a bee sting that was not considered related to study intervention.

Lymphadenopathy

Lymphadenopathy is identified as an adverse reaction for BNT162b2 vaccine.

In adolescents (12-15 years of age), 7 participants (0.6%) in the BNT162b2 group and 1 participant (0.1%) in the placebo group had lymphadenopathy events assessed by the investigator as related to study intervention. The majority of these events occurred in the arm and neck region, were reported within 2-10 days after vaccination, and approximately half of events resolved within 1-10 days (others were ongoing at the time of the data cutoff date).

In young adults (16-25 years of age), 1 related event of lymphadenopathy was reported up to the data cutoff date, occurring in the axilla within 1 day of Dose 2 and resolved within 5 days.

In adults (16-55 years of age), 52 participants (0.4%) in the BNT162b2 group and 2 participants (0.0%) in the placebo group had lymphadenopathy events reported up to the unblinding date and assessed by the investigator as related to study intervention (refer to Section 12.3.2.2.2). The majority of these events occurred in the arm and neck region, were reported within 2-4 days after vaccination (usually after Dose 2), and typically resolved within approximately 1 week.

Appendicitis

In adolescents (12-15 years of age), 2 participants in the placebo group had events of appendicitis reported as SAEs (refer to Section 12.4.2.1) and considered as not related to study intervention.

In young adults (16-25 years of age), 1 participant in the BNT162b2 group had an event of appendicitis reported as an SAE (refer to Section 12.4.2.1) and considered as not related to study intervention.

In adults (16-55 years of age), 12 cases of appendicitis were reported in the BNT162b2 group and 7 cases in the placebo group during blinded follow-up through the unblinding date. All were considered as SAEs (refer to Section 12.4.2.2), not related to study intervention, and all participants recovered.

Bell's Palsy/Facial Paralysis/Facial Paresis

No cases of facial paralysis were reported in adolescents (12-15 years of age) as of the data cutoff date (13 March 2021).

12.4.4.1. Narratives of Other Significant Adverse Events

Narratives of other significant AEs, including AEs of clinical interest (anaphylaxis, lymphadenopathy, appendicitis, Bell's palsy), as of the data cutoff date (13 March 2021) are provided in Section 14. Since participants 16 through 55 years of age are presented in this report for comparative purposes only, narratives for SAEs in these participants will be reported separately along with the full independent safety evaluation of these participants.

12.4.4.2. Other Safety Assessments

12.4.4.2.1. Severe COVID-19 Illness

Cases of COVID-19, both overall and those considered as severe, were evaluated per criteria described Appendix 16.1.1, Protocol Section 8.1.1. Results for efficacy against severe disease are discussed in Section 11.1.3.

The protocol had prespecified stopping rules that included monitoring of severe COVID-19 cases, and these stopping criteria were not met.

As of the data cutoff date (13 March 2021), no severe COVID-19 cases were reported in adolescents 12-15 years of age in Study C4591001 (Section 11.1.3), suggesting no evidence for vaccine-associated enhanced disease (VAED) including vaccine-associated enhanced respiratory disease (VAERD).

12.4.4.2.2. Pregnancy

As of the data cutoff date (13 March 2021), no pregnancies were reported in participants 12-15 years of age. Four pregnancies were reported in the young adults (16-25 years of age) that led to discontinuation from the vaccination period, and 1 additional participant in the

young adult group withdrew from the study due to a reported AE of exposure during pregnancy; none of these participants has given birth as of the data cutoff date.

Narratives for adolescent participants who reported a pregnancy during the study, including any reported outcomes, are provided in Section 14.

12.4.4.3. Analysis and Discussion of Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events

The proportions of adolescents and young adults (in the reactogenicity subset) who reported at least 1 SAE were low (Section 12.4.2.1) and few were withdrawn because of AEs (Section 12.4.3.1). The proportions/IRs of adults who reported at least 1 SAE were low (Section 12.4.2.2) and few were withdrawn because of AEs (Section 12.4.3.2).

No deaths were reported in adolescent or young adult groups evaluated in safety analyses up to the data cutoff date (13 March 2021) (Section 12.4.1). A total of 7 deaths were reported among Phase 2/3 adult participants through the unblinding date (3 in the BNT162b2 group and 4 in the placebo group) (Section 12.4.1). No reported deaths were assessed by the investigator as related to study intervention.

One case of anaphylactoid reaction was reported in a young adult participant 3 days after the first dose of BNT162b2 (Section 12.4.4).

Lymphadenopathy was assessed as related in 7 adolescents, 1 young adult, and 52 adults in the BNT162b2 group and less frequently in the placebo group (1 adolescent and 2 adults).

Appendicitis was reported in 1 young adult and 12 adults in the BNT162b2 group and in 2 adolescents and 7 adults in the placebo group; all were reported as SAEs and considered as not related to study intervention.

No cases of facial paralysis were reported in adolescents (12-15 years of age) as of the data cutoff date (13 March 2021).

12.4.5. Safety Conclusions

12.4.5.1. Participants 12 Through 15 Years of Age

Phase 3 data from approximately 2200 adolescents 12-15 years of age with a median follow-up time of at least 2 months after Dose 2 showed BNT162b2 at 30 µg was safe and well-tolerated.

Reactogenicity in adolescents 12-15 years of age was mostly mild to moderate and short-lived after dosing (ie, median onset mostly between 1-3 days after dosing and resolution within 1-3 days after onset), similar to the reactogenicity data in the young adults 16-25 years of age. Local reactions presented predominantly as injection site pain with minimal effect of dose number, and systemic events generally increased in frequency and/or severity with increasing dose number; also similar to findings in the 16-25 years of age group. Adolescents tended to have less severe local reactions and systemic events after each vaccine dose compared with young adults. The rate of fever was somewhat higher in the adolescent group

compared to the young adult group (10.1% vs 7.3% after Dose 1, respectively), especially after the second dose (19.6% vs 17.2%, respectively), but fevers were mostly mild to moderate in severity. The observed AE profile did not suggest any serious safety concerns for BNT162b2 vaccination of adolescents 12-15 years of age. Overall, AEs reported in the study for adolescents and young adults reflect age-appropriate events consistent with the general population.

As of the data cutoff date (13 March 2021), there were very few AEs of clinical interest corresponding to the CDC list of AESIs reported in adolescents. Lymphadenopathy has been identified as related to BNT162b2 in study participants ≥16 years of age and is also identified as related to BNT162b2 in the 12-15 year old adolescent group. One AE of anaphylactoid reaction was identified in a young adult participant (who has an ongoing medical history of drug hypersensitivity and non-drug allergies), which is consistent with post-authorization safety observations in individuals ≥16 years of age.

The incidence of SAEs was low in the context of the number of participants enrolled and comparable between BNT162b2 and placebo. The incidence of withdrawals due to AEs was also low and similar between BNT162b2 and placebo groups. No deaths were reported in adolescents 12-15 years of age or in young adults 16-25 years of age included in the safety analyses.

12.4.5.2. Participants 16 Through 55 Years of Age

The adult (16-25 years of age and 16-55 years of age) safety data included for reference purposes in the context of this CSR for adolescents 12-15 years of age is from approximately 26,000 adults 16-55 years of age, among whom a majority in the BNT162b2 group have at least 6 months of blinded follow-up after Dose 2 in Phase 2/3 of this study. These data show BNT162b2 at 30 μg was safe and well-tolerated in this age group. Reactogenicity was mostly mild to moderate and short-lived after dosing (ie, median onset between 1-2 days after dosing and resolution within 1-2 days after onset), with local reactions presenting predominantly as injection site pain with minimal effect of dose number, and systemic events generally increasing in frequency and/or severity with increasing dose number.

The review of AEs and SAEs in the adult (16-55 years of age) population presented in this CSR did not suggest new safety concerns to date. A full and independent safety evaluation of the adult population is being conducted to prepare a full CSR in support of licensing/marketing application submissions including a BLA planned in second quarter of 2021.

Comparing adolescents (12 through 15 years of age) to young adults (16 through 25 years of age) and adults (16-55 years of age) identifies very similar reactogenicity profiles. Reactogenicity after each dose was observed in all groups with similar patterns after Dose 1 and Dose 2. Fever was highest for the adolescent group compared to the young adult group but was still within tolerable limits. Arthralgia and muscle pain were higher in the young adult group than the adolescent group for both doses of BNT162b2. Overall, the differences in reported AEs were age appropriate and not related to vaccination.

13. DISCUSSION AND OVERALL CONCLUSIONS

13.1. Discussion

In this report, safety data are evaluated from approximately 2200 participants 12-15 years of age among whom a majority had follow-up to at least 2 months after Dose 2. Corresponding data from young adults 16-25 years of age (reactogenicity subset) is presented for reference as is safety data up to approximately 6 months after Dose 2 from the protocol specified younger adult group (16-55 years of age).

The reactogenicity profile of adolescents was typically mild to moderate, arose within the first 1-3 days after dosing, with reactions or events that were short-lived. The most common prompted local reaction in adolescents was injection site pain. The most common prompted systemic events reported in adolescents included fatigue, headache, muscle and joint pain, and chills. The frequency of any severe systemic event after dosing was low.

Comparing adolescents to young adults and adults 16-55 years of age identifies similar reactogenicity profiles. Reactogenicity after each dose was observed in all groups with similar patterns after Dose 1 and Dose 2. Fever incidence was somewhat higher for the adolescent group compared to the young adult group but was still within tolerable limits. Arthralgia and muscle pain were higher in the young adult group than the adolescent group for both doses of BNT162b2. Overall, the differences in reported AEs were age appropriate and not related to vaccination.

The AE profile among adolescents mostly reflects reactogenicity events, with low incidences of severe and/or related events. Lymphadenopathy has been identified as related to BNT162b2 in study participants ≥16 years of age and is also identified as related to BNT162b2 in the 12-15 year old adolescent group. The incidence of SAEs in adolescents was low and similar between the vaccine and placebo groups. Few adolescents withdrew from the study due to AEs. No deaths occurred in the adolescent group. Review of AEs, SAEs, and events of clinical interest suggested no clear patterns or additional safety concerns among adolescents. Safety follow-up in the larger study population of adults 16-55 years of age has suggested no new safety signals and continues to support a safe and tolerable profile for BNT162b2.

As of the safety data cutoff date (13 March 2021), no severe COVID-19 cases were reported in adolescent group.

Immunobridging based on NI of SARS-CoV-2 neutralizing GMTs for adolescents compared to young adults provides evidence of vaccine effectiveness in the adolescent group. Immunogenicity data from adolescent and young adult participants showed robust neutralizing GMTs after vaccination with 2 doses of BNT162b2 at 30 μg in both adolescents and young adults. This response was evident in the 50% neutralizing GMTs of participants with SARS-CoV-2 negative status, and further boosted in baseline SARS-CoV-2 positive participants with prior evidence of SARS-CoV-2 infection. Declaration of NI for neutralizing GMTs was based on a 1.5-fold margin for the adolescent versus young adult groups; adolescent immune responses actually exceeded that of young adults. These data provide

reassurance that the vaccine will provide a robust immune response to SARS-CoV-2 in the adolescent population.

Updated descriptive efficacy analyses for adolescents, based on confirmed cases COVID-19 reported from at least 7 days after Dose 2 through the data cutoff date (13 March 2021), included observed VE of 100.0% (2-sided 95% CI: 75.3%, 100.0%) for individuals without evidence of prior SARS-CoV-2 infection before and during vaccination regimen, and 100.0% (2-sided 95% CI: 78.1%, 100.0%) for individuals with or without evidence of prior SARS-CoV-2 infection before and during vaccination regimen. In the Dose 1 all-available (modified intention-to-treat) population, 3 participants in the BNT162b2 group and 35 participants in the placebo group had COVID-19 cases occurring after Dose 1, for an observed VE of 91.6% (2-sided 95% CI: 73.5%, 98.4%). All 3 cases in the BNT162b2 group occurred within the period from after Dose 1 up to <11 days after Dose 1 (prior to Dose 2), after which time the VE was 100.0% for BNT162b2 (assessed up to ≥2 months after Dose 2 and <4 months after Dose 2). No severe COVID-19 cases were reported in individuals in the 12-15 years of age group, based on either protocol definition (ie, per FDA criteria) or per CDC criteria for severity.

Taken together, efficacy and immunogenicity data strongly support a positive benefit for the BNT162b2 30 µg 2-dose regimen in adolescents 12-15 years of age. The vaccine provides protection against COVID-19 and induces a robust immune response for individuals 12-15 years of age that has greater magnitude than that observed in young adults, including immune responses for individuals with and without prior exposure to SARS-CoV-2.

13.2. Overall Conclusions

In Phase 2/3, BNT162b2 at 30 µg provided protection against COVID-19 in adolescents 12 through 15 years of age irrespective of evidence of prior infection with SARS-CoV-2 (100% VE), with no severe cases observed in this age group. The immune responses in adolescent participants were noninferior to the immune responses in young adults, and in fact were statistically greater than that observed in young adults. The tolerability and safety profile was acceptable and supports BNT162b2 at 30 µg administered as a 2-dose regimen (21 days apart) to adolescents 12 through 15 years of age for the prevention of COVID-19.

14. TABLES AND FIGURES

SUPPLEMENTAL TABLES

Conduct of Study

14.1. Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131) n[b] (%)	16-25 Years (N[a]=537) n[b] (%)	12-15 Years (N[a]=1129) n[b] (%)	16-25 Years (N[a]=561) n[b] (%)
Sex				
Male	567 (50.1)	255 (47.5)	585 (51.8)	269 (48.0)
Female	564 (49.9)	282 (52.5)	544 (48.2)	292 (52.0)
Race				
White	971 (85.9)	445 (82.9)	962 (85.2)	466 (83.1)
Black or African American	52 (4.6)	47 (8.8)	57 (5.0)	50 (8.9)
American Indian or Alaska Native	4 (0.4)	7 (1.3)	3 (0.3)	1 (0.2)
Asian	72 (6.4)	22 (4.1)	71 (6.3)	21 (3.7)
Native Hawaiian or other Pacific Islander	3 (0.3)	3 (0.6)	0	1 (0.2)
Multiracial	23 (2.0)	12 (2.2)	29 (2.6)	19 (3.4)
Not reported	6 (0.5)	1 (0.2)	7 (0.6)	3 (0.5)
Racial designation				
Japanese	5 (0.4)	0	2 (0.2)	0
Ethnicity				
Hispanic/Latino	132 (11.7)	112 (20.9)	130 (11.5)	105 (18.7)
Non-Hispanic/non-Latino	997 (88.2)	423 (78.8)	996 (88.2)	456 (81.3)
Not reported	2 (0.2)	2 (0.4)	3 (0.3)	0
Country				
Argentina	0	20 (3.7)	0	28 (5.0)
Brazil	0	24 (4.5)	0	19 (3.4)
Germany	0	11 (2.0)	0	20 (3.6)
South Africa	0	34 (6.3)	0	45 (8.0)
Turkey	0	12 (2.2)	0	15 (2.7)
USA	1131 (100.0)	436 (81.2)	1129 (100.0)	434 (77.4)
Age at vaccination (years)				
Mean (SD)	13.6 (1.11)	19.4 (3.26)	13.6 (1.11)	19.6 (3.33)
Median	14.0	18.0	14.0	19.0
Min, max	(12, 15)	(16, 25)	(12, 15)	(16, 25)
Baseline SARS-CoV-2 status				

14.1. Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131) n[b] (%)	16-25 Years (N[a]=537) n[b] (%)	12-15 Years (N[a]=1129) n[b] (%)	16-25 Years (N[a]=561) n[b] (%)
Positive[c]	46 (4.1)	30 (5.6)	47 (4.2)	34 (6.1)
Negative[d]	1028 (90.9)	497 (92.6)	1023 (90.6)	522 (93.0)
Missing	57 (5.0)	10 (1.9)	59 (5.2)	5 (0.9)
Body mass index (BMI) Obese[e]				
Yes	143 (12.6)	80 (14.9)	128 (11.3)	101 (18.0)
No	988 (87.4)	457 (85.1)	1001 (88.7)	460 (82.0)

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.
e. 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. For 16 through 25 years age group, obesity is defined as BMI≥30.0 kg/m^2.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 01APR2021 (22:12)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA1/adsl_s005_demo_ped_reac_saf

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N^a=1131)	16-25 Years (N^a=537)	12-15 Years (N^a=1129)	16-25 Years (N^a=561)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Any medical history	848 (75.0)	373 (69.5)	826 (73.2)	381 (67.9)
Blood and lymphatic system disorders	2 (0.2)	7 (1.3)	8 (0.7)	7 (1.2)
Anaemia	0	5 (0.9)	1 (0.1)	5 (0.9)
Antiphospholipid syndrome	0	0	0	1 (0.2)
Immune thrombocytopenia	2 (0.2)	0	1 (0.1)	0
Iron deficiency anaemia	0	2 (0.4)	3 (0.3)	1 (0.2)
Lymphadenopathy	0	0	2 (0.2)	0
Thrombocytopenia	0	0	1 (0.1)	0
Cardiac disorders	5 (0.4)	6 (1.1)	3 (0.3)	6 (1.1)
Aortic valve disease	2 (0.2)	0	0	0
Arrhythmia	1 (0.1)	0	0	0
Bradycardia neonatal	0	0	0	1 (0.2)
Cardiomyopathy	0	0	0	1 (0.2)
Palpitations	0	1 (0.2)	0	2 (0.4)
Pericarditis	0	1 (0.2)	0	0
Postural orthostatic tachycardia syndrome	1 (0.1)	0	1 (0.1)	0
Pulmonary valve stenosis	1 (0.1)	0	0	0
Sinus arrhythmia	0	0	0	1 (0.2)
Sinus tachycardia	0	2 (0.4)	0	0
Supraventricular tachycardia	0	0	1 (0.1)	1 (0.2)
Tachycardia	0	1 (0.2)	0	0
Ventricular extrasystoles	0	0	1 (0.1)	0
Wolff-Parkinson-White syndrome	0	1 (0.2)	0	0
Congenital, familial and genetic disorders	28 (2.5)	17 (3.2)	44 (3.9)	10 (1.8)
Adenomatous polyposis coli	0	0	1 (0.1)	0
Albinism	0	1 (0.2)	0	0
Anal atresia	0	1 (0.2)	0	0
Ankyloglossia congenital	0	0	1 (0.1)	0
Anorectal malformation	0	0	1 (0.1)	0

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N^a=1131)	16-25 Years (N^a=537)	12-15 Years (N^a=1129)	16-25 Years (N^a=561)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Arnold-Chiari malformation	0	1 (0.2)	0	1 (0.2)
Atrial septal defect	1 (0.1)	0	2 (0.2)	0
Bicuspid aortic valve	2 (0.2)	0	2 (0.2)	0
Birth mark	0	0	2 (0.2)	0
Cataract congenital	0	1 (0.2)	0	0
Cerebral cavernous malformation	0	0	1 (0.1)	0
Cerebral palsy	0	0	1 (0.1)	0
Chondrodystrophy	1 (0.1)	0	0	0
Cleft lip and palate	1 (0.1)	0	0	0
Cleft palate	1 (0.1)	0	1 (0.1)	0
Colour blindness	1 (0.1)	1 (0.2)	0	0
Congenital anomaly	1 (0.1)	0	0	0
Congenital diaphragmatic hernia	1 (0.1)	0	0	0
Congenital flat feet	1 (0.1)	2 (0.4)	0	0
Congenital megacolon	0	0	1 (0.1)	0
Congenital nystagmus	2 (0.2)	0	0	0
Congenital skin dimples	0	0	1 (0.1)	0
Cryptorchism	1 (0.1)	0	0	0
Cystic fibrosis	0	0	2 (0.2)	0
Developmental hip dysplasia	0	0	1 (0.1)	2 (0.4)
Ehlers-Danlos syndrome	0	0	1 (0.1)	1 (0.2)
Factor V Leiden carrier	1 (0.1)	0	1 (0.1)	0
Factor V Leiden mutation	0	0	1 (0.1)	1 (0.2)
Factor VII deficiency	0	0	0	1 (0.2)
Fallot's tetralogy	0	1 (0.2)	0	0
Familial mediterranean fever	0	1 (0.2)	0	0
Femoral anteversion	0	1 (0.2)	0	0
Gilbert's syndrome	0	0	1 (0.1)	0
Haemoglobinopathy	0	1 (0.2)	0	0
Hemivertebra	0	0	1 (0.1)	0
Hereditary motor and sensory neuropathy	0	0	1 (0.1)	0
Hereditary spherocytosis	0	0	1 (0.1)	0
Hypoplastic left heart syndrome	0	0	1 (0.1)	0
Hypospadias	0	1 (0.2)	1 (0.1)	1 (0.2)

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131)	16-25 Years (N[a]=537)	12-15 Years (N[a]=1129)	16-25 Years (N[a]=561)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Imperforate hymen	0	0	1 (0.1)	0
Malformation venous	1 (0.1)	0	0	0
Metabolic myopathy	1 (0.1)	0	0	0
Multiple epiphyseal dysplasia	0	0	1 (0.1)	0
Muscular dystrophy	0	1 (0.2)	0	0
Naevus flammeus	0	0	1 (0.1)	0
Neurofibromatosis	0	0	2 (0.2)	1 (0.2)
Oculoauriculovertebral dysplasia	0	0	1 (0.1)	0
Otospondylomegaepiphyseal dysplasia	1 (0.1)	0	0	0
Pectus carinatum	0	0	1 (0.1)	0
Pectus excavatum	2 (0.2)	0	1 (0.1)	0
Phimosis	1 (0.1)	1 (0.2)	1 (0.1)	1 (0.2)
Renal dysplasia	0	0	1 (0.1)	0
Sickle cell anaemia	1 (0.1)	0	0	0
Sickle cell trait	0	0	3 (0.3)	0
Spina bifida occulta	1 (0.1)	0	0	0
Strabismus congenital	1 (0.1)	0	0	0
Talipes	1 (0.1)	0	0	0
Thalassaemia beta	2 (0.2)	0	0	0
Thalassaemia minor	0	0	1 (0.1)	0
Thyroglossal cyst	1 (0.1)	0	0	0
Tourette's disorder	2 (0.2)	2 (0.4)	2 (0.2)	0
Transposition of the great vessels	0	0	1 (0.1)	0
Urethral valves	0	1 (0.2)	0	0
Ventricular septal defect	0	1 (0.2)	1 (0.1)	0
Vitello-intestinal duct remnant	0	0	0	1 (0.2)
Von Willebrand's disease	1 (0.1)	0	2 (0.2)	0
Ear and labyrinth disorders	11 (1.0)	4 (0.7)	10 (0.9)	1 (0.2)
Auditory disorder	1 (0.1)	0	0	0
Deafness	2 (0.2)	1 (0.2)	0	0
Deafness bilateral	1 (0.1)	0	0	1 (0.2)
Deafness unilateral	1 (0.1)	0	1 (0.1)	0
Ear pain	0	0	1 (0.1)	0

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131)	16-25 Years (N[a]=537)	12-15 Years (N[a]=1129)	16-25 Years (N[a]=561)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Eustachian tube disorder	1 (0.1)	0	0	0
Eustachian tube dysfunction	2 (0.2)	0	0	0
Hypoacusis	1 (0.1)	1 (0.2)	2 (0.2)	0
Meniere's disease	0	1 (0.2)	0	0
Middle ear adhesions	0	0	1 (0.1)	0
Motion sickness	0	1 (0.2)	1 (0.1)	0
Tinnitus	1 (0.1)	0	2 (0.2)	0
Tympanic membrane perforation	1 (0.1)	0	1 (0.1)	0
Vestibular disorder	0	0	1 (0.1)	0
Endocrine disorders	7 (0.6)	7 (1.3)	7 (0.6)	14 (2.5)
Autoimmune thyroiditis	0	1 (0.2)	1 (0.1)	1 (0.2)
Growth hormone deficiency	1 (0.1)	0	3 (0.3)	2 (0.4)
Hyperprolactinaemia	0	0	0	1 (0.2)
Hyperthyroidism	0	1 (0.2)	0	1 (0.2)
Hypopituitarism	1 (0.1)	0	0	0
Hypothyroidism	3 (0.3)	4 (0.7)	1 (0.1)	10 (1.8)
Precocious puberty	2 (0.2)	0	2 (0.2)	0
Thyroid mass	0	1 (0.2)	0	0
Eye disorders	46 (4.1)	28 (5.2)	59 (5.2)	33 (5.9)
Amblyopia	1 (0.1)	0	2 (0.2)	0
Amblyopia strabismic	1 (0.1)	0	0	0
Anisometropia	1 (0.1)	0	0	0
Astigmatism	1 (0.1)	1 (0.2)	6 (0.5)	3 (0.5)
Blepharitis	2 (0.2)	0	0	0
Blindness	0	1 (0.2)	0	0
Blindness unilateral	0	0	1 (0.1)	0
Borderline glaucoma	0	0	0	1 (0.2)
Cataract	1 (0.1)	0	0	0
Chalazion	0	0	1 (0.1)	0
Conjunctivitis allergic	1 (0.1)	0	0	0
Dacryostenosis acquired	0	0	1 (0.1)	0
Dry eye	0	1 (0.2)	0	0

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N^a=1131)	16-25 Years (N^a=537)	12-15 Years (N^a=1129)	16-25 Years (N^a=561)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Eyelid ptosis	1 (0.1)	0	0	1 (0.2)
Hypermetropia	5 (0.4)	4 (0.7)	7 (0.6)	4 (0.7)
Iridodialysis	0	0	0	1 (0.2)
Iritis	0	0	0	1 (0.2)
Myopia	20 (1.8)	17 (3.2)	27 (2.4)	20 (3.6)
Optic atrophy	0	0	1 (0.1)	0
Optic nerve cupping	0	0	1 (0.1)	0
Presbyopia	1 (0.1)	2 (0.4)	0	1 (0.2)
Punctate keratitis	1 (0.1)	0	0	0
Pupils unequal	0	0	1 (0.1)	0
Recession of chamber angle of eye	0	0	1 (0.1)	0
Refraction disorder	0	0	0	2 (0.4)
Refractive amblyopia	0	0	1 (0.1)	0
Retinoschisis	0	0	0	1 (0.2)
Strabismus	4 (0.4)	2 (0.4)	4 (0.4)	0
Visual acuity reduced	8 (0.7)	1 (0.2)	12 (1.1)	2 (0.4)
Gastrointestinal disorders	42 (3.7)	41 (7.6)	40 (3.5)	36 (6.4)
Abdominal hernia	1 (0.1)	1 (0.2)	0	0
Abdominal migraine	2 (0.2)	1 (0.2)	1 (0.1)	1 (0.2)
Abdominal pain	1 (0.1)	0	2 (0.2)	0
Abdominal pain lower	0	1 (0.2)	0	0
Abdominal pain upper	1 (0.1)	2 (0.4)	1 (0.1)	0
Aphthous ulcer	0	1 (0.2)	0	0
Chronic gastritis	0	1 (0.2)	0	0
Coeliac disease	4 (0.4)	1 (0.2)	4 (0.4)	1 (0.2)
Colitis ulcerative	0	1 (0.2)	0	1 (0.2)
Constipation	9 (0.8)	3 (0.6)	11 (1.0)	2 (0.4)
Crohn's disease	0	0	0	1 (0.2)
Cyclic vomiting syndrome	1 (0.1)	0	0	0
Diaphragmatic hernia	0	2 (0.4)	0	0
Diarrhoea	1 (0.1)	0	2 (0.2)	1 (0.2)
Dyspepsia	3 (0.3)	3 (0.6)	0	4 (0.7)
Dysphagia	0	0	1 (0.1)	0

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131)	16-25 Years (N[a]=537)	12-15 Years (N[a]=1129)	16-25 Years (N[a]=561)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Enterocolitis	1 (0.1)	0	0	0
Eosinophilic oesophagitis	1 (0.1)	0	3 (0.3)	1 (0.2)
Flatulence	0	0	0	1 (0.2)
Food poisoning	0	0	0	1 (0.2)
Gastritis	0	1 (0.2)	0	0
Gastrooesophageal reflux disease	12 (1.1)	15 (2.8)	13 (1.2)	10 (1.8)
Gingival discomfort	0	0	0	1 (0.2)
Haemorrhoids	0	1 (0.2)	0	0
Hiatus hernia	0	1 (0.2)	1 (0.1)	0
Inguinal hernia	1 (0.1)	0	1 (0.1)	2 (0.4)
Intussusception	2 (0.2)	0	0	0
Irritable bowel syndrome	2 (0.2)	5 (0.9)	2 (0.2)	5 (0.9)
Malabsorption	1 (0.1)	0	0	0
Oesophagitis	1 (0.1)	0	0	1 (0.2)
Pancreatitis	0	0	0	1 (0.2)
Rectal prolapse	0	0	0	1 (0.2)
Salivary gland disorder	0	0	0	1 (0.2)
Short-bowel syndrome	0	1 (0.2)	0	0
Tooth impacted	0	2 (0.4)	0	3 (0.5)
Toothache	0	0	1 (0.1)	1 (0.2)
Umbilical hernia	2 (0.2)	2 (0.4)	3 (0.3)	1 (0.2)
Volvulus	0	1 (0.2)	0	0
General disorders and administration site conditions	10 (0.9)	5 (0.9)	10 (0.9)	3 (0.5)
Adverse food reaction	1 (0.1)	0	0	0
Cyst	1 (0.1)	0	1 (0.1)	1 (0.2)
Developmental delay	0	0	2 (0.2)	0
Drug intolerance	1 (0.1)	1 (0.2)	2 (0.2)	0
Fatigue	0	0	0	1 (0.2)
Hernia	0	1 (0.2)	0	0
Medical device pain	1 (0.1)	0	1 (0.1)	0
Pain	5 (0.4)	1 (0.2)	3 (0.3)	1 (0.2)
Peripheral swelling	1 (0.1)	1 (0.2)	0	0
Pyrexia	0	1 (0.2)	1 (0.1)	0

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N^a=1131)	16-25 Years (N^a=537)	12-15 Years (N^a=1129)	16-25 Years (N^a=561)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Hepatobiliary disorders	4 (0.4)	1 (0.2)	0	5 (0.9)
Cholelithiasis	2 (0.2)	0	0	4 (0.7)
Cholelithiasis obstructive	0	1 (0.2)	0	0
Hepatic steatosis	1 (0.1)	0	0	1 (0.2)
Non-alcoholic steatohepatitis	1 (0.1)	0	0	0
Immune system disorders	398 (35.2)	137 (25.5)	386 (34.2)	139 (24.8)
Allergy to animal	24 (2.1)	4 (0.7)	19 (1.7)	6 (1.1)
Allergy to arthropod bite	1 (0.1)	0	2 (0.2)	0
Allergy to arthropod sting	2 (0.2)	1 (0.2)	4 (0.4)	1 (0.2)
Allergy to chemicals	1 (0.1)	0	0	1 (0.2)
Allergy to metals	0	0	2 (0.2)	0
Allergy to plants	4 (0.4)	0	2 (0.2)	0
Anaphylactic reaction	1 (0.1)	0	0	0
Cockroach allergy	1 (0.1)	0	1 (0.1)	0
Drug hypersensitivity	129 (11.4)	37 (6.9)	97 (8.6)	47 (8.4)
Dust allergy	0	0	0	2 (0.4)
Flour sensitivity	0	0	0	1 (0.2)
Food allergy	31 (2.7)	15 (2.8)	39 (3.5)	11 (2.0)
Hypersensitivity	22 (1.9)	7 (1.3)	15 (1.3)	6 (1.1)
Milk allergy	3 (0.3)	0	5 (0.4)	1 (0.2)
Mite allergy	1 (0.1)	1 (0.2)	4 (0.4)	0
Multiple allergies	0	0	1 (0.1)	0
Mycotic allergy	0	0	1 (0.1)	0
Oral allergy syndrome	0	0	4 (0.4)	0
Perennial allergy	2 (0.2)	0	3 (0.3)	0
Perfume sensitivity	1 (0.1)	0	0	0
Reaction to colouring	1 (0.1)	0	0	1 (0.2)
Reaction to food additive	0	0	1 (0.1)	0
Rubber sensitivity	6 (0.5)	1 (0.2)	5 (0.4)	3 (0.5)
Seasonal allergy	240 (21.2)	90 (16.8)	244 (21.6)	83 (14.8)
Selective IgA immunodeficiency	0	0	1 (0.1)	0
Serum sickness	1 (0.1)	0	0	0

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N^a=1131)	16-25 Years (N^a=537)	12-15 Years (N^a=1129)	16-25 Years (N^a=561)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Infections and infestations	72 (6.4)	39 (7.3)	52 (4.6)	36 (6.4)
Abscess limb	0	0	1 (0.1)	0
Adenoiditis	11 (1.0)	0	6 (0.5)	1 (0.2)
Appendicitis	6 (0.5)	4 (0.7)	9 (0.8)	1 (0.2)
Bacterial vaginosis	0	0	0	1 (0.2)
Bacterial vulvovaginitis	0	1 (0.2)	0	0
Body tinea	1 (0.1)	0	0	0
Cellulitis	1 (0.1)	1 (0.2)	0	1 (0.2)
Chlamydial infection	0	1 (0.2)	0	1 (0.2)
Cholecystitis infective	0	0	0	1 (0.2)
Chronic sinusitis	2 (0.2)	2 (0.4)	1 (0.1)	0
Chronic tonsillitis	2 (0.2)	1 (0.2)	3 (0.3)	0
Conjunctivitis	1 (0.1)	0	1 (0.1)	0
Croup infectious	1 (0.1)	0	1 (0.1)	0
Dermatophytosis of nail	1 (0.1)	0	0	0
Ear infection	12 (1.1)	3 (0.6)	8 (0.7)	3 (0.5)
Escherichia infection	0	0	0	1 (0.2)
Folliculitis	0	1 (0.2)	0	2 (0.4)
Gastrointestinal viral infection	1 (0.1)	0	0	0
Genital herpes	0	0	0	1 (0.2)
Gingivitis	0	0	0	1 (0.2)
Herpes simplex	1 (0.1)	2 (0.4)	0	2 (0.4)
Herpes virus infection	0	1 (0.2)	0	0
Histoplasmosis	1 (0.1)	0	0	0
Impetigo	1 (0.1)	0	0	0
Infectious mononucleosis	0	1 (0.2)	1 (0.1)	1 (0.2)
Kidney infection	1 (0.1)	0	0	1 (0.2)
Labyrinthitis	0	1 (0.2)	0	0
Lyme disease	2 (0.2)	1 (0.2)	0	0
Mastitis	0	0	0	1 (0.2)
Mastoiditis	0	0	0	1 (0.2)
Meningitis	1 (0.1)	0	0	0
Meningitis viral	1 (0.1)	0	0	0

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131)	16-25 Years (N[a]=537)	12-15 Years (N[a]=1129)	16-25 Years (N[a]=561)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Molluscum contagiosum	0	0	1 (0.1)	0
Nail infection	1 (0.1)	0	0	0
Oral herpes	1 (0.1)	3 (0.6)	0	3 (0.5)
Osteomyelitis	2 (0.2)	0	0	0
Otitis externa	0	0	0	1 (0.2)
Otitis media	3 (0.3)	0	1 (0.1)	0
Otitis media acute	1 (0.1)	0	0	0
Otitis media chronic	1 (0.1)	1 (0.2)	2 (0.2)	0
Papilloma viral infection	0	1 (0.2)	0	0
Paronychia	1 (0.1)	0	0	1 (0.2)
Pharyngeal abscess	0	0	1 (0.1)	0
Pharyngitis	2 (0.2)	1 (0.2)	0	1 (0.2)
Pharyngitis streptococcal	1 (0.1)	0	3 (0.3)	0
Pneumonia	6 (0.5)	3 (0.6)	4 (0.4)	0
Pneumonia viral	0	1 (0.2)	0	0
Pulmonary tuberculosis	0	0	0	1 (0.2)
Respiratory syncytial virus bronchiolitis	0	0	1 (0.1)	0
Respiratory syncytial virus infection	1 (0.1)	1 (0.2)	0	0
Rhinitis	1 (0.1)	0	1 (0.1)	0
Rotavirus infection	0	0	1 (0.1)	0
Scarlet fever	1 (0.1)	0	1 (0.1)	0
Sinusitis	4 (0.4)	0	1 (0.1)	1 (0.2)
Staphylococcal scalded skin syndrome	1 (0.1)	0	0	0
Tinea infection	0	0	1 (0.1)	0
Tinea pedis	0	1 (0.2)	0	0
Tinea versicolour	0	0	0	1 (0.2)
Tonsillitis	11 (1.0)	7 (1.3)	8 (0.7)	6 (1.1)
Urinary tract infection	0	2 (0.4)	2 (0.2)	4 (0.7)
Viral infection	1 (0.1)	0	0	0
Vulvovaginal mycotic infection	1 (0.1)	0	0	0
Injury, poisoning and procedural complications	58 (5.1)	37 (6.9)	47 (4.2)	26 (4.6)
Ankle fracture	5 (0.4)	3 (0.6)	1 (0.1)	0
Back injury	0	0	0	1 (0.2)

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131)	16-25 Years (N[a]=537)	12-15 Years (N[a]=1129)	16-25 Years (N[a]=561)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Cartilage injury	0	1 (0.2)	0	0
Cataract traumatic	0	0	0	1 (0.2)
Chest injury	1 (0.1)	0	0	0
Chillblains	1 (0.1)	0	0	0
Clavicle fracture	2 (0.2)	2 (0.4)	3 (0.3)	3 (0.5)
Concussion	5 (0.4)	5 (0.9)	3 (0.3)	2 (0.4)
Contusion	1 (0.1)	0	0	0
Epicondylitis	0	1 (0.2)	0	0
Epiphyseal fracture	1 (0.1)	0	0	1 (0.2)
Exposure to communicable disease	0	1 (0.2)	0	0
Eye injury	0	0	0	1 (0.2)
Facial bones fracture	1 (0.1)	0	2 (0.2)	1 (0.2)
Fall	1 (0.1)	0	0	0
Femur fracture	0	1 (0.2)	1 (0.1)	0
Fibula fracture	1 (0.1)	1 (0.2)	0	1 (0.2)
Foot fracture	8 (0.7)	4 (0.7)	3 (0.3)	1 (0.2)
Forearm fracture	0	0	0	1 (0.2)
Foreign body in ear	0	0	1 (0.1)	0
Hand fracture	8 (0.7)	4 (0.7)	5 (0.4)	1 (0.2)
Hip fracture	0	0	0	1 (0.2)
Humerus fracture	0	0	1 (0.1)	1 (0.2)
Hyphaema	0	0	0	1 (0.2)
Injury to brachial plexus due to birth trauma	0	0	0	1 (0.2)
Jaw fracture	0	0	1 (0.1)	0
Joint dislocation	0	3 (0.6)	1 (0.1)	1 (0.2)
Joint injury	0	0	2 (0.2)	1 (0.2)
Ligament injury	1 (0.1)	0	0	0
Ligament rupture	1 (0.1)	2 (0.4)	0	1 (0.2)
Ligament sprain	0	2 (0.4)	2 (0.2)	0
Limb fracture	2 (0.2)	0	0	0
Limb injury	1 (0.1)	2 (0.4)	0	1 (0.2)
Limb traumatic amputation	0	1 (0.2)	0	0
Lower limb fracture	1 (0.1)	0	1 (0.1)	0
Meniscus injury	2 (0.2)	1 (0.2)	0	0

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N^a=1131)	16-25 Years (N^a=537)	12-15 Years (N^a=1129)	16-25 Years (N^a=561)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Muscle injury	0	1 (0.2)	0	0
Muscle strain	4 (0.4)	0	1 (0.1)	1 (0.2)
Nasal injury	0	0	1 (0.1)	0
Pelvic fracture	0	1 (0.2)	0	0
Post concussion syndrome	0	0	1 (0.1)	0
Radius fracture	5 (0.4)	2 (0.4)	1 (0.1)	1 (0.2)
Rib fracture	0	0	0	1 (0.2)
Scar	0	1 (0.2)	0	0
Skeletal injury	0	0	0	2 (0.4)
Skin laceration	0	0	1 (0.1)	0
Stress fracture	1 (0.1)	0	2 (0.2)	2 (0.4)
Tibia fracture	3 (0.3)	1 (0.2)	5 (0.4)	0
Torus fracture	0	0	2 (0.2)	0
Traumatic arthritis	0	1 (0.2)	0	0
Ulna fracture	0	1 (0.2)	0	1 (0.2)
Upper limb fracture	12 (1.1)	2 (0.4)	11 (1.0)	4 (0.7)
VIIth nerve injury	1 (0.1)	0	0	0
Wrist fracture	10 (0.9)	3 (0.6)	6 (0.5)	2 (0.4)
Investigations	14 (1.2)	7 (1.3)	8 (0.7)	14 (2.5)
Arthroscopy	0	1 (0.2)	0	2 (0.4)
Biopsy liver	0	0	0	1 (0.2)
Blood cholesterol increased	0	1 (0.2)	0	0
Blood pressure increased	1 (0.1)	0	2 (0.2)	0
Body height decreased	1 (0.1)	0	0	0
Body mass index increased	0	0	0	1 (0.2)
Bronchoscopy	0	0	0	1 (0.2)
Cardiac murmur	9 (0.8)	1 (0.2)	4 (0.4)	1 (0.2)
Cardiac murmur functional	0	0	0	1 (0.2)
Endoscopy	1 (0.1)	1 (0.2)	0	0
Endoscopy upper gastrointestinal tract	0	0	1 (0.1)	0
HIV test positive	0	1 (0.2)	0	0
Heart rate increased	0	0	0	1 (0.2)
Heart rate irregular	0	1 (0.2)	0	1 (0.2)

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N^a=1131)	16-25 Years (N^a=537)	12-15 Years (N^a=1129)	16-25 Years (N^a=561)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Human papilloma virus test positive	0	1 (0.2)	0	1 (0.2)
Menstruation normal	1 (0.1)	0	1 (0.1)	0
Progesterone decreased	0	0	0	1 (0.2)
Serum ferritin decreased	1 (0.1)	0	0	0
Thyroid function test abnormal	0	0	0	1 (0.2)
Vitamin D decreased	0	0	0	2 (0.4)
Weight decreased	1 (0.1)	0	0	0
Metabolism and nutrition disorders	39 (3.4)	31 (5.8)	51 (4.5)	30 (5.3)
Calcium deficiency	0	0	1 (0.1)	0
Dairy intolerance	1 (0.1)	0	1 (0.1)	0
Decreased appetite	2 (0.2)	0	1 (0.1)	0
Dehydration	1 (0.1)	0	0	0
Dyslipidaemia	1 (0.1)	0	2 (0.2)	0
Food intolerance	2 (0.2)	0	2 (0.2)	0
Fructose intolerance	1 (0.1)	0	1 (0.1)	0
Glucose tolerance impaired	1 (0.1)	0	0	1 (0.2)
Gluten sensitivity	0	3 (0.6)	2 (0.2)	1 (0.2)
Hypercholesterolaemia	0	2 (0.4)	0	1 (0.2)
Hyperglycaemia	1 (0.1)	0	0	0
Hyperlipidaemia	4 (0.4)	1 (0.2)	0	0
Hypertriglyceridaemia	1 (0.1)	0	1 (0.1)	0
Hypoglycaemia	0	0	0	1 (0.2)
Insulin resistance	0	1 (0.2)	0	0
Iron deficiency	0	1 (0.2)	2 (0.2)	2 (0.4)
Lactose intolerance	5 (0.4)	5 (0.9)	7 (0.6)	2 (0.4)
Obesity	15 (1.3)	12 (2.2)	20 (1.8)	18 (3.2)
Overweight	1 (0.1)	1 (0.2)	4 (0.4)	0
Type 1 diabetes mellitus	2 (0.2)	1 (0.2)	5 (0.4)	2 (0.4)
Type 2 diabetes mellitus	0	2 (0.4)	0	1 (0.2)
Underweight	1 (0.1)	1 (0.2)	0	1 (0.2)
Vitamin D deficiency	4 (0.4)	2 (0.4)	6 (0.5)	1 (0.2)
Musculoskeletal and connective tissue disorders	55 (4.9)	29 (5.4)	48 (4.3)	19 (3.4)

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N^a=1131)	16-25 Years (N^a=537)	12-15 Years (N^a=1129)	16-25 Years (N^a=561)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Arthralgia	12 (1.1)	3 (0.6)	8 (0.7)	5 (0.9)
Back pain	1 (0.1)	4 (0.7)	1 (0.1)	2 (0.4)
Deformity thorax	0	1 (0.2)	0	0
Discoid meniscus	0	0	1 (0.1)	0
Exostosis	1 (0.1)	1 (0.2)	0	0
Fibromyalgia	0	0	0	1 (0.2)
Foot deformity	2 (0.2)	3 (0.6)	2 (0.2)	0
Growing pains	1 (0.1)	0	0	0
Growth retardation	1 (0.1)	0	0	0
Hypermobility syndrome	0	0	1 (0.1)	0
Intervertebral disc protrusion	0	3 (0.6)	0	0
Juvenile idiopathic arthritis	0	0	1 (0.1)	0
Knee deformity	2 (0.2)	0	0	0
Kyphosis	1 (0.1)	0	1 (0.1)	0
Lordosis	1 (0.1)	0	0	0
Muscle tightness	0	1 (0.2)	0	0
Myalgia	1 (0.1)	0	5 (0.4)	2 (0.4)
Neck pain	0	1 (0.2)	0	0
Osteitis	1 (0.1)	0	1 (0.1)	0
Osteochondrosis	3 (0.3)	2 (0.4)	4 (0.4)	1 (0.2)
Pain in extremity	2 (0.2)	0	3 (0.3)	1 (0.2)
Pain in jaw	1 (0.1)	0	0	0
Patellofemoral pain syndrome	0	2 (0.4)	2 (0.2)	0
Plantar fascial fibromatosis	0	0	1 (0.1)	0
Plantar fasciitis	0	0	0	1 (0.2)
Rotator cuff syndrome	1 (0.1)	0	0	0
Scapular dyskinesis	0	1 (0.2)	0	0
Scoliosis	21 (1.9)	5 (0.9)	12 (1.1)	4 (0.7)
Short stature	6 (0.5)	0	2 (0.2)	0
Shoulder deformity	0	0	1 (0.1)	0
Spinal osteoarthritis	0	1 (0.2)	0	0
Spondylolisthesis	0	1 (0.2)	0	0
Spondylolysis	0	1 (0.2)	0	0
Synovial cyst	0	1 (0.2)	1 (0.1)	0

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131)	16-25 Years (N[a]=537)	12-15 Years (N[a]=1129)	16-25 Years (N[a]=561)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Temporomandibular joint syndrome	2 (0.2)	0	1 (0.1)	2 (0.4)
Tendon disorder	0	0	1 (0.1)	0
Tendonitis	1 (0.1)	0	3 (0.3)	0
Toe walking	1 (0.1)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9 (0.8)	4 (0.7)	14 (1.2)	7 (1.2)
Benign ear neoplasm	1 (0.1)	0	0	0
Benign neoplasm of skin	0	1 (0.2)	0	1 (0.2)
Cholesteatoma	0	0	1 (0.1)	1 (0.2)
Colon adenoma	0	0	0	1 (0.2)
Eyelid haemangioma	1 (0.1)	0	0	0
Fibroadenoma of breast	0	1 (0.2)	1 (0.1)	0
Fibroma	0	0	1 (0.1)	0
Haemangioma	1 (0.1)	0	0	0
Lipoma	0	0	1 (0.1)	0
Melanocytic naevus	1 (0.1)	0	3 (0.3)	2 (0.4)
Nephroblastoma	0	0	1 (0.1)	0
Ovarian neoplasm	0	0	0	1 (0.2)
Pituitary tumour benign	0	1 (0.2)	0	0
Skin papilloma	5 (0.4)	1 (0.2)	6 (0.5)	1 (0.2)
Nervous system disorders	94 (8.3)	58 (10.8)	67 (5.9)	58 (10.3)
Apraxia	1 (0.1)	0	0	0
Arachnoid cyst	1 (0.1)	0	0	0
Benign rolandic epilepsy	1 (0.1)	0	0	0
Central auditory processing disorder	0	1 (0.2)	0	0
Cluster headache	0	2 (0.4)	0	0
Convulsion in childhood	1 (0.1)	0	0	0
Disturbance in attention	4 (0.4)	0	0	0
Dizziness	2 (0.2)	1 (0.2)	0	0
Dysgraphia	0	0	2 (0.2)	0
Dyslexia	1 (0.1)	2 (0.4)	6 (0.5)	1 (0.2)
Epilepsy	4 (0.4)	0	1 (0.1)	1 (0.2)
Essential tremor	0	1 (0.2)	0	0

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131)	16-25 Years (N[a]=537)	12-15 Years (N[a]=1129)	16-25 Years (N[a]=561)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Facial paralysis	0	0	0	1 (0.2)
Febrile convulsion	3 (0.3)	1 (0.2)	0	0
Headache	38 (3.4)	19 (3.5)	29 (2.6)	24 (4.3)
Hydrocephalus	0	0	1 (0.1)	0
Hypersomnia	0	0	0	1 (0.2)
Idiopathic intracranial hypertension	0	0	1 (0.1)	1 (0.2)
Mental impairment	2 (0.2)	0	0	0
Migraine	30 (2.7)	30 (5.6)	25 (2.2)	20 (3.6)
Migraine with aura	2 (0.2)	1 (0.2)	2 (0.2)	0
Migraine without aura	0	1 (0.2)	2 (0.2)	0
Narcolepsy	0	1 (0.2)	0	1 (0.2)
Neuropathy peripheral	0	0	0	2 (0.4)
Nystagmus	1 (0.1)	1 (0.2)	0	0
Paroxysmal choreoathetosis	0	0	0	1 (0.2)
Petit mal epilepsy	0	0	0	1 (0.2)
Restless legs syndrome	0	0	0	1 (0.2)
Retinal migraine	1 (0.1)	0	0	0
Seizure	1 (0.1)	0	1 (0.1)	0
Sensory disturbance	0	0	1 (0.1)	0
Sensory processing disorder	1 (0.1)	0	1 (0.1)	0
Speech disorder	2 (0.2)	0	0	0
Syncope	1 (0.1)	0	1 (0.1)	0
Tension headache	1 (0.1)	7 (1.3)	0	3 (0.5)
Tethered cord syndrome	1 (0.1)	0	0	0
Tremor	0	1 (0.2)	0	1 (0.2)
Pregnancy, puerperium and perinatal conditions	2 (0.2)	3 (0.6)	1 (0.1)	2 (0.4)
Delivery	0	2 (0.4)	0	1 (0.2)
Premature baby	2 (0.2)	1 (0.2)	1 (0.1)	1 (0.2)
Product issues	0	0	1 (0.1)	0
Device breakage	0	0	1 (0.1)	0
Psychiatric disorders	290 (25.6)	119 (22.2)	281 (24.9)	130 (23.2)

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131)	16-25 Years (N[a]=537)	12-15 Years (N[a]=1129)	16-25 Years (N[a]=561)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Adjustment disorder	0	0	0	2 (0.4)
Adjustment disorder with depressed mood	1 (0.1)	1 (0.2)	1 (0.1)	0
Adjustment disorder with mixed anxiety and depressed mood	0	1 (0.2)	1 (0.1)	0
Affective disorder	0	1 (0.2)	0	0
Aggression	1 (0.1)	0	1 (0.1)	0
Anger	0	0	1 (0.1)	1 (0.2)
Anxiety	104 (9.2)	52 (9.7)	93 (8.2)	49 (8.7)
Anxiety disorder	4 (0.4)	3 (0.6)	3 (0.3)	6 (1.1)
Attention deficit hyperactivity disorder	182 (16.1)	39 (7.3)	165 (14.6)	53 (9.4)
Autism spectrum disorder	10 (0.9)	4 (0.7)	10 (0.9)	4 (0.7)
Behaviour disorder	2 (0.2)	0	1 (0.1)	0
Bipolar disorder	2 (0.2)	5 (0.9)	0	3 (0.5)
Bulimia nervosa	0	0	0	2 (0.4)
Childhood depression	1 (0.1)	0	0	0
Chronic tic disorder	0	0	2 (0.2)	0
Depression	49 (4.3)	48 (8.9)	45 (4.0)	43 (7.7)
Depressive symptom	0	0	1 (0.1)	0
Disruptive mood dysregulation disorder	3 (0.3)	0	2 (0.2)	0
Eating disorder	1 (0.1)	0	2 (0.2)	0
Encopresis	0	1 (0.2)	0	0
Enuresis	3 (0.3)	0	2 (0.2)	0
Gender dysphoria	2 (0.2)	0	0	0
Generalised anxiety disorder	8 (0.7)	9 (1.7)	14 (1.2)	5 (0.9)
Hallucination, auditory	1 (0.1)	0	0	0
Impulse-control disorder	2 (0.2)	0	0	0
Impulsive behaviour	0	0	1 (0.1)	0
Insomnia	27 (2.4)	14 (2.6)	28 (2.5)	11 (2.0)
Irritability	0	0	0	1 (0.2)
Learning disorder	0	0	1 (0.1)	0
Major depression	4 (0.4)	2 (0.4)	5 (0.4)	3 (0.5)
Mental disorder	0	1 (0.2)	0	0
Neurodevelopmental disorder	1 (0.1)	0	0	0
Nightmare	1 (0.1)	0	0	0
Obsessive-compulsive disorder	5 (0.4)	4 (0.7)	8 (0.7)	2 (0.4)

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131)	16-25 Years (N[a]=537)	12-15 Years (N[a]=1129)	16-25 Years (N[a]=561)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Oppositional defiant disorder	2 (0.2)	0	3 (0.3)	0
Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection	0	0	1 (0.1)	0
Panic attack	0	0	0	2 (0.4)
Panic disorder	0	2 (0.4)	0	1 (0.2)
Persistent depressive disorder	1 (0.1)	0	0	1 (0.2)
Post-traumatic stress disorder	4 (0.4)	1 (0.2)	5 (0.4)	0
Reactive attachment disorder of infancy or early childhood	0	0	1 (0.1)	0
Reading disorder	0	0	1 (0.1)	0
Selective eating disorder	0	1 (0.2)	0	0
Separation anxiety disorder	1 (0.1)	0	0	0
Sleep disorder	0	1 (0.2)	3 (0.3)	0
Social anxiety disorder	0	0	1 (0.1)	1 (0.2)
Speech sound disorder	1 (0.1)	0	0	0
Suicidal ideation	1 (0.1)	1 (0.2)	1 (0.1)	1 (0.2)
Tic	3 (0.3)	2 (0.4)	2 (0.2)	1 (0.2)
Renal and urinary disorders	5 (0.4)	5 (0.9)	6 (0.5)	2 (0.4)
Dysuria	0	0	1 (0.1)	0
Haematuria	1 (0.1)	0	1 (0.1)	0
Hydronephrosis	1 (0.1)	1 (0.2)	0	0
Hypertonic bladder	0	2 (0.4)	0	0
Nephrolithiasis	1 (0.1)	1 (0.2)	0	2 (0.4)
Nephrotic syndrome	0	1 (0.2)	0	0
Renal cyst	0	0	1 (0.1)	0
Renal disorder	1 (0.1)	0	0	0
Single functional kidney	0	0	1 (0.1)	0
Urinary retention	0	0	1 (0.1)	0
Urinary tract disorder	1 (0.1)	0	0	0
Vesicoureteric reflux	1 (0.1)	0	1 (0.1)	0
Reproductive system and breast disorders	32 (2.8)	33 (6.1)	35 (3.1)	27 (4.8)
Amenorrhoea	0	1 (0.2)	0	0
Breast cyst	1 (0.1)	1 (0.2)	0	0
Dysfunctional uterine bleeding	1 (0.1)	0	1 (0.1)	0

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131)	16-25 Years (N[a]=537)	12-15 Years (N[a]=1129)	16-25 Years (N[a]=561)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Dysmenorrhoea	11 (1.0)	17 (3.2)	15 (1.3)	12 (2.1)
Endometriosis	0	2 (0.4)	0	1 (0.2)
Epididymal cyst	1 (0.1)	1 (0.2)	0	0
Erectile dysfunction	0	0	0	1 (0.2)
Gynaecomastia	0	0	1 (0.1)	0
Menorrhagia	7 (0.6)	7 (1.3)	9 (0.8)	4 (0.7)
Menstrual disorder	0	0	0	1 (0.2)
Menstruation irregular	4 (0.4)	1 (0.2)	6 (0.5)	4 (0.7)
Metrorrhagia	0	0	1 (0.1)	0
Ovarian cyst	0	1 (0.2)	0	3 (0.5)
Ovulation disorder	1 (0.1)	0	0	0
Polycystic ovaries	3 (0.3)	4 (0.7)	1 (0.1)	3 (0.5)
Premenstrual dysphoric disorder	0	0	2 (0.2)	0
Testicular torsion	1 (0.1)	2 (0.4)	0	1 (0.2)
Uterine haemorrhage	1 (0.1)	0	0	0
Vaginal disorder	1 (0.1)	0	0	0
Varicocele	1 (0.1)	0	1 (0.1)	0
Respiratory, thoracic and mediastinal disorders	178 (15.7)	75 (14.0)	178 (15.8)	79 (14.1)
Adenoidal hypertrophy	1 (0.1)	1 (0.2)	0	0
Asthma	107 (9.5)	43 (8.0)	109 (9.7)	46 (8.2)
Asthma exercise induced	11 (1.0)	9 (1.7)	16 (1.4)	5 (0.9)
Bronchial hyperreactivity	6 (0.5)	1 (0.2)	4 (0.4)	0
Bronchitis chronic	0	0	1 (0.1)	0
Bronchospasm	0	1 (0.2)	1 (0.1)	2 (0.4)
Epistaxis	6 (0.5)	2 (0.4)	5 (0.4)	0
Infantile apnoea	0	0	0	1 (0.2)
Nasal inflammation	1 (0.1)	0	0	0
Nasal polyps	0	0	1 (0.1)	0
Nasal septum deviation	1 (0.1)	1 (0.2)	1 (0.1)	1 (0.2)
Nasal turbinate hypertrophy	3 (0.3)	0	0	0
Oropharyngeal pain	1 (0.1)	0	1 (0.1)	0
Pneumothorax spontaneous	0	1 (0.2)	0	0
Rhinitis allergic	41 (3.6)	22 (4.1)	46 (4.1)	25 (4.5)

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N^a=1131)	16-25 Years (N^a=537)	12-15 Years (N^a=1129)	16-25 Years (N^a=561)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Rhinitis perennial	1 (0.1)	0	0	0
Sinus congestion	0	1 (0.2)	0	1 (0.2)
Sinus disorder	0	1 (0.2)	0	0
Sleep apnoea syndrome	5 (0.4)	1 (0.2)	3 (0.3)	2 (0.4)
Snoring	2 (0.2)	0	0	1 (0.2)
Thoracic insufficiency syndrome	0	1 (0.2)	0	0
Tonsillar hypertrophy	2 (0.2)	0	1 (0.1)	1 (0.2)
Tonsillolith	1 (0.1)	0	0	0
Tracheomalacia	0	0	1 (0.1)	0
Vasomotor rhinitis	1 (0.1)	0	0	0
Vocal cord disorder	1 (0.1)	0	0	0
Vocal cord dysfunction	0	0	0	1 (0.2)
Vocal cord thickening	1 (0.1)	0	0	0
Wheezing	2 (0.2)	0	0	0
Skin and subcutaneous tissue disorders	169 (14.9)	70 (13.0)	180 (15.9)	73 (13.0)
Acanthosis nigricans	0	0	1 (0.1)	0
Acne	95 (8.4)	49 (9.1)	97 (8.6)	47 (8.4)
Acne cosmetica	1 (0.1)	0	0	0
Acne cystic	0	3 (0.6)	1 (0.1)	0
Actinic keratosis	1 (0.1)	0	1 (0.1)	0
Alopecia	1 (0.1)	1 (0.2)	0	2 (0.4)
Alopecia areata	1 (0.1)	0	0	0
Blister	1 (0.1)	0	0	0
Chronic spontaneous urticaria	0	0	0	1 (0.2)
Dermatitis	4 (0.4)	2 (0.4)	1 (0.1)	0
Dermatitis allergic	0	0	1 (0.1)	0
Dermatitis atopic	10 (0.9)	2 (0.4)	12 (1.1)	5 (0.9)
Dermatitis contact	5 (0.4)	1 (0.2)	4 (0.4)	1 (0.2)
Drug eruption	0	1 (0.2)	3 (0.3)	0
Dry skin	0	0	1 (0.1)	0
Dyshidrotic eczema	0	0	0	1 (0.2)
Eczema	35 (3.1)	6 (1.1)	44 (3.9)	15 (2.7)
Erythema annulare	0	1 (0.2)	0	0

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131)	16-25 Years (N[a]=537)	12-15 Years (N[a]=1129)	16-25 Years (N[a]=561)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Granuloma annulare	0	0	0	1 (0.2)
Hand dermatitis	8 (0.7)	0	2 (0.2)	0
Hidradenitis	0	1 (0.2)	0	0
Hirsutism	0	0	1 (0.1)	0
Hyperhidrosis	1 (0.1)	2 (0.4)	3 (0.3)	1 (0.2)
Hyperkeratosis	1 (0.1)	0	0	0
Idiopathic urticaria	2 (0.2)	0	0	0
Ingrowing nail	1 (0.1)	0	1 (0.1)	0
Keloid scar	0	1 (0.2)	0	0
Keratosis pilaris	1 (0.1)	1 (0.2)	2 (0.2)	0
Mechanical urticaria	0	0	0	1 (0.2)
Miliaria	1 (0.1)	0	0	0
Nail psoriasis	1 (0.1)	0	0	0
Pityriasis	0	1 (0.2)	0	0
Pityriasis alba	0	0	1 (0.1)	0
Pityriasis rosea	0	0	1 (0.1)	0
Psoriasis	6 (0.5)	1 (0.2)	7 (0.6)	3 (0.5)
Rash	0	1 (0.2)	2 (0.2)	0
Rosacea	1 (0.1)	0	1 (0.1)	0
Seborrhoea	1 (0.1)	0	0	0
Seborrhoeic dermatitis	0	2 (0.4)	0	0
Spider naevus	0	0	1 (0.1)	0
Urticaria	8 (0.7)	1 (0.2)	2 (0.2)	1 (0.2)
Vitiligo	0	0	2 (0.2)	0
Social circumstances	104 (9.2)	11 (2.0)	95 (8.4)	10 (1.8)
Alcohol use	0	1 (0.2)	0	0
Celibacy	0	0	0	1 (0.2)
Corrective lens user	8 (0.7)	5 (0.9)	10 (0.9)	6 (1.1)
Ex-tobacco user	0	1 (0.2)	0	0
Inadequate diet	0	0	0	1 (0.2)
Menarche	11 (1.0)	0	16 (1.4)	0
Premenarche	88 (7.8)	0	69 (6.1)	0
Substance use	0	2 (0.4)	0	0

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131)	16-25 Years (N[a]=537)	12-15 Years (N[a]=1129)	16-25 Years (N[a]=561)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Tobacco user	0	4 (0.7)	0	1 (0.2)
Vegan	1 (0.1)	0	0	1 (0.2)
Vegetarian	2 (0.2)	0	6 (0.5)	0
Woman of childbearing potential	0	0	1 (0.1)	0
Surgical and medical procedures	110 (9.7)	92 (17.1)	117 (10.4)	91 (16.2)
Abdominal hernia repair	1 (0.1)	1 (0.2)	0	0
Abscess drainage	0	0	2 (0.2)	0
Adenoidectomy	33 (2.9)	3 (0.6)	22 (1.9)	5 (0.9)
Adenotonsillectomy	1 (0.1)	1 (0.2)	2 (0.2)	0
Ankle arthroplasty	0	0	0	1 (0.2)
Ankle operation	0	1 (0.2)	1 (0.1)	1 (0.2)
Anorectal operation	0	0	1 (0.1)	0
Antibiotic therapy	0	1 (0.2)	0	0
Appendicectomy	9 (0.8)	8 (1.5)	10 (0.9)	2 (0.4)
Arterial switch operation	0	0	1 (0.1)	0
Atrial septal defect repair	1 (0.1)	0	1 (0.1)	0
Benign breast lump removal	0	1 (0.2)	0	0
Bone lesion excision	0	1 (0.2)	0	0
Bone operation	1 (0.1)	2 (0.4)	1 (0.1)	2 (0.4)
Brain operation	0	1 (0.2)	0	0
Breast operation	0	0	0	1 (0.2)
Caesarean section	0	1 (0.2)	0	2 (0.4)
Cardiac ablation	0	0	1 (0.1)	1 (0.2)
Cardiac operation	0	1 (0.2)	1 (0.1)	0
Cataract operation	0	0	1 (0.1)	0
Cautery to nose	1 (0.1)	0	1 (0.1)	0
Central venous catheterisation	1 (0.1)	0	0	0
Cerebral cyst excision	1 (0.1)	0	0	0
Cholecystectomy	1 (0.1)	3 (0.6)	0	5 (0.9)
Cholesteatoma removal	0	0	0	1 (0.2)
Chondroplasty	1 (0.1)	1 (0.2)	0	0
Circumcision	2 (0.2)	2 (0.4)	4 (0.4)	1 (0.2)
Cochlea implant	0	0	0	1 (0.2)

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131)	16-25 Years (N[a]=537)	12-15 Years (N[a]=1129)	16-25 Years (N[a]=561)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Colectomy	0	1 (0.2)	0	0
Colon operation	0	0	1 (0.1)	0
Contraception	0	0	0	1 (0.2)
Contraceptive implant	0	1 (0.2)	0	2 (0.4)
Dacryocystorhinostomy	0	0	1 (0.1)	0
Diverticulectomy	0	0	0	1 (0.2)
Ear operation	0	0	1 (0.1)	1 (0.2)
Ear tube insertion	12 (1.1)	3 (0.6)	10 (0.9)	4 (0.7)
Ear tube removal	1 (0.1)	0	1 (0.1)	0
Elbow operation	0	1 (0.2)	1 (0.1)	1 (0.2)
Enterostomy	0	1 (0.2)	0	0
Epiphyseal surgery	1 (0.1)	0	0	0
Epiphysiodesis	1 (0.1)	0	0	0
Eye operation	2 (0.2)	0	4 (0.4)	0
Facial lesion excision	1 (0.1)	0	1 (0.1)	0
Finger amputation	1 (0.1)	0	1 (0.1)	0
Foot operation	0	3 (0.6)	1 (0.1)	1 (0.2)
Fracture treatment	3 (0.3)	2 (0.4)	5 (0.4)	2 (0.4)
Gastrectomy	0	1 (0.2)	0	1 (0.2)
Gastric bypass	0	0	0	1 (0.2)
Gingival operation	0	0	0	1 (0.2)
Heart valve replacement	0	1 (0.2)	0	0
Hernia diaphragmatic repair	1 (0.1)	1 (0.2)	1 (0.1)	0
Hernia repair	2 (0.2)	1 (0.2)	0	3 (0.5)
Hip surgery	0	0	1 (0.1)	1 (0.2)
Hydrocele operation	1 (0.1)	0	0	0
Hymenectomy	1 (0.1)	0	0	0
Inguinal hernia repair	1 (0.1)	0	1 (0.1)	2 (0.4)
Intervertebral disc operation	0	1 (0.2)	0	0
Intestinal operation	1 (0.1)	0	0	0
Intestinal resection	0	1 (0.2)	0	0
Intra-uterine contraceptive device insertion	0	2 (0.4)	0	1 (0.2)
Intrauterine contraception	2 (0.2)	1 (0.2)	0	0
Jaw operation	1 (0.1)	0	0	0

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131)	16-25 Years (N[a]=537)	12-15 Years (N[a]=1129)	16-25 Years (N[a]=561)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Joint stabilisation	0	0	1 (0.1)	0
Knee operation	2 (0.2)	0	0	1 (0.2)
Lacrimal duct procedure	0	0	1 (0.1)	0
Ligament operation	1 (0.1)	4 (0.7)	0	1 (0.2)
Limb operation	2 (0.2)	1 (0.2)	1 (0.1)	1 (0.2)
Limb reconstructive surgery	0	0	1 (0.1)	0
Lipoma excision	0	0	1 (0.1)	0
Liposuction	0	0	1 (0.1)	0
Lung assist device therapy	0	1 (0.2)	0	0
Lymphadenectomy	0	0	1 (0.1)	0
Mammoplasty	0	0	0	1 (0.2)
Mass excision	1 (0.1)	0	0	0
Mastoidectomy	1 (0.1)	0	0	1 (0.2)
Medical device change	0	0	1 (0.1)	0
Medical device removal	0	1 (0.2)	0	0
Medical diet	1 (0.1)	0	0	0
Meniscus operation	1 (0.1)	1 (0.2)	0	0
Metabolic surgery	0	1 (0.2)	0	0
Middle ear operation	1 (0.1)	0	0	0
Mole excision	0	0	1 (0.1)	0
Myringotomy	11 (1.0)	1 (0.2)	8 (0.7)	0
Nail operation	1 (0.1)	0	0	0
Nasal septal operation	0	0	0	1 (0.2)
Nephrectomy	0	0	1 (0.1)	0
Oesophagogastric fundoplasty	0	0	1 (0.1)	0
Open reduction of fracture	2 (0.2)	1 (0.2)	1 (0.1)	1 (0.2)
Oral surgery	0	1 (0.2)	0	0
Orchidectomy	0	1 (0.2)	0	2 (0.4)
Orchidopexy	1 (0.1)	0	0	0
Ostectomy	1 (0.1)	0	0	0
Otoplasty	0	0	0	1 (0.2)
Ovarian cystectomy	0	0	0	1 (0.2)
Papilloma excision	0	1 (0.2)	0	0
Penis frenulectomy	0	1 (0.2)	0	0

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N^a=1131)	16-25 Years (N^a=537)	12-15 Years (N^a=1129)	16-25 Years (N^a=561)
	n^b (%)	n^b (%)	n^b (%)	n^b (%)
Peripheral nerve operation	0	0	0	1 (0.2)
Pharyngeal reconstruction	0	0	1 (0.1)	0
Pilonidal sinus repair	0	1 (0.2)	1 (0.1)	0
Portal shunt procedure	0	0	1 (0.1)	0
Rectal prolapse repair	0	0	0	1 (0.2)
Removal of foreign body from external ear	0	0	1 (0.1)	0
Rhinoplasty	0	2 (0.4)	1 (0.1)	2 (0.4)
Salivary gland resection	0	0	0	1 (0.2)
Salpingectomy	0	0	0	1 (0.2)
Scar excision	0	0	0	1 (0.2)
Scleral buckling surgery	0	0	0	1 (0.2)
Scoliosis surgery	1 (0.1)	1 (0.2)	1 (0.1)	0
Scrotal cystectomy	0	0	1 (0.1)	0
Sinuplasty	0	0	1 (0.1)	0
Skin lesion removal	1 (0.1)	0	0	0
Spinal fusion surgery	2 (0.2)	1 (0.2)	1 (0.1)	0
Splenectomy	0	0	0	1 (0.2)
Splenorrhaphy	0	1 (0.2)	0	0
Stoma closure	0	1 (0.2)	0	0
Strabismus correction	2 (0.2)	2 (0.4)	2 (0.2)	0
Suture insertion	1 (0.1)	0	0	0
Synovial cyst removal	0	1 (0.2)	0	0
Temporomandibular joint surgery	0	0	1 (0.1)	0
Tendon graft	0	1 (0.2)	0	0
Tenoplasty	0	1 (0.2)	0	0
Tenotomy	0	1 (0.2)	0	0
Testes exploration	1 (0.1)	0	0	0
Testicular operation	1 (0.1)	1 (0.2)	0	0
Tetralogy of Fallot repair	0	1 (0.2)	0	0
Thoracic operation	0	1 (0.2)	0	0
Thyroglossal cyst excision	1 (0.1)	0	0	0
Thyroidectomy	0	1 (0.2)	0	1 (0.2)
Toe operation	1 (0.1)	0	0	2 (0.4)
Tongue tie operation	0	0	0	1 (0.2)

14.2. Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131)	16-25 Years (N[a]=537)	12-15 Years (N[a]=1129)	16-25 Years (N[a]=561)
	n[b] (%)	n[b] (%)	n[b] (%)	n[b] (%)
Tonsillectomy	33 (2.9)	17 (3.2)	31 (2.7)	20 (3.6)
Tooth extraction	1 (0.1)	0	1 (0.1)	2 (0.4)
Transgender hormonal therapy	0	0	1 (0.1)	0
Turbinectomy	1 (0.1)	0	0	0
Turbinoplasty	1 (0.1)	0	0	0
Tympanoplasty	1 (0.1)	1 (0.2)	0	0
Umbilical hernia repair	2 (0.2)	2 (0.4)	3 (0.3)	0
Urethral operation	0	1 (0.2)	0	0
Urethral repair	1 (0.1)	0	1 (0.1)	1 (0.2)
Urinary tract operation	0	0	1 (0.1)	0
Varicocele repair	0	0	0	1 (0.2)
Ventricular septal defect repair	0	1 (0.2)	0	0
Vitrectomy	0	0	1 (0.1)	0
Wisdom teeth removal	2 (0.2)	10 (1.9)	5 (0.4)	11 (2.0)
Wound closure	0	0	0	1 (0.2)
Vascular disorders	3 (0.3)	1 (0.2)	2 (0.2)	4 (0.7)
Hypertension	0	0	1 (0.1)	2 (0.4)
Hypotension	1 (0.1)	0	1 (0.1)	0
Orthostatic hypertension	0	1 (0.2)	0	0
Peripheral venous disease	1 (0.1)	0	0	0
Raynaud's phenomenon	1 (0.1)	0	0	2 (0.4)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic. 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 (01:42)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/admh s002 ped saf

14.3. Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 All-Available Immunogenicity Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=210) n[b] (%)	16-25 Years (N[a]=191) n[b] (%)	12-15 Years (N[a]=36) n[b] (%)	16-25 Years (N[a]=34) n[b] (%)
Sex				
Male	107 (51.0)	93 (48.7)	21 (58.3)	14 (41.2)
Female	103 (49.0)	98 (51.3)	15 (41.7)	20 (58.8)
Race				
White	185 (88.1)	151 (79.1)	31 (86.1)	30 (88.2)
Black or African American	16 (7.6)	15 (7.9)	3 (8.3)	2 (5.9)
American Indian or Alaska Native	1 (0.5)	3 (1.6)	0	1 (2.9)
Asian	5 (2.4)	10 (5.2)	1 (2.8)	1 (2.9)
Native Hawaiian or other Pacific Islander	0	4 (2.1)	0	0
Multiracial	3 (1.4)	6 (3.1)	1 (2.8)	0
Not reported	0	2 (1.0)	0	0
Racial designation				
Japanese	1 (0.5)	0	0	0
Ethnicity				
Hispanic/Latino	22 (10.5)	31 (16.2)	2 (5.6)	7 (20.6)
Non-Hispanic/non-Latino	188 (89.5)	159 (83.2)	34 (94.4)	27 (79.4)
Not reported	0	1 (0.5)	0	0
Country				
USA	210 (100.0)	191 (100.0)	36 (100.0)	34 (100.0)
Age at vaccination (years)				
Mean (SD)	13.5 (1.12)	20.7 (3.08)	13.4 (1.17)	20.5 (3.06)
Median	14.0	21.0	13.0	20.5
Min, max	(12, 15)	(16, 25)	(12, 15)	(16, 25)
Baseline SARS-CoV-2 status				
Positive[c]	10 (4.8)	8 (4.2)	2 (5.6)	1 (2.9)
Negative[d]	195 (92.9)	183 (95.8)	33 (91.7)	33 (97.1)
Missing	5 (2.4)	0	1 (2.8)	0
Body mass index (BMI) Obese[e]				
Yes	24 (11.4)	43 (22.5)	3 (8.3)	5 (14.7)
No	186 (88.6)	148 (77.5)	33 (91.7)	29 (85.3)

14.3. Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 All-Available Immunogenicity Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=210) n[b] (%)	16-25 Years (N[a]=191) n[b] (%)	12-15 Years (N[a]=36) n[b] (%)	16-25 Years (N[a]=34) 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.
e. 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. For 16 through 25 years age group, obesity is defined as BMI≥30.0 kg/m^2.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 01APR2021 (23:43)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA1/adsl_s005_demo_ped_d2_aai

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Any medical history	9598 (73.4)	9726 (74.3)
Blood and lymphatic system disorders	165 (1.3)	172 (1.3)
Anaemia	98 (0.7)	114 (0.9)
Anaemia of pregnancy	0	1 (0.0)
Antiphospholipid syndrome	3 (0.0)	3 (0.0)
Blood loss anaemia	1 (0.0)	0
Coagulopathy	2 (0.0)	1 (0.0)
Eosinophilia	1 (0.0)	0
Haemolytic anaemia	0	1 (0.0)
Haemolytic uraemic syndrome	1 (0.0)	0
Hypercoagulation	2 (0.0)	0
Hypersplenism	1 (0.0)	0
Hypochromic anaemia	1 (0.0)	0
Immune thrombocytopenia	1 (0.0)	7 (0.1)
Increased tendency to bruise	2 (0.0)	0
Iron deficiency anaemia	33 (0.3)	31 (0.2)
Leukopenia	2 (0.0)	2 (0.0)
Lymphadenitis	0	1 (0.0)
Lymphadenopathy	5 (0.0)	2 (0.0)
Macrocytosis	1 (0.0)	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)
Neutropenia	0	3 (0.0)
Normocytic anaemia	1 (0.0)	0
Pernicious anaemia	3 (0.0)	0
Polycythaemia	2 (0.0)	0
Spherocytic anaemia	0	1 (0.0)
Splenomegaly	1 (0.0)	1 (0.0)
Thrombocytopenia	5 (0.0)	5 (0.0)
Thrombocytosis	0	1 (0.0)
Cardiac disorders	250 (1.9)	234 (1.8)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Acute coronary syndrome	0	1 (0.0)
Acute myocardial infarction	12 (0.1)	0
Adams-Stokes syndrome	1 (0.0)	0
Angina pectoris	2 (0.0)	8 (0.1)
Angina unstable	1 (0.0)	0
Aortic valve incompetence	2 (0.0)	1 (0.0)
Aortic valve stenosis	0	1 (0.0)
Arrhythmia	12 (0.1)	19 (0.1)
Arteriosclerosis coronary artery	2 (0.0)	0
Arteriospasm coronary	1 (0.0)	3 (0.0)
Atrial fibrillation	22 (0.2)	20 (0.2)
Atrial flutter	0	1 (0.0)
Atrial tachycardia	3 (0.0)	1 (0.0)
Atrioventricular block complete	0	2 (0.0)
Atrioventricular block first degree	1 (0.0)	1 (0.0)
Bradycardia	6 (0.0)	3 (0.0)
Bradycardia neonatal	0	1 (0.0)
Bundle branch block left	2 (0.0)	3 (0.0)
Bundle branch block right	2 (0.0)	4 (0.0)
Cardiac arrest	1 (0.0)	1 (0.0)
Cardiac disorder	1 (0.0)	0
Cardiac failure	4 (0.0)	4 (0.0)
Cardiac failure chronic	1 (0.0)	1 (0.0)
Cardiac failure congestive	12 (0.1)	8 (0.1)
Cardiac ventricular thrombosis	1 (0.0)	0
Cardiomegaly	1 (0.0)	0
Cardiomyopathy	3 (0.0)	3 (0.0)
Cardiovascular disorder	1 (0.0)	2 (0.0)
Congestive cardiomyopathy	1 (0.0)	0
Coronary artery aneurysm	0	1 (0.0)
Coronary artery disease	21 (0.2)	22 (0.2)
Coronary artery insufficiency	1 (0.0)	0
Coronary artery occlusion	2 (0.0)	2 (0.0)
Diastolic dysfunction	0	1 (0.0)
Extrasystoles	1 (0.0)	1 (0.0)
Ischaemic cardiomyopathy	1 (0.0)	0
Left ventricular failure	0	2 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Left ventricular hypertrophy	2 (0.0)	1 (0.0)
Long QT syndrome	1 (0.0)	0
Mitral valve disease	1 (0.0)	1 (0.0)
Mitral valve incompetence	7 (0.1)	5 (0.0)
Mitral valve prolapse	19 (0.1)	17 (0.1)
Mitral valve stenosis	1 (0.0)	0
Myocardial infarction	21 (0.2)	26 (0.2)
Myocardial ischaemia	0	1 (0.0)
Myocarditis	1 (0.0)	0
Palpitations	24 (0.2)	18 (0.1)
Pericardial effusion	1 (0.0)	0
Pericarditis	3 (0.0)	3 (0.0)
Postural orthostatic tachycardia syndrome	3 (0.0)	2 (0.0)
Prinzmetal angina	1 (0.0)	0
Pulmonary valve incompetence	1 (0.0)	0
Pulmonary valve stenosis	2 (0.0)	2 (0.0)
Right atrial enlargement	0	1 (0.0)
Right ventricular failure	1 (0.0)	0
Sinus arrhythmia	0	3 (0.0)
Sinus bradycardia	0	2 (0.0)
Sinus node dysfunction	2 (0.0)	0
Sinus tachycardia	7 (0.1)	6 (0.0)
Stress cardiomyopathy	0	1 (0.0)
Supraventricular extrasystoles	1 (0.0)	3 (0.0)
Supraventricular tachycardia	24 (0.2)	13 (0.1)
Tachyarrhythmia	1 (0.0)	0
Tachycardia	18 (0.1)	16 (0.1)
Tachycardia paroxysmal	0	1 (0.0)
Tricuspid valve disease	1 (0.0)	0
Ventricular extrasystoles	10 (0.1)	14 (0.1)
Ventricular tachycardia	3 (0.0)	2 (0.0)
Wolff-Parkinson-White syndrome	4 (0.0)	6 (0.0)
Congenital, familial and genetic disorders	216 (1.7)	262 (2.0)
Acrocephalosyndactyly	1 (0.0)	0
Adrenogenital syndrome	1 (0.0)	0
Albinism	1 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Alpha-1 antitrypsin deficiency	2 (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	1 (0.0)
Arnold-Chiari malformation	5 (0.0)	3 (0.0)
Arteriovenous malformation	2 (0.0)	1 (0.0)
Asplenia	1 (0.0)	0
Ataxia telangiectasia	0	1 (0.0)
Atrial septal defect	3 (0.0)	9 (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	5 (0.0)	4 (0.0)
Bicuspid pulmonary valve	0	1 (0.0)
Brachymetatarsia	0	1 (0.0)
Branchial cyst	1 (0.0)	0
Cancer gene carrier	0	3 (0.0)
Cataract congenital	2 (0.0)	1 (0.0)
Cerebral palsy	1 (0.0)	8 (0.1)
Cerebrovascular arteriovenous malformation	0	2 (0.0)
Checkpoint kinase 2 gene mutation	1 (0.0)	0
Cleft lip	0	2 (0.0)
Cleft palate	2 (0.0)	4 (0.0)
Coarctation of the aorta	1 (0.0)	1 (0.0)
Colour blindness	2 (0.0)	1 (0.0)
Congenital anomaly	0	1 (0.0)
Congenital aortic anomaly	0	1 (0.0)
Congenital aortic stenosis	2 (0.0)	1 (0.0)
Congenital cerebrovascular anomaly	1 (0.0)	0
Congenital coronary artery malformation	0	1 (0.0)
Congenital cystic kidney disease	5 (0.0)	1 (0.0)
Congenital cystic lung	2 (0.0)	0
Congenital ectodermal dysplasia	0	1 (0.0)
Congenital eye disorder	1 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
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	2 (0.0)	2 (0.0)
Congenital joint malformation	1 (0.0)	0
Congenital lymphoedema	0	1 (0.0)
Congenital multiplex arthrogryposis	2 (0.0)	0
Congenital myopathy	0	1 (0.0)
Congenital neoplasm	0	1 (0.0)
Congenital osteodystrophy	1 (0.0)	0
Congenital skin disorder	0	1 (0.0)
Congenital small intestinal atresia	0	1 (0.0)
Congenital spinal stenosis	1 (0.0)	0
Congenital toxoplasmosis	1 (0.0)	0
Congenital ureteric anomaly	0	1 (0.0)
Congenital uterine anomaly	1 (0.0)	2 (0.0)
Corneal dystrophy	1 (0.0)	2 (0.0)
Cornelia de Lange syndrome	0	1 (0.0)
Craniosynostosis	0	1 (0.0)
Cryptorchism	3 (0.0)	2 (0.0)
Cystic fibrosis	0	2 (0.0)
Deafness congenital	2 (0.0)	2 (0.0)
Dermoid cyst	1 (0.0)	0
Developmental glaucoma	0	1 (0.0)
Developmental hip dysplasia	1 (0.0)	6 (0.0)
Dextrocardia	0	1 (0.0)
Diverticulitis Meckel's	1 (0.0)	0
Dolichocolon	0	1 (0.0)
Dysmorphism	1 (0.0)	1 (0.0)
Eagle Barrett syndrome	1 (0.0)	0
Ear malformation	1 (0.0)	0
Ectopic kidney	1 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Ehlers-Danlos syndrome	12 (0.1)	7 (0.1)
Factor II deficiency	0	1 (0.0)
Factor V Leiden carrier	1 (0.0)	1 (0.0)
Factor V Leiden mutation	7 (0.1)	11 (0.1)
Factor V deficiency	3 (0.0)	0
Factor VII deficiency	0	2 (0.0)
Factor VIII deficiency	1 (0.0)	1 (0.0)
Factor XI deficiency	1 (0.0)	1 (0.0)
Factor XII deficiency	1 (0.0)	0
Fallot's tetralogy	2 (0.0)	2 (0.0)
Familial mediterranean fever	1 (0.0)	2 (0.0)
Familial tremor	0	1 (0.0)
Femoral anteversion	1 (0.0)	0
Gaucher's disease	0	1 (0.0)
Gene mutation	1 (0.0)	1 (0.0)
Gilbert's syndrome	10 (0.1)	7 (0.1)
Glucose-6-phosphate dehydrogenase deficiency	2 (0.0)	5 (0.0)
Haemangioma congenital	1 (0.0)	0
Haemoglobin C trait	0	1 (0.0)
Haemoglobinopathy	2 (0.0)	3 (0.0)
Heart disease congenital	1 (0.0)	1 (0.0)
Hepato-lenticular degeneration	0	1 (0.0)
Hereditary motor and sensory neuropathy	1 (0.0)	0
Hereditary non-polyposis colorectal cancer syndrome	0	2 (0.0)
Hereditary pancreatitis	0	1 (0.0)
Hereditary spherocytosis	1 (0.0)	0
Hydrocele	2 (0.0)	2 (0.0)
Hypertrophic cardiomyopathy	1 (0.0)	4 (0.0)
Hypochondroplasia	0	1 (0.0)
Hypospadias	1 (0.0)	1 (0.0)
Imperforate hymen	0	1 (0.0)
Keratosis follicular	1 (0.0)	0
Kidney malformation	0	1 (0.0)
Klinefelter's syndrome	2 (0.0)	0
Klippel-Feil syndrome	1 (0.0)	2 (0.0)
Kyphosis congenital	1 (0.0)	0
Leptin receptor deficiency	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Limb reduction defect	1 (0.0)	0
Marfan's syndrome	2 (0.0)	1 (0.0)
Methylenetetrahydrofolate reductase gene mutation	0	4 (0.0)
Micrognathia	0	2 (0.0)
Microphthalmos	1 (0.0)	0
Muscular dystrophy	1 (0.0)	0
Myocardial bridging	0	1 (0.0)
Myotonia congenita	0	1 (0.0)
Myotonic dystrophy	0	1 (0.0)
Naevus flammeus	1 (0.0)	0
Neurofibromatosis	5 (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	1 (0.0)
Pectus carinatum	0	1 (0.0)
Pectus excavatum	3 (0.0)	3 (0.0)
Pelvic kidney	0	1 (0.0)
Phenylketonuria	0	1 (0.0)
Phimosis	3 (0.0)	5 (0.0)
Poland's syndrome	1 (0.0)	0
Polycystic liver disease	0	1 (0.0)
Polydactyly	0	1 (0.0)
Protein C deficiency	0	1 (0.0)
Protein S deficiency	3 (0.0)	2 (0.0)
Pulmonary hypoplasia	1 (0.0)	0
Pulmonary malformation	1 (0.0)	0
Pyloric stenosis	2 (0.0)	7 (0.1)
Renal aplasia	3 (0.0)	3 (0.0)
Renal dysplasia	1 (0.0)	0
Renal fusion anomaly	2 (0.0)	1 (0.0)
Retinitis pigmentosa	1 (0.0)	2 (0.0)
Schizencephaly	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
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	4 (0.0)	6 (0.0)
Spina bifida	2 (0.0)	1 (0.0)
Spina bifida occulta	0	2 (0.0)
Spine malformation	1 (0.0)	0
Stargardt's disease	0	1 (0.0)
Supernumerary nipple	1 (0.0)	0
Syndactyly	1 (0.0)	1 (0.0)
Syringomyelia	1 (0.0)	0
Talipes	3 (0.0)	3 (0.0)
Thalassaemia	8 (0.1)	4 (0.0)
Thalassaemia alpha	1 (0.0)	2 (0.0)
Thalassaemia beta	2 (0.0)	6 (0.0)
Thalassaemia minor	5 (0.0)	5 (0.0)
Thyroglossal cyst	1 (0.0)	1 (0.0)
Tourette's disorder	4 (0.0)	2 (0.0)
Tracheo-oesophageal fistula	1 (0.0)	0
Transitional vertebrae	1 (0.0)	0
Tuberous sclerosis complex	1 (0.0)	2 (0.0)
Type IIa hyperlipidaemia	6 (0.0)	5 (0.0)
Type V hyperlipidaemia	9 (0.1)	9 (0.1)
Umbilical malformation	0	1 (0.0)
Urethral valves	1 (0.0)	0
VACTERL syndrome	0	1 (0.0)
Ventricular septal defect	2 (0.0)	9 (0.1)
Vitello-intestinal duct remnant	1 (0.0)	1 (0.0)
Von Willebrand's disease	1 (0.0)	2 (0.0)
Wolff-Parkinson-White syndrome congenital	1 (0.0)	0
Ear and labyrinth disorders	169 (1.3)	180 (1.4)
Auditory disorder	0	1 (0.0)
Aural polyp	0	1 (0.0)
Cerumen impaction	3 (0.0)	2 (0.0)
Conductive deafness	1 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Deafness	14 (0.1)	23 (0.2)
Deafness bilateral	17 (0.1)	14 (0.1)
Deafness neurosensory	4 (0.0)	3 (0.0)
Deafness unilateral	18 (0.1)	17 (0.1)
Ear deformity acquired	1 (0.0)	0
Ear disorder	1 (0.0)	3 (0.0)
Ear pain	1 (0.0)	3 (0.0)
Ear pruritus	0	1 (0.0)
Eustachian tube dysfunction	1 (0.0)	5 (0.0)
Eustachian tube patulous	1 (0.0)	0
Eustachian tube stenosis	0	1 (0.0)
Excessive cerumen production	0	1 (0.0)
Exostosis of external ear canal	1 (0.0)	1 (0.0)
Hypoacusis	15 (0.1)	16 (0.1)
Inner ear disorder	1 (0.0)	0
Meniere's disease	10 (0.1)	11 (0.1)
Middle ear effusion	1 (0.0)	0
Motion sickness	5 (0.0)	1 (0.0)
Otosclerosis	3 (0.0)	3 (0.0)
Sudden hearing loss	1 (0.0)	0
Tinnitus	46 (0.4)	51 (0.4)
Tympanic membrane perforation	7 (0.1)	6 (0.0)
Vertigo	20 (0.2)	30 (0.2)
Vertigo positional	3 (0.0)	3 (0.0)
Vestibular disorder	1 (0.0)	1 (0.0)
Endocrine disorders	765 (5.9)	810 (6.2)
Adrenal insufficiency	1 (0.0)	0
Adrenal mass	0	1 (0.0)
Androgen deficiency	2 (0.0)	3 (0.0)
Anovulatory cycle	1 (0.0)	1 (0.0)
Autoimmune hypothyroidism	0	1 (0.0)
Autoimmune thyroiditis	47 (0.4)	40 (0.3)
Basedow's disease	11 (0.1)	10 (0.1)
Diabetes insipidus	0	1 (0.0)
Endocrine disorder	1 (0.0)	0
Goitre	17 (0.1)	22 (0.2)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Gonadotrophin deficiency	0	1 (0.0)
Growth hormone deficiency	1 (0.0)	2 (0.0)
Hyperaldosteronism	1 (0.0)	0
Hyperandrogenism	0	1 (0.0)
Hyperparathyroidism	2 (0.0)	0
Hyperprolactinaemia	3 (0.0)	1 (0.0)
Hyperthyroidism	29 (0.2)	32 (0.2)
Hypogonadism	24 (0.2)	30 (0.2)
Hypogonadism male	7 (0.1)	4 (0.0)
Hypoparathyroidism	3 (0.0)	1 (0.0)
Hypopituitarism	1 (0.0)	0
Hypothalamo-pituitary disorder	0	1 (0.0)
Hypothyroidism	616 (4.7)	654 (5.0)
Oestrogen deficiency	1 (0.0)	3 (0.0)
Pituitary-dependent Cushing's syndrome	1 (0.0)	0
Primary hypogonadism	0	1 (0.0)
Secondary hypogonadism	2 (0.0)	0
Secondary hypothyroidism	0	1 (0.0)
Testicular failure	3 (0.0)	2 (0.0)
Thyroid calcification	1 (0.0)	0
Thyroid cyst	6 (0.0)	3 (0.0)
Thyroid disorder	3 (0.0)	1 (0.0)
Thyroid mass	23 (0.2)	20 (0.2)
Thyroid stimulating hormone deficiency	0	1 (0.0)
Thyroiditis	1 (0.0)	0
Thyroiditis subacute	0	1 (0.0)
Eye disorders	831 (6.4)	880 (6.7)
Amaurosis	1 (0.0)	1 (0.0)
Amblyopia	11 (0.1)	6 (0.0)
Angle closure glaucoma	1 (0.0)	0
Anisometropia	0	1 (0.0)
Astigmatism	42 (0.3)	49 (0.4)
Binocular eye movement disorder	1 (0.0)	0
Blepharitis	1 (0.0)	0
Blepharospasm	0	1 (0.0)
Blindness	2 (0.0)	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Blindness unilateral	11 (0.1)	10 (0.1)
Borderline glaucoma	1 (0.0)	2 (0.0)
Cataract	21 (0.2)	23 (0.2)
Chalazion	0	1 (0.0)
Chorioretinopathy	7 (0.1)	2 (0.0)
Conjunctival haemorrhage	0	1 (0.0)
Conjunctivitis allergic	9 (0.1)	5 (0.0)
Corneal degeneration	1 (0.0)	1 (0.0)
Corneal disorder	0	1 (0.0)
Corneal scar	0	1 (0.0)
Dacryostenosis acquired	2 (0.0)	2 (0.0)
Diabetic eye disease	1 (0.0)	0
Diabetic retinopathy	5 (0.0)	5 (0.0)
Diplopia	0	1 (0.0)
Dry eye	20 (0.2)	20 (0.2)
Entropion	0	1 (0.0)
Exophthalmos	0	1 (0.0)
Extraocular muscle paresis	0	1 (0.0)
Eye allergy	1 (0.0)	1 (0.0)
Eye disorder	0	1 (0.0)
Eye haemorrhage	1 (0.0)	0
Eye irritation	0	1 (0.0)
Eye movement disorder	0	1 (0.0)
Eye pruritus	1 (0.0)	0
Eye swelling	0	1 (0.0)
Eyelid cyst	0	1 (0.0)
Eyelid ptosis	4 (0.0)	2 (0.0)
Giant papillary conjunctivitis	0	1 (0.0)
Glaucoma	29 (0.2)	42 (0.3)
Heterophoria	0	1 (0.0)
Hypermetropia	111 (0.8)	107 (0.8)
Iridocyclitis	0	1 (0.0)
Iridodialysis	0	1 (0.0)
Iris disorder	0	1 (0.0)
Iritis	1 (0.0)	3 (0.0)
Keratitis	1 (0.0)	1 (0.0)
Keratoconus	8 (0.1)	5 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Lacrimal disorder	0	1 (0.0)
Macular degeneration	1 (0.0)	0
Maculopathy	2 (0.0)	2 (0.0)
Meibomian gland dysfunction	1 (0.0)	0
Mydriasis	2 (0.0)	0
Myopia	457 (3.5)	445 (3.4)
Necrotising retinitis	1 (0.0)	0
Ocular hypertension	2 (0.0)	3 (0.0)
Ocular rosacea	0	1 (0.0)
Open angle glaucoma	0	4 (0.0)
Optic disc drusen	1 (0.0)	0
Optic ischaemic neuropathy	0	1 (0.0)
Optic nerve cupping	0	1 (0.0)
Optic neuropathy	1 (0.0)	0
Pinguecula	1 (0.0)	0
Presbyopia	90 (0.7)	98 (0.7)
Pterygium	3 (0.0)	4 (0.0)
Punctate keratitis	2 (0.0)	0
Pupils unequal	0	1 (0.0)
Refraction disorder	1 (0.0)	5 (0.0)
Refractive amblyopia	0	1 (0.0)
Retinal artery thrombosis	1 (0.0)	0
Retinal degeneration	2 (0.0)	0
Retinal detachment	11 (0.1)	9 (0.1)
Retinal disorder	1 (0.0)	0
Retinal scar	0	1 (0.0)
Retinal tear	3 (0.0)	2 (0.0)
Retinal vein occlusion	0	1 (0.0)
Retinopathy	1 (0.0)	0
Retinoschisis	0	1 (0.0)
Strabismus	14 (0.1)	21 (0.2)
Uveitis	2 (0.0)	2 (0.0)
Vision blurred	2 (0.0)	3 (0.0)
Visual acuity reduced	49 (0.4)	65 (0.5)
Visual impairment	7 (0.1)	20 (0.2)
Vitreous degeneration	1 (0.0)	0
Vitreous detachment	2 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Vitreous floaters	2 (0.0)	1 (0.0)
Gastrointestinal disorders	1573 (12.0)	1561 (11.9)
Abdominal adhesions	0	1 (0.0)
Abdominal distension	2 (0.0)	5 (0.0)
Abdominal fat apron	1 (0.0)	0
Abdominal hernia	19 (0.1)	22 (0.2)
Abdominal mass	1 (0.0)	0
Abdominal migraine	1 (0.0)	1 (0.0)
Abdominal pain	15 (0.1)	11 (0.1)
Abdominal pain lower	1 (0.0)	2 (0.0)
Abdominal pain upper	8 (0.1)	4 (0.0)
Abdominal tenderness	1 (0.0)	0
Acquired oesophageal web	1 (0.0)	2 (0.0)
Anal fissure	3 (0.0)	4 (0.0)
Anal fistula	3 (0.0)	8 (0.1)
Anal prolapse	0	1 (0.0)
Anal skin tags	1 (0.0)	0
Anogenital dysplasia	1 (0.0)	1 (0.0)
Aphthous ulcer	5 (0.0)	3 (0.0)
Appendicitis noninfective	0	1 (0.0)
Barrett's oesophagus	8 (0.1)	11 (0.1)
Bile acid malabsorption	1 (0.0)	1 (0.0)
Cannabinoid hyperemesis syndrome	0	1 (0.0)
Chronic gastritis	8 (0.1)	10 (0.1)
Coeliac disease	27 (0.2)	32 (0.2)
Colitis	5 (0.0)	3 (0.0)
Colitis ischaemic	0	1 (0.0)
Colitis microscopic	1 (0.0)	2 (0.0)
Colitis ulcerative	12 (0.1)	16 (0.1)
Constipation	78 (0.6)	72 (0.5)
Crohn's disease	8 (0.1)	9 (0.1)
Dental caries	4 (0.0)	9 (0.1)
Diaphragmatic hernia	3 (0.0)	1 (0.0)
Diarrhoea	26 (0.2)	24 (0.2)
Diverticulum	23 (0.2)	16 (0.1)
Diverticulum intestinal	3 (0.0)	4 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Dry mouth	2 (0.0)	0
Dumping syndrome	0	1 (0.0)
Duodenal ulcer	2 (0.0)	0
Duodenogastric reflux	2 (0.0)	2 (0.0)
Dyspepsia	150 (1.1)	142 (1.1)
Dysphagia	8 (0.1)	6 (0.0)
Enlarged uvula	0	1 (0.0)
Enterovesical fistula	1 (0.0)	0
Eosinophilic oesophagitis	7 (0.1)	9 (0.1)
Epigastric discomfort	1 (0.0)	0
Epiploic appendagitis	0	1 (0.0)
Erosive oesophagitis	1 (0.0)	0
Femoral hernia	2 (0.0)	1 (0.0)
Flatulence	2 (0.0)	1 (0.0)
Food poisoning	1 (0.0)	4 (0.0)
Functional gastrointestinal disorder	1 (0.0)	0
Gastric disorder	3 (0.0)	1 (0.0)
Gastric haemorrhage	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	17 (0.1)	18 (0.1)
Gastric ulcer perforation	0	1 (0.0)
Gastritis	43 (0.3)	45 (0.3)
Gastritis erosive	1 (0.0)	1 (0.0)
Gastroenteritis eosinophilic	1 (0.0)	0
Gastrointestinal disorder	2 (0.0)	2 (0.0)
Gastrointestinal haemorrhage	4 (0.0)	4 (0.0)
Gastrointestinal hypomotility	1 (0.0)	1 (0.0)
Gastrointestinal inflammation	0	1 (0.0)
Gastrointestinal necrosis	1 (0.0)	0
Gastrointestinal pain	2 (0.0)	2 (0.0)
Gastrointestinal scarring	0	1 (0.0)
Gastrooesophageal reflux disease	781 (6.0)	775 (5.9)
Gingival discomfort	0	1 (0.0)
Gingival recession	1 (0.0)	3 (0.0)
Haematochezia	2 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Haemorrhoids	57 (0.4)	67 (0.5)
Haemorrhoids thrombosed	1 (0.0)	0
Hiatus hernia	27 (0.2)	46 (0.4)
Hyperaesthesia teeth	1 (0.0)	0
Impaired gastric emptying	10 (0.1)	9 (0.1)
Inflammatory bowel disease	1 (0.0)	1 (0.0)
Inguinal hernia	83 (0.6)	93 (0.7)
Intestinal cyst	1 (0.0)	0
Intestinal obstruction	5 (0.0)	4 (0.0)
Intestinal perforation	1 (0.0)	2 (0.0)
Intestinal polyp	1 (0.0)	0
Intestinal prolapse	0	1 (0.0)
Intestinal strangulation	1 (0.0)	0
Intussusception	0	1 (0.0)
Irritable bowel syndrome	164 (1.3)	152 (1.2)
Large intestinal obstruction	1 (0.0)	1 (0.0)
Large intestine perforation	2 (0.0)	0
Large intestine polyp	16 (0.1)	16 (0.1)
Lumbar hernia	3 (0.0)	4 (0.0)
Malabsorption	2 (0.0)	0
Malocclusion	4 (0.0)	3 (0.0)
Mouth ulceration	2 (0.0)	3 (0.0)
Nausea	11 (0.1)	15 (0.1)
Necrotising colitis	1 (0.0)	0
Noninfective sialoadenitis	2 (0.0)	0
Obstruction gastric	0	1 (0.0)
Oesophageal achalasia	2 (0.0)	2 (0.0)
Oesophageal disorder	1 (0.0)	0
Oesophageal perforation	0	1 (0.0)
Oesophageal spasm	1 (0.0)	1 (0.0)
Oesophageal stenosis	3 (0.0)	2 (0.0)
Oesophageal ulcer	2 (0.0)	0
Oesophagitis	9 (0.1)	11 (0.1)
Pancreatic failure	0	2 (0.0)
Pancreatitis	14 (0.1)	7 (0.1)
Pancreatitis acute	3 (0.0)	0
Pancreatitis chronic	3 (0.0)	4 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Pancreatitis necrotising	0	1 (0.0)
Pelvic floor dysfunction	2 (0.0)	1 (0.0)
Peptic ulcer	4 (0.0)	9 (0.1)
Periodontal disease	0	1 (0.0)
Peritoneal cyst	0	1 (0.0)
Proctitis ulcerative	1 (0.0)	2 (0.0)
Rectal fissure	2 (0.0)	1 (0.0)
Rectal haemorrhage	4 (0.0)	3 (0.0)
Rectal polyp	0	1 (0.0)
Rectal prolapse	1 (0.0)	2 (0.0)
Reflux gastritis	1 (0.0)	0
Salivary gland calculus	0	1 (0.0)
Salivary gland cyst	1 (0.0)	0
Salivary gland disorder	0	1 (0.0)
Short-bowel syndrome	2 (0.0)	0
Small intestinal obstruction	3 (0.0)	0
Stomatitis	1 (0.0)	1 (0.0)
Superior mesenteric artery syndrome	0	1 (0.0)
Swollen tongue	1 (0.0)	1 (0.0)
Tooth impacted	30 (0.2)	19 (0.1)
Tooth loss	2 (0.0)	1 (0.0)
Toothache	5 (0.0)	9 (0.1)
Umbilical hernia	52 (0.4)	59 (0.5)
Upper gastrointestinal haemorrhage	1 (0.0)	0
Volvulus	1 (0.0)	3 (0.0)
Vomiting	4 (0.0)	1 (0.0)
General disorders and administration site conditions	161 (1.2)	161 (1.2)
Adverse drug reaction	7 (0.1)	5 (0.0)
Application site vesicles	0	1 (0.0)
Asthenia	0	1 (0.0)
Calcinosis	0	1 (0.0)
Chest discomfort	0	1 (0.0)
Chest pain	8 (0.1)	8 (0.1)
Chronic fatigue syndrome	1 (0.0)	3 (0.0)
Cyst	9 (0.1)	11 (0.1)
Cyst rupture	1 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Discomfort	0	2 (0.0)
Disease susceptibility	0	1 (0.0)
Drug intolerance	23 (0.2)	24 (0.2)
Dysplasia	1 (0.0)	0
Face oedema	1 (0.0)	0
Fat tissue increased	0	1 (0.0)
Fatigue	17 (0.1)	19 (0.1)
Feeling abnormal	1 (0.0)	0
Generalised oedema	1 (0.0)	0
Hernia	21 (0.2)	17 (0.1)
Hyperplasia	2 (0.0)	0
Inflammation	2 (0.0)	0
Injection site erythema	0	1 (0.0)
Injection site swelling	0	1 (0.0)
Injury associated with device	1 (0.0)	0
Lithiasis	0	1 (0.0)
Localised oedema	0	1 (0.0)
Medical device site scar	0	1 (0.0)
Nodule	0	1 (0.0)
Oedema	5 (0.0)	6 (0.0)
Oedema peripheral	17 (0.1)	21 (0.2)
Pain	32 (0.2)	30 (0.2)
Perforated ulcer	2 (0.0)	0
Peripheral swelling	4 (0.0)	0
Polyp	1 (0.0)	1 (0.0)
Precancerous condition	2 (0.0)	1 (0.0)
Pyrexia	1 (0.0)	0
Surgical failure	0	1 (0.0)
Temperature intolerance	1 (0.0)	0
Treatment noncompliance	1 (0.0)	1 (0.0)
Ulcer	1 (0.0)	0
Vaccination site reaction	0	1 (0.0)
Vaccination site swelling	1 (0.0)	0
Vascular stent occlusion	0	1 (0.0)
Xerosis	1 (0.0)	0
Hepatobiliary disorders	348 (2.7)	369 (2.8)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Bile duct stone	2 (0.0)	2 (0.0)
Biliary colic	5 (0.0)	0
Biliary cyst	0	1 (0.0)
Biliary dyskinesia	2 (0.0)	1 (0.0)
Biliary polyp	0	1 (0.0)
Biliary tract disorder	2 (0.0)	0
Cholecystitis	74 (0.6)	88 (0.7)
Cholecystitis acute	2 (0.0)	1 (0.0)
Cholelithiasis	178 (1.4)	191 (1.5)
Cholelithiasis obstructive	1 (0.0)	0
Cholestasis	1 (0.0)	1 (0.0)
Cirrhosis alcoholic	0	1 (0.0)
Gallbladder disorder	28 (0.2)	27 (0.2)
Gallbladder hypofunction	4 (0.0)	2 (0.0)
Gallbladder obstruction	0	1 (0.0)
Gallbladder oedema	2 (0.0)	0
Gallbladder polyp	1 (0.0)	4 (0.0)
Hepatic cirrhosis	5 (0.0)	1 (0.0)
Hepatic cyst	0	1 (0.0)
Hepatic function abnormal	0	1 (0.0)
Hepatic lesion	1 (0.0)	0
Hepatic mass	0	3 (0.0)
Hepatic steatosis	40 (0.3)	36 (0.3)
Hepatitis	0	1 (0.0)
Hepatitis alcoholic	0	1 (0.0)
Hepatomegaly	2 (0.0)	1 (0.0)
Hepatorenal syndrome	0	1 (0.0)
Hyperbilirubinaemia	1 (0.0)	1 (0.0)
Jaundice	0	1 (0.0)
Liver disorder	1 (0.0)	3 (0.0)
Non-alcoholic steatohepatitis	3 (0.0)	3 (0.0)
Nonalcoholic fatty liver disease	7 (0.1)	7 (0.1)
Immune system disorders	3238 (24.8)	3285 (25.1)
Allergic oedema	5 (0.0)	2 (0.0)
Allergy to animal	87 (0.7)	90 (0.7)
Allergy to arthropod bite	0	3 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Allergy to arthropod sting	32 (0.2)	36 (0.3)
Allergy to chemicals	10 (0.1)	11 (0.1)
Allergy to metals	12 (0.1)	15 (0.1)
Allergy to plants	14 (0.1)	18 (0.1)
Allergy to surgical sutures	0	2 (0.0)
Allergy to synthetic fabric	1 (0.0)	0
Allergy to vaccine	6 (0.0)	4 (0.0)
Amyloidosis	1 (0.0)	0
Anaphylactic reaction	10 (0.1)	8 (0.1)
Anaphylactic shock	1 (0.0)	0
Atopy	1 (0.0)	2 (0.0)
Cockroach allergy	1 (0.0)	0
Contrast media allergy	13 (0.1)	12 (0.1)
Contrast media reaction	0	1 (0.0)
Drug hypersensitivity	1360 (10.4)	1310 (10.0)
Dust allergy	21 (0.2)	31 (0.2)
Flour sensitivity	0	1 (0.0)
Food allergy	244 (1.9)	259 (2.0)
Hypersensitivity	118 (0.9)	117 (0.9)
Iodine allergy	21 (0.2)	29 (0.2)
Milk allergy	9 (0.1)	18 (0.1)
Mite allergy	19 (0.1)	15 (0.1)
Multiple allergies	13 (0.1)	14 (0.1)
Mycotic allergy	16 (0.1)	12 (0.1)
Oral allergy syndrome	1 (0.0)	1 (0.0)
Perennial allergy	17 (0.1)	20 (0.2)
Perfume sensitivity	1 (0.0)	2 (0.0)
Reaction to colouring	3 (0.0)	4 (0.0)
Reaction to food additive	4 (0.0)	4 (0.0)
Reaction to preservatives	0	1 (0.0)
Rubber sensitivity	60 (0.5)	75 (0.6)
Sarcoidosis	7 (0.1)	4 (0.0)
Seasonal allergy	1888 (14.4)	1931 (14.7)
Smoke sensitivity	1 (0.0)	0
Sunscreen sensitivity	0	1 (0.0)
Infections and infestations	1173 (9.0)	1072 (8.2)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Abscess limb	1 (0.0)	0
Abscess neck	1 (0.0)	0
Abscess soft tissue	0	1 (0.0)
Acarodermatitis	0	1 (0.0)
Actinomycosis	0	1 (0.0)
Acute sinusitis	1 (0.0)	3 (0.0)
Adenoiditis	9 (0.1)	11 (0.1)
American trypanosomiasis	2 (0.0)	1 (0.0)
Anorectal human papilloma virus infection	0	1 (0.0)
Appendicitis	221 (1.7)	197 (1.5)
Appendicitis perforated	4 (0.0)	3 (0.0)
Arthritis bacterial	1 (0.0)	3 (0.0)
Arthritis infective	0	2 (0.0)
Asymptomatic HIV infection	1 (0.0)	1 (0.0)
Atypical pneumonia	1 (0.0)	0
Babesiosis	0	1 (0.0)
Bacterial allergy	0	1 (0.0)
Bacterial infection	1 (0.0)	0
Bacterial tracheitis	1 (0.0)	0
Bacterial vaginosis	3 (0.0)	3 (0.0)
Bacterial vulvovaginitis	1 (0.0)	0
Bartonellosis	0	1 (0.0)
Body tinea	0	1 (0.0)
Bone abscess	1 (0.0)	0
Brain abscess	0	1 (0.0)
Breast abscess	2 (0.0)	0
Bronchitis	19 (0.1)	14 (0.1)
COVID-19	1 (0.0)	0
Candida infection	1 (0.0)	2 (0.0)
Cat scratch disease	3 (0.0)	2 (0.0)
Cellulitis	6 (0.0)	5 (0.0)
Cellulitis orbital	0	1 (0.0)
Cervicitis human papilloma virus	2 (0.0)	1 (0.0)
Chikungunya virus infection	5 (0.0)	2 (0.0)
Chlamydial infection	12 (0.1)	9 (0.1)
Cholecystitis infective	0	1 (0.0)
Chronic hepatitis B	1 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Chronic sinusitis	40 (0.3)	35 (0.3)
Chronic tonsillitis	5 (0.0)	6 (0.0)
Clostridial infection	1 (0.0)	0
Clostridium difficile colitis	3 (0.0)	1 (0.0)
Clostridium difficile infection	1 (0.0)	1 (0.0)
Coccidioidomycosis	2 (0.0)	0
Conjunctivitis	2 (0.0)	0
Conjunctivitis viral	0	1 (0.0)
Croup infectious	0	1 (0.0)
Cyclosporidium infection	0	1 (0.0)
Cystitis	1 (0.0)	2 (0.0)
Cytomegalovirus hepatitis	0	1 (0.0)
Dengue fever	4 (0.0)	7 (0.1)
Dermatophytosis	0	1 (0.0)
Device related infection	1 (0.0)	0
Diverticulitis	26 (0.2)	24 (0.2)
Ear infection	31 (0.2)	25 (0.2)
Eczema infected	1 (0.0)	0
Encephalitis	0	1 (0.0)
Encephalomyelitis	1 (0.0)	0
Endocarditis	1 (0.0)	1 (0.0)
Enterobiasis	1 (0.0)	0
Epididymitis	2 (0.0)	0
Epstein-Barr virus infection	0	1 (0.0)
Escherichia infection	0	1 (0.0)
Escherichia sepsis	0	1 (0.0)
Eye infection	0	1 (0.0)
Eye infection toxoplasmal	0	1 (0.0)
Eyelid infection	1 (0.0)	0
Folliculitis	5 (0.0)	6 (0.0)
Fracture infection	1 (0.0)	0
Fungal infection	6 (0.0)	2 (0.0)
Fungal skin infection	2 (0.0)	4 (0.0)
Furuncle	1 (0.0)	2 (0.0)
Gastroenteritis	2 (0.0)	4 (0.0)
Gastroenteritis norovirus	1 (0.0)	0
Gastroenteritis viral	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Gastrointestinal bacterial overgrowth	0	1 (0.0)
Gastrointestinal infection	0	2 (0.0)
Genital herpes	29 (0.2)	27 (0.2)
Genital herpes simplex	11 (0.1)	7 (0.1)
Genitourinary chlamydia infection	0	1 (0.0)
Giardiasis	1 (0.0)	0
Gingivitis	0	2 (0.0)
Gonorrhoea	2 (0.0)	1 (0.0)
Groin infection	1 (0.0)	0
HIV infection	13 (0.1)	16 (0.1)
Hand-foot-and-mouth disease	0	1 (0.0)
Helicobacter gastritis	5 (0.0)	1 (0.0)
Helicobacter infection	2 (0.0)	6 (0.0)
Hepatitis A	13 (0.1)	13 (0.1)
Hepatitis B	5 (0.0)	4 (0.0)
Hepatitis C	8 (0.1)	9 (0.1)
Herpes dermatitis	1 (0.0)	0
Herpes ophthalmic	0	1 (0.0)
Herpes simplex	73 (0.6)	77 (0.6)
Herpes virus infection	12 (0.1)	6 (0.0)
Herpes zoster	44 (0.3)	39 (0.3)
Histoplasmosis	1 (0.0)	0
Hordeolum	2 (0.0)	2 (0.0)
Human ehrlichiosis	0	1 (0.0)
Impetigo	0	1 (0.0)
Infected cyst	0	2 (0.0)
Infected dermal cyst	1 (0.0)	0
Infectious mononucleosis	5 (0.0)	5 (0.0)
Infective myositis	0	1 (0.0)
Infective tenosynovitis	1 (0.0)	0
Influenza	2 (0.0)	3 (0.0)
Joint abscess	0	1 (0.0)
Kidney infection	2 (0.0)	5 (0.0)
Labyrinthitis	4 (0.0)	5 (0.0)
Laryngitis	1 (0.0)	0
Latent tuberculosis	7 (0.1)	5 (0.0)
Localised infection	1 (0.0)	2 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Lyme disease	4 (0.0)	12 (0.1)
Lymph gland infection	0	1 (0.0)
Lymph node abscess	1 (0.0)	0
Mastitis	0	4 (0.0)
Mastoiditis	0	2 (0.0)
Mediastinitis	1 (0.0)	0
Meningitis	3 (0.0)	5 (0.0)
Meningitis aseptic	1 (0.0)	0
Meningitis herpes	0	1 (0.0)
Meningitis viral	3 (0.0)	2 (0.0)
Myringitis	1 (0.0)	1 (0.0)
Nasopharyngitis	2 (0.0)	2 (0.0)
Oesophagitis bacterial	1 (0.0)	0
Onychomycosis	20 (0.2)	25 (0.2)
Ophthalmic herpes simplex	0	1 (0.0)
Ophthalmic herpes zoster	0	1 (0.0)
Oral candidiasis	0	1 (0.0)
Oral herpes	58 (0.4)	52 (0.4)
Oral infection	1 (0.0)	0
Osteomyelitis	4 (0.0)	3 (0.0)
Otitis externa	2 (0.0)	2 (0.0)
Otitis media	7 (0.1)	8 (0.1)
Otitis media acute	1 (0.0)	1 (0.0)
Otitis media chronic	4 (0.0)	3 (0.0)
Overgrowth bacterial	0	1 (0.0)
Papilloma viral infection	9 (0.1)	5 (0.0)
Parasite allergy	1 (0.0)	0
Paronychia	0	2 (0.0)
Parotitis	0	1 (0.0)
Pelvic infection	0	1 (0.0)
Pelvic inflammatory disease	1 (0.0)	2 (0.0)
Periodontal destruction	1 (0.0)	0
Perirectal abscess	0	1 (0.0)
Peritonitis	3 (0.0)	2 (0.0)
Peritonsillar abscess	2 (0.0)	0
Pertussis	1 (0.0)	2 (0.0)
Pharyngitis	4 (0.0)	4 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Pharyngitis streptococcal	16 (0.1)	12 (0.1)
Pharyngotonsillitis	0	1 (0.0)
Pilonidal cyst	9 (0.1)	10 (0.1)
Pleurisy viral	0	1 (0.0)
Pneumonia	41 (0.3)	29 (0.2)
Pneumonia adenoviral	0	1 (0.0)
Pneumonia bacterial	1 (0.0)	1 (0.0)
Pneumonia streptococcal	1 (0.0)	0
Pneumonia viral	1 (0.0)	0
Post procedural sepsis	0	1 (0.0)
Postoperative abscess	1 (0.0)	0
Presumed ocular histoplasmosis syndrome	0	1 (0.0)
Pulmonary tuberculosis	4 (0.0)	2 (0.0)
Pyelonephritis	3 (0.0)	3 (0.0)
Rectal abscess	1 (0.0)	0
Respiratory syncytial virus infection	1 (0.0)	1 (0.0)
Respiratory tract infection	1 (0.0)	0
Rhinitis	21 (0.2)	11 (0.1)
Rocky mountain spotted fever	1 (0.0)	0
Root canal infection	0	1 (0.0)
Rubella	0	1 (0.0)
Salpingitis	2 (0.0)	1 (0.0)
Scarlet fever	2 (0.0)	2 (0.0)
Scrotal infection	1 (0.0)	0
Sepsis	3 (0.0)	2 (0.0)
Sepsis syndrome	1 (0.0)	0
Septic arthritis staphylococcal	2 (0.0)	0
Septic shock	0	1 (0.0)
Sinusitis	57 (0.4)	50 (0.4)
Sinusitis fungal	1 (0.0)	1 (0.0)
Skin bacterial infection	2 (0.0)	0
Skin infection	0	2 (0.0)
Staphylococcal infection	10 (0.1)	11 (0.1)
Staphylococcal skin infection	1 (0.0)	1 (0.0)
Streptococcal infection	6 (0.0)	1 (0.0)
Subcutaneous abscess	2 (0.0)	0
Syphilis	5 (0.0)	5 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Tinea pedis	9 (0.1)	3 (0.0)
Tinea versicolour	15 (0.1)	10 (0.1)
Tonsillitis	209 (1.6)	192 (1.5)
Tonsillitis streptococcal	1 (0.0)	0
Tooth abscess	1 (0.0)	3 (0.0)
Tooth infection	2 (0.0)	3 (0.0)
Toxic shock syndrome	1 (0.0)	1 (0.0)
Trichomoniasis	2 (0.0)	0
Tuberculosis	7 (0.1)	3 (0.0)
Tuberculous pleurisy	1 (0.0)	1 (0.0)
Typhoid fever	1 (0.0)	0
Typhus	0	1 (0.0)
Upper respiratory tract infection	5 (0.0)	3 (0.0)
Urinary tract infection	43 (0.3)	51 (0.4)
Urinary tract infection bacterial	1 (0.0)	1 (0.0)
Urosepsis	1 (0.0)	0
Vaginal infection	2 (0.0)	2 (0.0)
Vaginitis chlamydial	0	2 (0.0)
Vaginitis gardnerella	1 (0.0)	0
Varicella	6 (0.0)	4 (0.0)
Varicella zoster virus infection	1 (0.0)	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)	2 (0.0)
West Nile viral infection	0	1 (0.0)
Injury, poisoning and procedural complications	745 (5.7)	752 (5.7)
Abdominal injury	2 (0.0)	1 (0.0)
Accident	0	1 (0.0)
Accidental poisoning	1 (0.0)	0
Acetabulum fracture	0	1 (0.0)
Alcohol poisoning	0	1 (0.0)
Animal bite	0	1 (0.0)
Animal scratch	1 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Ankle fracture	44 (0.3)	49 (0.4)
Arterial injury	0	2 (0.0)
Arthropod bite	3 (0.0)	4 (0.0)
Avulsion fracture	0	1 (0.0)
Back injury	11 (0.1)	8 (0.1)
Bladder injury	0	1 (0.0)
Blindness traumatic	0	1 (0.0)
Brachial plexus injury	1 (0.0)	0
Burns second degree	2 (0.0)	0
Burns third degree	0	2 (0.0)
Bursa injury	0	1 (0.0)
Cartilage injury	27 (0.2)	30 (0.2)
Cataract traumatic	0	1 (0.0)
Cervical vertebral fracture	6 (0.0)	2 (0.0)
Clavicle fracture	21 (0.2)	25 (0.2)
Concussion	18 (0.1)	10 (0.1)
Contusion	0	2 (0.0)
Corneal abrasion	0	2 (0.0)
Craniocerebral injury	6 (0.0)	7 (0.1)
Dislocation of vertebra	1 (0.0)	0
Epicondylitis	6 (0.0)	8 (0.1)
Epiphyseal fracture	0	1 (0.0)
Exposure to communicable disease	1 (0.0)	3 (0.0)
Eye injury	2 (0.0)	4 (0.0)
Face injury	2 (0.0)	1 (0.0)
Facial bones fracture	21 (0.2)	27 (0.2)
Fall	2 (0.0)	2 (0.0)
Fascial rupture	1 (0.0)	0
Femoral neck fracture	0	1 (0.0)
Femur fracture	16 (0.1)	15 (0.1)
Fibula fracture	11 (0.1)	10 (0.1)
Foot fracture	36 (0.3)	29 (0.2)
Forearm fracture	7 (0.1)	5 (0.0)
Foreign body	1 (0.0)	1 (0.0)
Foreign body in ear	0	1 (0.0)
Foreign body in eye	0	1 (0.0)
Foreign body in gastrointestinal tract	1 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Fracture	0	1 (0.0)
Fractured coccyx	2 (0.0)	4 (0.0)
Gastrointestinal injury	0	1 (0.0)
Gastrointestinal procedural complication	0	1 (0.0)
Gun shot wound	5 (0.0)	6 (0.0)
Hand fracture	44 (0.3)	47 (0.4)
Head injury	5 (0.0)	13 (0.1)
Hip fracture	4 (0.0)	6 (0.0)
Humerus fracture	6 (0.0)	6 (0.0)
Hyphaema	0	1 (0.0)
Iliotibial band syndrome	0	3 (0.0)
Ilium fracture	0	1 (0.0)
Incisional hernia	4 (0.0)	3 (0.0)
Injury	0	1 (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	3 (0.0)	1 (0.0)
Jaw fracture	7 (0.1)	6 (0.0)
Joint dislocation	20 (0.2)	22 (0.2)
Joint injury	16 (0.1)	30 (0.2)
Ligament injury	6 (0.0)	9 (0.1)
Ligament rupture	85 (0.7)	78 (0.6)
Ligament sprain	7 (0.1)	8 (0.1)
Limb fracture	1 (0.0)	1 (0.0)
Limb injury	25 (0.2)	20 (0.2)
Limb traumatic amputation	1 (0.0)	1 (0.0)
Lisfranc fracture	1 (0.0)	1 (0.0)
Lower limb fracture	28 (0.2)	16 (0.1)
Lumbar vertebral fracture	7 (0.1)	3 (0.0)
Mallet finger	0	1 (0.0)
Maternal drugs affecting foetus	1 (0.0)	0
Meniscus injury	87 (0.7)	78 (0.6)
Multiple fractures	0	1 (0.0)
Multiple injuries	1 (0.0)	0
Muscle injury	1 (0.0)	4 (0.0)
Muscle rupture	10 (0.1)	5 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Muscle strain	13 (0.1)	9 (0.1)
Musculoskeletal foreign body	1 (0.0)	1 (0.0)
Nail injury	0	1 (0.0)
Nasal injury	2 (0.0)	3 (0.0)
Neck injury	4 (0.0)	4 (0.0)
Nerve injury	2 (0.0)	4 (0.0)
Overdose	2 (0.0)	0
Pancreatic injury	1 (0.0)	0
Patella fracture	7 (0.1)	1 (0.0)
Pelvic fracture	5 (0.0)	2 (0.0)
Penetrating abdominal trauma	1 (0.0)	0
Penis injury	0	1 (0.0)
Peripheral nerve injury	1 (0.0)	6 (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)	0
Post laminectomy syndrome	0	1 (0.0)
Post procedural complication	1 (0.0)	0
Post procedural diarrhoea	0	1 (0.0)
Post procedural hypothyroidism	6 (0.0)	2 (0.0)
Post procedural pulmonary embolism	0	1 (0.0)
Post-traumatic neck syndrome	2 (0.0)	0
Post-traumatic pain	1 (0.0)	0
Postoperative adhesion	1 (0.0)	0
Procedural pain	3 (0.0)	3 (0.0)
Procedural pneumothorax	1 (0.0)	0
Radius fracture	10 (0.1)	9 (0.1)
Repetitive strain injury	2 (0.0)	1 (0.0)
Respiratory fume inhalation disorder	0	1 (0.0)
Retinal injury	0	1 (0.0)
Rib fracture	6 (0.0)	5 (0.0)
Road traffic accident	16 (0.1)	21 (0.2)
Scar	32 (0.2)	35 (0.3)
Sciatic nerve injury	2 (0.0)	0
Sinus barotrauma	0	1 (0.0)
Skeletal injury	4 (0.0)	5 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Skin injury	0	2 (0.0)
Skin laceration	8 (0.1)	11 (0.1)
Skull fracture	1 (0.0)	4 (0.0)
Skull fractured base	1 (0.0)	1 (0.0)
Snake bite	1 (0.0)	0
Spinal column injury	1 (0.0)	1 (0.0)
Spinal compression fracture	3 (0.0)	2 (0.0)
Spinal cord injury	1 (0.0)	1 (0.0)
Spinal cord injury cervical	1 (0.0)	0
Spinal cord injury thoracic	0	1 (0.0)
Spinal fracture	4 (0.0)	5 (0.0)
Splenic rupture	3 (0.0)	1 (0.0)
Sports injury	1 (0.0)	0
Stab wound	1 (0.0)	0
Sternal fracture	1 (0.0)	1 (0.0)
Stress fracture	0	6 (0.0)
Subarachnoid haematoma	1 (0.0)	0
Subdural haematoma	1 (0.0)	2 (0.0)
Suture rupture	1 (0.0)	0
Tendon injury	5 (0.0)	3 (0.0)
Tendon rupture	27 (0.2)	31 (0.2)
Testicular injury	1 (0.0)	1 (0.0)
Thermal burn	3 (0.0)	2 (0.0)
Thermal burns of eye	0	1 (0.0)
Thoracic vertebral fracture	1 (0.0)	1 (0.0)
Tibia fracture	19 (0.1)	18 (0.1)
Tooth fracture	1 (0.0)	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 lung injury	0	3 (0.0)
Traumatic renal injury	2 (0.0)	0
Ulna fracture	3 (0.0)	10 (0.1)
Ulnar nerve injury	0	1 (0.0)
Upper limb fracture	36 (0.3)	45 (0.3)
Uterine perforation	1 (0.0)	0
Uterine rupture	1 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Wrist fracture	39 (0.3)	46 (0.4)
Investigations	587 (4.5)	563 (4.3)
Alanine aminotransferase increased	2 (0.0)	0
Angiocardiogram	0	1 (0.0)
Angiogram	1 (0.0)	2 (0.0)
Anti-platelet antibody positive	1 (0.0)	0
Anti-thyroid antibody positive	1 (0.0)	0
Antinuclear antibody positive	0	1 (0.0)
Aortic bruit	0	1 (0.0)
Apolipoprotein E	1 (0.0)	0
Arthroscopy	47 (0.4)	59 (0.5)
Aspiration bone marrow	1 (0.0)	0
Aspiration breast	1 (0.0)	0
Aspiration joint	0	2 (0.0)
Aspiration pleural cavity	0	2 (0.0)
Biopsy	1 (0.0)	3 (0.0)
Biopsy bone marrow	0	1 (0.0)
Biopsy breast	5 (0.0)	10 (0.1)
Biopsy breast normal	5 (0.0)	3 (0.0)
Biopsy cervix	1 (0.0)	5 (0.0)
Biopsy cervix abnormal	1 (0.0)	0
Biopsy cervix normal	2 (0.0)	0
Biopsy colon	2 (0.0)	2 (0.0)
Biopsy endometrium normal	1 (0.0)	1 (0.0)
Biopsy liver	1 (0.0)	2 (0.0)
Biopsy liver normal	1 (0.0)	0
Biopsy lung	0	1 (0.0)
Biopsy lymph gland	2 (0.0)	1 (0.0)
Biopsy pharynx normal	1 (0.0)	0
Biopsy prostate	0	3 (0.0)
Biopsy site unspecified normal	1 (0.0)	0
Biopsy skin	2 (0.0)	4 (0.0)
Biopsy thyroid gland	0	1 (0.0)
Biopsy uterus	1 (0.0)	0
Blood bilirubin increased	1 (0.0)	1 (0.0)
Blood cholesterol	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Blood cholesterol increased	160 (1.2)	154 (1.2)
Blood cholinesterase decreased	0	1 (0.0)
Blood creatine phosphokinase increased	0	1 (0.0)
Blood glucose	1 (0.0)	0
Blood glucose abnormal	1 (0.0)	0
Blood glucose increased	4 (0.0)	2 (0.0)
Blood iron decreased	2 (0.0)	2 (0.0)
Blood oestrogen	0	1 (0.0)
Blood oestrogen decreased	2 (0.0)	0
Blood oestrogen increased	2 (0.0)	0
Blood potassium decreased	2 (0.0)	1 (0.0)
Blood pressure diastolic increased	1 (0.0)	1 (0.0)
Blood pressure increased	10 (0.1)	8 (0.1)
Blood prolactin increased	1 (0.0)	1 (0.0)
Blood testosterone	0	1 (0.0)
Blood testosterone decreased	54 (0.4)	57 (0.4)
Blood thyroid stimulating hormone abnormal	1 (0.0)	0
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	16 (0.1)	10 (0.1)
Blood uric acid increased	1 (0.0)	1 (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)
Bronchoscopy	2 (0.0)	3 (0.0)
Cardiac murmur	42 (0.3)	28 (0.2)
Cardiac murmur functional	0	2 (0.0)
Cardiac stress test	0	1 (0.0)
Catheterisation cardiac	3 (0.0)	3 (0.0)
Chlamydia test positive	0	1 (0.0)
Coagulation factor V level	1 (0.0)	1 (0.0)
Coagulation factor VIII level decreased	0	1 (0.0)
Colonoscopy	42 (0.3)	29 (0.2)
Colonoscopy normal	1 (0.0)	1 (0.0)
Colposcopy	3 (0.0)	2 (0.0)
Colposcopy normal	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Cystoscopy	1 (0.0)	4 (0.0)
Cystoscopy normal	0	1 (0.0)
Dehydroepiandrosterone increased	1 (0.0)	0
Diagnostic aspiration	1 (0.0)	0
Diagnostic procedure	2 (0.0)	0
Discogram	1 (0.0)	0
Ejection fraction decreased	1 (0.0)	0
Electrocardiogram QT prolonged	1 (0.0)	1 (0.0)
Electrocardiogram ST segment depression	1 (0.0)	0
Electrocardiogram abnormal	1 (0.0)	0
Endoscopy	6 (0.0)	4 (0.0)
Endoscopy upper gastrointestinal tract	6 (0.0)	4 (0.0)
Epstein-Barr virus test positive	0	1 (0.0)
False positive investigation result	0	1 (0.0)
Gene mutation identification test positive	0	1 (0.0)
Glycosylated haemoglobin increased	1 (0.0)	0
HIV test positive	60 (0.5)	52 (0.4)
HLA marker study	0	2 (0.0)
HLA-B*27 positive	1 (0.0)	1 (0.0)
Haemoglobin decreased	0	1 (0.0)
Heart rate increased	1 (0.0)	2 (0.0)
Heart rate irregular	9 (0.1)	9 (0.1)
Helicobacter test positive	1 (0.0)	0
Hepatic enzyme abnormal	1 (0.0)	0
Hepatic enzyme increased	8 (0.1)	2 (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	0	1 (0.0)
Hepatitis B test negative	0	1 (0.0)
Hepatitis C core antibody negative	0	1 (0.0)
Hepatitis C test negative	0	1 (0.0)
High density lipoprotein decreased	4 (0.0)	1 (0.0)
Hormone level abnormal	0	3 (0.0)
Human papilloma virus test	0	1 (0.0)
Human papilloma virus test positive	24 (0.2)	23 (0.2)
Hysteroscopy	5 (0.0)	4 (0.0)
Intraocular pressure increased	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Laparoscopy	15 (0.1)	11 (0.1)
Lipids increased	2 (0.0)	3 (0.0)
Lipoprotein (a) increased	0	1 (0.0)
Liver function test abnormal	0	1 (0.0)
Liver function test increased	8 (0.1)	2 (0.0)
Low density lipoprotein increased	0	1 (0.0)
Lumbar puncture	0	1 (0.0)
Lumbar puncture normal	1 (0.0)	0
Magnetic resonance imaging	0	1 (0.0)
Mammogram abnormal	3 (0.0)	0
Mean cell volume increased	0	1 (0.0)
Mediastinoscopy	0	2 (0.0)
Mumps antibody test positive	1 (0.0)	0
Mycobacterium tuberculosis complex test negative	1 (0.0)	0
Mycobacterium tuberculosis complex test positive	2 (0.0)	0
Nasoendoscopy	1 (0.0)	1 (0.0)
Oesophagogastroduodenoscopy	2 (0.0)	2 (0.0)
Oesophagoscopy	1 (0.0)	0
Pelvic laparoscopy	2 (0.0)	0
Precancerous cells present	4 (0.0)	8 (0.1)
Progesterone decreased	0	3 (0.0)
Prostatic specific antigen increased	2 (0.0)	1 (0.0)
Pulmonary function test decreased	0	1 (0.0)
Red blood cell count increased	0	1 (0.0)
Serum ferritin decreased	1 (0.0)	1 (0.0)
Serum ferritin increased	0	1 (0.0)
Sigmoidoscopy	0	1 (0.0)
Sleep study	1 (0.0)	0
Smear cervix abnormal	19 (0.1)	10 (0.1)
Streptococcus test positive	0	1 (0.0)
Thyroid function test abnormal	0	1 (0.0)
Transaminases increased	2 (0.0)	0
Tuberculin test	0	1 (0.0)
Tuberculin test positive	3 (0.0)	3 (0.0)
Vitamin B12 decreased	1 (0.0)	0
Vitamin D abnormal	0	1 (0.0)
Vitamin D decreased	4 (0.0)	9 (0.1)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Weight decreased	3 (0.0)	1 (0.0)
Weight increased	3 (0.0)	0
White blood cell count decreased	1 (0.0)	1 (0.0)
White blood cell count increased	1 (0.0)	0
X-ray	1 (0.0)	0
Metabolism and nutrition disorders	2414 (18.5)	2357 (18.0)
Abnormal loss of weight	0	1 (0.0)
Abnormal weight gain	0	1 (0.0)
Calcium deficiency	0	2 (0.0)
Central obesity	2 (0.0)	0
Cholesterosis	1 (0.0)	0
Dairy intolerance	2 (0.0)	0
Decreased appetite	1 (0.0)	2 (0.0)
Dehydration	1 (0.0)	2 (0.0)
Diabetes mellitus	13 (0.1)	10 (0.1)
Diabetes mellitus inadequate control	1 (0.0)	0
Diabetic ketoacidosis	1 (0.0)	1 (0.0)
Disaccharide metabolism disorder	1 (0.0)	0
Dyslipidaemia	158 (1.2)	121 (0.9)
Fluid retention	8 (0.1)	5 (0.0)
Folate deficiency	0	2 (0.0)
Food intolerance	1 (0.0)	2 (0.0)
Fructose intolerance	1 (0.0)	0
Glucose tolerance impaired	80 (0.6)	74 (0.6)
Gluten sensitivity	17 (0.1)	15 (0.1)
Gout	54 (0.4)	59 (0.5)
Haemochromatosis	7 (0.1)	0
Histamine intolerance	0	1 (0.0)
Hypercalcaemia	2 (0.0)	0
Hypercholesterolaemia	322 (2.5)	320 (2.4)
Hyperglycaemia	10 (0.1)	9 (0.1)
Hyperhomocysteinaemia	1 (0.0)	0
Hyperinsulinaemia	0	1 (0.0)
Hyperinsulinism	1 (0.0)	0
Hyperkalaemia	1 (0.0)	0
Hyperlactacidaemia	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Hyperlipidaemia	322 (2.5)	311 (2.4)
Hypernatraemia	1 (0.0)	0
Hyperphagia	1 (0.0)	0
Hypertriglyceridaemia	40 (0.3)	30 (0.2)
Hyperuricaemia	7 (0.1)	8 (0.1)
Hypocalcaemia	0	1 (0.0)
Hypocholesterolaemia	5 (0.0)	2 (0.0)
Hypoglycaemia	9 (0.1)	3 (0.0)
Hypokalaemia	6 (0.0)	9 (0.1)
Hypolipidaemia	0	1 (0.0)
Hypomagnesaemia	0	1 (0.0)
Hyponatraemia	1 (0.0)	0
Hypovitaminosis	1 (0.0)	2 (0.0)
Impaired fasting glucose	11 (0.1)	3 (0.0)
Insulin resistance	7 (0.1)	9 (0.1)
Insulin resistant diabetes	0	1 (0.0)
Iron deficiency	10 (0.1)	19 (0.1)
Iron metabolism disorder	0	1 (0.0)
Lactose intolerance	43 (0.3)	50 (0.4)
Latent autoimmune diabetes in adults	1 (0.0)	0
Lipid metabolism disorder	0	1 (0.0)
Lipoedema	1 (0.0)	0
Lipomatosis	0	1 (0.0)
Malnutrition	1 (0.0)	0
Metabolic acidosis	1 (0.0)	0
Metabolic disorder	1 (0.0)	0
Metabolic syndrome	12 (0.1)	2 (0.0)
Monogenic diabetes	0	1 (0.0)
Obesity	1013 (7.8)	1001 (7.6)
Overweight	180 (1.4)	200 (1.5)
Refeeding syndrome	0	1 (0.0)
Type 1 diabetes mellitus	63 (0.5)	53 (0.4)
Type 2 diabetes mellitus	405 (3.1)	419 (3.2)
Underweight	2 (0.0)	6 (0.0)
Vitamin A deficiency	2 (0.0)	0
Vitamin B complex deficiency	3 (0.0)	2 (0.0)
Vitamin B12 deficiency	24 (0.2)	21 (0.2)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Vitamin D deficiency	152 (1.2)	138 (1.1)
Vitamin E deficiency	1 (0.0)	0
Musculoskeletal and connective tissue disorders	1382 (10.6)	1355 (10.3)
Ankle impingement	0	1 (0.0)
Ankylosing spondylitis	2 (0.0)	2 (0.0)
Arthralgia	168 (1.3)	195 (1.5)
Arthritis	60 (0.5)	49 (0.4)
Arthritis reactive	1 (0.0)	1 (0.0)
Arthropathy	5 (0.0)	5 (0.0)
Articular calcification	0	1 (0.0)
Back disorder	1 (0.0)	1 (0.0)
Back pain	374 (2.9)	360 (2.7)
Bone cyst	3 (0.0)	3 (0.0)
Bone deformity	0	1 (0.0)
Bone disorder	0	1 (0.0)
Bone hypertrophy	1 (0.0)	0
Bone lesion	1 (0.0)	0
Bursitis	14 (0.1)	14 (0.1)
CREST syndrome	0	1 (0.0)
Cervical spinal stenosis	1 (0.0)	2 (0.0)
Chondromalacia	2 (0.0)	0
Chondropathy	3 (0.0)	2 (0.0)
Coccydynia	1 (0.0)	0
Compartment syndrome	3 (0.0)	3 (0.0)
Connective tissue disorder	0	1 (0.0)
Costochondritis	2 (0.0)	1 (0.0)
Deformity thorax	1 (0.0)	0
Diastasis recti abdominis	1 (0.0)	0
Diffuse idiopathic skeletal hyperostosis	1 (0.0)	0
Dupuytren's contracture	1 (0.0)	2 (0.0)
Dwarfism	1 (0.0)	0
Eagle's syndrome	1 (0.0)	0
Epiphysiolysis	1 (0.0)	0
Exostosis	25 (0.2)	16 (0.1)
Facet joint syndrome	3 (0.0)	0
Femoroacetabular impingement	1 (0.0)	2 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Fibromyalgia	70 (0.5)	47 (0.4)
Fistula	1 (0.0)	0
Flank pain	1 (0.0)	1 (0.0)
Floating patella	0	1 (0.0)
Foot deformity	32 (0.2)	36 (0.3)
Fracture nonunion	0	1 (0.0)
Growth retardation	0	1 (0.0)
Hypermobility syndrome	4 (0.0)	3 (0.0)
Intervertebral disc compression	2 (0.0)	6 (0.0)
Intervertebral disc degeneration	56 (0.4)	38 (0.3)
Intervertebral disc disorder	6 (0.0)	1 (0.0)
Intervertebral disc displacement	0	1 (0.0)
Intervertebral disc protrusion	140 (1.1)	108 (0.8)
Jaw cyst	1 (0.0)	0
Jaw disorder	2 (0.0)	2 (0.0)
Joint effusion	0	1 (0.0)
Joint instability	2 (0.0)	2 (0.0)
Joint range of motion decreased	0	1 (0.0)
Joint stiffness	1 (0.0)	0
Joint swelling	2 (0.0)	4 (0.0)
Juvenile idiopathic arthritis	2 (0.0)	1 (0.0)
Knee deformity	0	1 (0.0)
Kyphosis	1 (0.0)	2 (0.0)
Ligament disorder	1 (0.0)	1 (0.0)
Ligament laxity	1 (0.0)	1 (0.0)
Limb asymmetry	3 (0.0)	1 (0.0)
Limb deformity	0	1 (0.0)
Limb mass	1 (0.0)	1 (0.0)
Lordosis	0	1 (0.0)
Lumbar spinal stenosis	6 (0.0)	3 (0.0)
Metatarsalgia	0	1 (0.0)
Mobility decreased	0	2 (0.0)
Morphoea	1 (0.0)	0
Muscle atrophy	1 (0.0)	1 (0.0)
Muscle contracture	0	1 (0.0)
Muscle disorder	0	1 (0.0)
Muscle spasms	40 (0.3)	54 (0.4)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Muscle tightness	2 (0.0)	2 (0.0)
Muscle twitching	1 (0.0)	0
Muscular weakness	2 (0.0)	1 (0.0)
Musculoskeletal chest pain	3 (0.0)	1 (0.0)
Musculoskeletal disorder	1 (0.0)	0
Musculoskeletal pain	1 (0.0)	1 (0.0)
Musculoskeletal stiffness	1 (0.0)	1 (0.0)
Myalgia	42 (0.3)	58 (0.4)
Myalgia intercostal	0	1 (0.0)
Myofascial pain syndrome	3 (0.0)	3 (0.0)
Myositis	0	1 (0.0)
Neck mass	1 (0.0)	0
Neck pain	47 (0.4)	53 (0.4)
Neuropathic arthropathy	1 (0.0)	0
Os trigonum syndrome	1 (0.0)	0
Osteitis	1 (0.0)	0
Osteitis deformans	0	1 (0.0)
Osteoarthritis	245 (1.9)	234 (1.8)
Osteochondritis	1 (0.0)	2 (0.0)
Osteochondrosis	11 (0.1)	6 (0.0)
Osteolysis	0	1 (0.0)
Osteonecrosis	4 (0.0)	4 (0.0)
Osteopenia	12 (0.1)	14 (0.1)
Osteoporosis	15 (0.1)	20 (0.2)
Pain in extremity	22 (0.2)	28 (0.2)
Pain in jaw	1 (0.0)	4 (0.0)
Patellofemoral pain syndrome	8 (0.1)	3 (0.0)
Periarthritis	5 (0.0)	5 (0.0)
Perthes disease	1 (0.0)	0
Plantar fascial fibromatosis	0	1 (0.0)
Plantar fasciitis	21 (0.2)	25 (0.2)
Plica syndrome	0	2 (0.0)
Polyarthritis	2 (0.0)	1 (0.0)
Posterior tibial tendon dysfunction	1 (0.0)	0
Prognathism	1 (0.0)	0
Psoriatic arthropathy	1 (0.0)	4 (0.0)
Retrognathia	1 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Reynold's syndrome	1 (0.0)	0
Rhabdomyolysis	2 (0.0)	3 (0.0)
Rheumatic fever	1 (0.0)	1 (0.0)
Rheumatoid arthritis	15 (0.1)	12 (0.1)
Rotator cuff syndrome	59 (0.5)	40 (0.3)
Sacroiliac joint dysfunction	1 (0.0)	0
Sacroiliitis	2 (0.0)	2 (0.0)
Scapular dyskinesis	1 (0.0)	0
Scleroderma	1 (0.0)	1 (0.0)
Scoliosis	44 (0.3)	48 (0.4)
Seronegative arthritis	1 (0.0)	1 (0.0)
Sjogren's syndrome	1 (0.0)	2 (0.0)
Soft tissue mass	0	1 (0.0)
Spinal deformity	0	2 (0.0)
Spinal disorder	8 (0.1)	4 (0.0)
Spinal flattening	0	1 (0.0)
Spinal osteoarthritis	44 (0.3)	39 (0.3)
Spinal pain	5 (0.0)	6 (0.0)
Spinal stenosis	9 (0.1)	8 (0.1)
Spondylitis	5 (0.0)	9 (0.1)
Spondyloarthropathy	2 (0.0)	0
Spondylolisthesis	6 (0.0)	6 (0.0)
Spondylolysis	4 (0.0)	0
Symphysiolysis	0	1 (0.0)
Synovial cyst	13 (0.1)	13 (0.1)
Synovitis	0	1 (0.0)
Systemic lupus erythematosus	2 (0.0)	1 (0.0)
Temporomandibular joint syndrome	26 (0.2)	21 (0.2)
Tendon disorder	3 (0.0)	2 (0.0)
Tendon laxity	0	2 (0.0)
Tendon pain	2 (0.0)	1 (0.0)
Tendonitis	27 (0.2)	29 (0.2)
Tenosynovitis	2 (0.0)	1 (0.0)
Tenosynovitis stenosans	1 (0.0)	3 (0.0)
Torticollis	1 (0.0)	2 (0.0)
Trigger finger	10 (0.1)	7 (0.1)
Vertebral foraminal stenosis	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Vertebral osteophyte	0	2 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	487 (3.7)	492 (3.8)
Abdominal neoplasm	1 (0.0)	0
Abdominal wall neoplasm	0	1 (0.0)
Acoustic neuroma	2 (0.0)	1 (0.0)
Acute lymphocytic leukaemia	1 (0.0)	1 (0.0)
Adenocarcinoma of the cervix	0	1 (0.0)
Adenoid cystic carcinoma	1 (0.0)	0
Adenoma benign	3 (0.0)	2 (0.0)
Adrenal adenoma	2 (0.0)	2 (0.0)
Adrenal neoplasm	0	1 (0.0)
Angiomyolipoma	0	1 (0.0)
Anogenital warts	1 (0.0)	3 (0.0)
Appendix cancer	1 (0.0)	0
Astrocytoma	1 (0.0)	0
B-cell lymphoma	1 (0.0)	0
Basal cell carcinoma	41 (0.3)	41 (0.3)
Basosquamous carcinoma	0	1 (0.0)
Basosquamous carcinoma of skin	0	1 (0.0)
Benign bone neoplasm	1 (0.0)	2 (0.0)
Benign breast neoplasm	10 (0.1)	10 (0.1)
Benign cardiac neoplasm	0	1 (0.0)
Benign hydatidiform mole	1 (0.0)	0
Benign lung neoplasm	0	2 (0.0)
Benign muscle neoplasm	1 (0.0)	0
Benign neoplasm	3 (0.0)	3 (0.0)
Benign neoplasm of adrenal gland	0	1 (0.0)
Benign neoplasm of bladder	1 (0.0)	0
Benign neoplasm of eye	0	1 (0.0)
Benign neoplasm of skin	3 (0.0)	3 (0.0)
Benign neoplasm of thyroid gland	11 (0.1)	15 (0.1)
Benign ovarian tumour	2 (0.0)	1 (0.0)
Benign uterine neoplasm	1 (0.0)	1 (0.0)
Benign vascular neoplasm	0	1 (0.0)
Bladder cancer	1 (0.0)	0
Bowen's disease	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Brain neoplasm	1 (0.0)	0
Brain neoplasm benign	1 (0.0)	1 (0.0)
Brain neoplasm malignant	1 (0.0)	0
Breast cancer	31 (0.2)	29 (0.2)
Breast cancer metastatic	1 (0.0)	0
Breast cancer stage I	1 (0.0)	1 (0.0)
Breast fibroma	2 (0.0)	0
Breast neoplasm	1 (0.0)	2 (0.0)
Carcinoid tumour	1 (0.0)	0
Carcinoid tumour of the gastrointestinal tract	1 (0.0)	0
Cervix carcinoma	6 (0.0)	6 (0.0)
Cervix carcinoma stage 0	1 (0.0)	0
Cholesteatoma	2 (0.0)	3 (0.0)
Chronic lymphocytic leukaemia	1 (0.0)	0
Colon adenoma	3 (0.0)	1 (0.0)
Colon cancer	3 (0.0)	4 (0.0)
Colon cancer stage II	0	1 (0.0)
Colon cancer stage III	1 (0.0)	0
Cutaneous T-cell lymphoma	0	1 (0.0)
Desmoplastic melanoma	0	1 (0.0)
Dysplastic naevus	1 (0.0)	2 (0.0)
Ear neoplasm malignant	0	1 (0.0)
Elastofibroma	1 (0.0)	0
Enchondromatosis	0	1 (0.0)
Endometrial cancer	0	1 (0.0)
Essential thrombocythaemia	2 (0.0)	0
Ewing's sarcoma	0	1 (0.0)
Extragonadal primary seminoma (pure)	0	1 (0.0)
Eye naevus	0	1 (0.0)
Eyelid haemangioma	1 (0.0)	0
Fibroadenoma of breast	3 (0.0)	8 (0.1)
Fibroma	4 (0.0)	3 (0.0)
Fibrosarcoma	1 (0.0)	0
Fibrous histiocytoma	1 (0.0)	1 (0.0)
Ganglioneuroblastoma	0	1 (0.0)
Gastric neoplasm	1 (0.0)	0
Gastrointestinal melanoma	1 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Gastrointestinal tract adenoma	1 (0.0)	0
Gestational trophoblastic tumour	1 (0.0)	0
Haemangioma	1 (0.0)	5 (0.0)
Haemangioma of spleen	1 (0.0)	0
Hepatic adenoma	1 (0.0)	1 (0.0)
Hodgkin's disease	4 (0.0)	6 (0.0)
Intraductal proliferative breast lesion	0	3 (0.0)
Intraocular melanoma	1 (0.0)	0
Iris melanoma	0	1 (0.0)
Langerhans' cell histiocytosis	1 (0.0)	0
Laryngeal papilloma	1 (0.0)	0
Leiomyoma	2 (0.0)	3 (0.0)
Leukaemia	3 (0.0)	2 (0.0)
Lip and/or oral cavity cancer	1 (0.0)	0
Lip squamous cell carcinoma	1 (0.0)	0
Lipoma	14 (0.1)	16 (0.1)
Lipoma of breast	1 (0.0)	0
Lobular breast carcinoma in situ	1 (0.0)	0
Lung adenocarcinoma	1 (0.0)	0
Lung neoplasm malignant	0	1 (0.0)
Lymphangioma	1 (0.0)	0
Lymphoma	0	3 (0.0)
Malignant melanoma	26 (0.2)	10 (0.1)
Malignant melanoma in situ	2 (0.0)	1 (0.0)
Malignant melanoma stage I	1 (0.0)	1 (0.0)
Melanocytic naevus	9 (0.1)	12 (0.1)
Meningioma	3 (0.0)	5 (0.0)
Meningioma benign	2 (0.0)	1 (0.0)
Nasopharyngeal cancer	1 (0.0)	0
Neoplasm	0	3 (0.0)
Neoplasm malignant	0	2 (0.0)
Neoplasm of appendix	1 (0.0)	0
Nephroblastoma	1 (0.0)	1 (0.0)
Nervous system neoplasm benign	0	1 (0.0)
Neurilemmoma benign	0	1 (0.0)
Neurofibroma	1 (0.0)	0
Neuroma	5 (0.0)	4 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Non-Hodgkin's lymphoma	2 (0.0)	2 (0.0)
Oesophageal adenocarcinoma	1 (0.0)	0
Osteochondroma	0	3 (0.0)
Osteoma	0	1 (0.0)
Osteosarcoma	0	2 (0.0)
Ovarian cancer	1 (0.0)	4 (0.0)
Ovarian cancer stage III	0	1 (0.0)
Ovarian cancer stage IV	1 (0.0)	0
Ovarian fibroma	2 (0.0)	0
Ovarian germ cell teratoma	1 (0.0)	0
Ovarian germ cell teratoma benign	0	3 (0.0)
Ovarian neoplasm	1 (0.0)	1 (0.0)
Papillary thyroid cancer	5 (0.0)	8 (0.1)
Parathyroid tumour benign	1 (0.0)	2 (0.0)
Phaeochromocytoma	0	1 (0.0)
Phyllodes tumour	1 (0.0)	0
Pineal germinoma	0	1 (0.0)
Pituitary tumour	0	2 (0.0)
Pituitary tumour benign	8 (0.1)	9 (0.1)
Pleural neoplasm	0	1 (0.0)
Prolactin-producing pituitary tumour	1 (0.0)	2 (0.0)
Prostate cancer	5 (0.0)	8 (0.1)
Rectal cancer	0	1 (0.0)
Renal cancer	3 (0.0)	1 (0.0)
Renal cell carcinoma	1 (0.0)	0
Renal hamartoma	1 (0.0)	1 (0.0)
Renal neoplasm	1 (0.0)	0
Retinoblastoma	1 (0.0)	1 (0.0)
Salivary gland neoplasm	0	1 (0.0)
Sarcoma	0	1 (0.0)
Schwannoma	0	1 (0.0)
Seborrhoeic keratosis	0	2 (0.0)
Skin cancer	2 (0.0)	2 (0.0)
Skin papilloma	10 (0.1)	5 (0.0)
Soft tissue sarcoma	0	1 (0.0)
Spinal cord neoplasm	0	1 (0.0)
Squamous cell carcinoma	9 (0.1)	4 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Squamous cell carcinoma of lung	1 (0.0)	0
Squamous cell carcinoma of skin	3 (0.0)	4 (0.0)
Sweat gland tumour	0	1 (0.0)
Synovial sarcoma	0	1 (0.0)
Testis cancer	11 (0.1)	9 (0.1)
Thymoma	1 (0.0)	0
Thyroid cancer	19 (0.1)	22 (0.2)
Thyroid neoplasm	0	2 (0.0)
Tongue neoplasm	0	1 (0.0)
Uterine cancer	4 (0.0)	2 (0.0)
Uterine leiomyoma	159 (1.2)	161 (1.2)
Uterine neoplasm	1 (0.0)	0
Vulval cancer	2 (0.0)	1 (0.0)
Vulvovaginal warts	1 (0.0)	0
Xanthogranuloma	1 (0.0)	0
Nervous system disorders	1466 (11.2)	1450 (11.1)
Akathisia	1 (0.0)	0
Amnesia	2 (0.0)	5 (0.0)
Anosmia	2 (0.0)	2 (0.0)
Arachnoid cyst	5 (0.0)	1 (0.0)
Arachnoiditis	0	1 (0.0)
Autonomic nervous system imbalance	0	1 (0.0)
Balance disorder	0	1 (0.0)
Brachial plexopathy	1 (0.0)	0
Brain injury	2 (0.0)	1 (0.0)
Brain stem stroke	1 (0.0)	0
Carotid arterial embolus	0	1 (0.0)
Carotid arteriosclerosis	1 (0.0)	1 (0.0)
Carotid artery dissection	3 (0.0)	1 (0.0)
Carotid artery stenosis	3 (0.0)	0
Carpal tunnel syndrome	62 (0.5)	64 (0.5)
Central auditory processing disorder	2 (0.0)	0
Cerebellar infarction	1 (0.0)	0
Cerebellar stroke	2 (0.0)	0
Cerebral atrophy	1 (0.0)	0
Cerebral cyst	1 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Cerebral haemorrhage	1 (0.0)	1 (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	22 (0.2)	18 (0.1)
Cervical radiculopathy	6 (0.0)	7 (0.1)
Cervicobrachial syndrome	1 (0.0)	0
Cervicogenic headache	0	1 (0.0)
Chronic inflammatory demyelinating polyradiculoneuropathy	0	2 (0.0)
Circadian rhythm sleep disorder	1 (0.0)	0
Cluster headache	8 (0.1)	4 (0.0)
Cognitive disorder	0	1 (0.0)
Colloid brain cyst	0	1 (0.0)
Complex regional pain syndrome	1 (0.0)	2 (0.0)
Convulsive threshold lowered	0	1 (0.0)
Cramp-fasciculation syndrome	0	1 (0.0)
Cranial nerve disorder	0	1 (0.0)
Cubital tunnel syndrome	0	1 (0.0)
Diabetic neuropathy	16 (0.1)	14 (0.1)
Disturbance in attention	2 (0.0)	3 (0.0)
Dizziness	11 (0.1)	6 (0.0)
Drug withdrawal headache	1 (0.0)	0
Dyslexia	4 (0.0)	3 (0.0)
Dystonia	2 (0.0)	0
Encephalopathy	0	2 (0.0)
Epilepsy	32 (0.2)	35 (0.3)
Essential tremor	6 (0.0)	9 (0.1)
Extrapyramidal disorder	1 (0.0)	2 (0.0)
Facial nerve disorder	0	1 (0.0)
Facial neuralgia	1 (0.0)	0
Facial paralysis	7 (0.1)	7 (0.1)
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	0	3 (0.0)
Glossopharyngeal neuralgia	1 (0.0)	0
Haemorrhagic stroke	1 (0.0)	3 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Headache	352 (2.7)	366 (2.8)
Hemiparesis	1 (0.0)	3 (0.0)
Hemiplegia	0	2 (0.0)
Hemiplegic migraine	1 (0.0)	1 (0.0)
Hydrocephalus	2 (0.0)	6 (0.0)
Hypersomnia	7 (0.1)	7 (0.1)
Hypoaesthesia	4 (0.0)	6 (0.0)
Hyposmia	0	2 (0.0)
IVth nerve paralysis	1 (0.0)	0
Idiopathic generalised epilepsy	0	1 (0.0)
Idiopathic intracranial hypertension	1 (0.0)	3 (0.0)
Intention tremor	0	1 (0.0)
Intercostal neuralgia	0	1 (0.0)
Intracranial aneurysm	3 (0.0)	4 (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	2 (0.0)	1 (0.0)
Juvenile myoclonic epilepsy	0	1 (0.0)
Lumbar radiculopathy	8 (0.1)	10 (0.1)
Lumbosacral radiculopathy	0	1 (0.0)
Medication overuse headache	1 (0.0)	0
Memory impairment	1 (0.0)	0
Mental impairment	1 (0.0)	0
Migraine	631 (4.8)	666 (5.1)
Migraine with aura	16 (0.1)	15 (0.1)
Migraine without aura	19 (0.1)	14 (0.1)
Monoplegia	1 (0.0)	0
Morton's neuralgia	2 (0.0)	3 (0.0)
Multiple sclerosis	1 (0.0)	2 (0.0)
Muscle contractions involuntary	1 (0.0)	3 (0.0)
Myasthenia gravis	1 (0.0)	1 (0.0)
Narcolepsy	5 (0.0)	11 (0.1)
Nerve compression	13 (0.1)	8 (0.1)
Nervous system disorder	1 (0.0)	1 (0.0)
Neuralgia	19 (0.1)	7 (0.1)
Neuritis	1 (0.0)	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Neuropathy peripheral	52 (0.4)	43 (0.3)
Nystagmus	2 (0.0)	2 (0.0)
Occipital neuralgia	2 (0.0)	1 (0.0)
Optic neuritis	2 (0.0)	1 (0.0)
Paraesthesia	4 (0.0)	6 (0.0)
Paraparesis	0	1 (0.0)
Paraplegia	0	1 (0.0)
Parkinson's disease	2 (0.0)	0
Paroxysmal choreoathetosis	0	1 (0.0)
Perineurial cyst	1 (0.0)	0
Periodic limb movement disorder	1 (0.0)	2 (0.0)
Peripheral nerve lesion	1 (0.0)	0
Peroneal nerve palsy	1 (0.0)	2 (0.0)
Petit mal epilepsy	0	2 (0.0)
Piriformis syndrome	2 (0.0)	0
Polyneuropathy	1 (0.0)	0
Post herpetic neuralgia	1 (0.0)	2 (0.0)
Post-traumatic epilepsy	0	1 (0.0)
Post-traumatic headache	1 (0.0)	2 (0.0)
Posterior reversible encephalopathy syndrome	0	1 (0.0)
Postural tremor	1 (0.0)	0
Presyncope	1 (0.0)	2 (0.0)
Psychomotor hyperactivity	0	3 (0.0)
Radial nerve compression	1 (0.0)	0
Radiculopathy	5 (0.0)	3 (0.0)
Restless legs syndrome	38 (0.3)	46 (0.4)
Ruptured cerebral aneurysm	0	1 (0.0)
Sciatica	41 (0.3)	41 (0.3)
Seizure	25 (0.2)	21 (0.2)
Serotonin syndrome	1 (0.0)	1 (0.0)
Shift work disorder	3 (0.0)	1 (0.0)
Sinus headache	24 (0.2)	18 (0.1)
Sleep deficit	1 (0.0)	1 (0.0)
Somnolence	1 (0.0)	0
Spasmodic dysphonia	0	1 (0.0)
Speech disorder	0	1 (0.0)
Spinal cord disorder	1 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Syncope	16 (0.1)	12 (0.1)
Tardive dyskinesia	2 (0.0)	1 (0.0)
Tarsal tunnel syndrome	4 (0.0)	1 (0.0)
Temporal lobe epilepsy	1 (0.0)	0
Tension headache	92 (0.7)	53 (0.4)
Thoracic outlet syndrome	0	3 (0.0)
Transient ischaemic attack	9 (0.1)	12 (0.1)
Tremor	6 (0.0)	3 (0.0)
Trigeminal nerve disorder	0	1 (0.0)
Trigeminal neuralgia	5 (0.0)	2 (0.0)
Vertebral artery dissection	1 (0.0)	0
Vestibular migraine	1 (0.0)	3 (0.0)
Visual field defect	0	1 (0.0)
Vocal cord paralysis	0	1 (0.0)
Pregnancy, puerperium and perinatal conditions	93 (0.7)	103 (0.8)
Abnormal cord insertion	1 (0.0)	0
Abortion	5 (0.0)	2 (0.0)
Abortion incomplete	0	1 (0.0)
Abortion spontaneous	15 (0.1)	17 (0.1)
Breech presentation	1 (0.0)	1 (0.0)
Cephalo-pelvic disproportion	0	1 (0.0)
Complication of pregnancy	1 (0.0)	0
Delivery	33 (0.3)	32 (0.2)
Eclampsia	1 (0.0)	0
Ectopic pregnancy	12 (0.1)	16 (0.1)
Foetal death	0	1 (0.0)
Foetal distress syndrome	0	1 (0.0)
Gestational diabetes	10 (0.1)	14 (0.1)
Gestational hypertension	1 (0.0)	4 (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)	1 (0.0)
Post abortion haemorrhage	0	1 (0.0)
Postpartum haemorrhage	2 (0.0)	3 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Pre-eclampsia	8 (0.1)	5 (0.0)
Pregnancy	3 (0.0)	7 (0.1)
Premature baby	1 (0.0)	2 (0.0)
Premature labour	1 (0.0)	0
Premature separation of placenta	0	1 (0.0)
Stillbirth	0	1 (0.0)
Unintended pregnancy	0	1 (0.0)
Product issues	0	1 (0.0)
Device malfunction	0	1 (0.0)
Psychiatric disorders	2695 (20.6)	2819 (21.5)
Adjustment disorder	3 (0.0)	7 (0.1)
Adjustment disorder with depressed mood	6 (0.0)	5 (0.0)
Adjustment disorder with mixed anxiety and depressed mood	3 (0.0)	3 (0.0)
Aerophobia	0	1 (0.0)
Affect lability	0	1 (0.0)
Affective disorder	9 (0.1)	4 (0.0)
Aggression	0	1 (0.0)
Alcohol abuse	8 (0.1)	9 (0.1)
Alcohol problem	0	1 (0.0)
Alcohol use disorder	1 (0.0)	2 (0.0)
Alcoholism	8 (0.1)	10 (0.1)
Anger	1 (0.0)	3 (0.0)
Anorexia nervosa	2 (0.0)	3 (0.0)
Anxiety	1208 (9.2)	1264 (9.7)
Anxiety disorder	94 (0.7)	87 (0.7)
Attention deficit hyperactivity disorder	486 (3.7)	458 (3.5)
Autism spectrum disorder	19 (0.1)	18 (0.1)
Behaviour disorder	1 (0.0)	1 (0.0)
Binge eating	3 (0.0)	7 (0.1)
Bipolar I disorder	4 (0.0)	5 (0.0)
Bipolar II disorder	15 (0.1)	9 (0.1)
Bipolar disorder	116 (0.9)	119 (0.9)
Borderline personality disorder	4 (0.0)	1 (0.0)
Bruxism	0	3 (0.0)
Bulimia nervosa	2 (0.0)	4 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Chronic tic disorder	1 (0.0)	0
Cyclothymic disorder	1 (0.0)	2 (0.0)
Dependence	1 (0.0)	1 (0.0)
Depressed mood	2 (0.0)	0
Depression	1114 (8.5)	1133 (8.7)
Depression suicidal	0	1 (0.0)
Depressive symptom	1 (0.0)	0
Dissociative disorder	0	1 (0.0)
Drug abuse	12 (0.1)	14 (0.1)
Drug dependence	7 (0.1)	7 (0.1)
Drug use disorder	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)
Gambling disorder	0	1 (0.0)
Gastrointestinal somatic symptom disorder	1 (0.0)	0
Gender dysphoria	5 (0.0)	2 (0.0)
Generalised anxiety disorder	71 (0.5)	81 (0.6)
Grief reaction	0	1 (0.0)
Hallucination	0	1 (0.0)
Initial insomnia	0	2 (0.0)
Insomnia	475 (3.6)	501 (3.8)
Intentional self-injury	1 (0.0)	0
Intermittent explosive disorder	0	1 (0.0)
Irritability	1 (0.0)	3 (0.0)
Libido decreased	7 (0.1)	4 (0.0)
Major depression	69 (0.5)	91 (0.7)
Mania	0	2 (0.0)
Mental disorder	3 (0.0)	3 (0.0)
Mood swings	1 (0.0)	1 (0.0)
Nicotine dependence	16 (0.1)	11 (0.1)
Nightmare	1 (0.0)	1 (0.0)
Obsessive-compulsive disorder	34 (0.3)	37 (0.3)
Obsessive-compulsive personality disorder	0	1 (0.0)
Obsessive-compulsive symptom	1 (0.0)	0
Oppositional defiant disorder	0	4 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Panic attack	22 (0.2)	21 (0.2)
Panic disorder	13 (0.1)	7 (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	1 (0.0)	10 (0.1)
Personality disorder	0	1 (0.0)
Post-traumatic amnestic disorder	0	1 (0.0)
Post-traumatic stress disorder	82 (0.6)	83 (0.6)
Postpartum anxiety	2 (0.0)	0
Premature ejaculation	1 (0.0)	5 (0.0)
Psychotic disorder	2 (0.0)	2 (0.0)
Rapid eye movements sleep abnormal	1 (0.0)	0
Restlessness	0	2 (0.0)
Schizoaffective disorder	5 (0.0)	2 (0.0)
Schizophrenia	17 (0.1)	19 (0.1)
Seasonal affective disorder	7 (0.1)	4 (0.0)
Selective eating disorder	1 (0.0)	1 (0.0)
Sleep disorder	12 (0.1)	19 (0.1)
Sleep disorder due to general medical condition, insomnia type	1 (0.0)	0
Sleep terror	2 (0.0)	1 (0.0)
Social anxiety disorder	7 (0.1)	1 (0.0)
Somatic symptom disorder	1 (0.0)	1 (0.0)
Somnambulism	0	1 (0.0)
Stress	2 (0.0)	2 (0.0)
Substance abuse	4 (0.0)	1 (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)	2 (0.0)
Tachyphrenia	0	1 (0.0)
Tic	2 (0.0)	2 (0.0)
Tobacco abuse	8 (0.1)	4 (0.0)
Trichotillomania	2 (0.0)	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Renal and urinary disorders	311 (2.4)	313 (2.4)
Acute kidney injury	2 (0.0)	1 (0.0)
Bladder disorder	0	1 (0.0)
Bladder diverticulum	1 (0.0)	0
Bladder dysfunction	0	1 (0.0)
Bladder irritation	0	1 (0.0)
Bladder malposition acquired	1 (0.0)	0
Bladder obstruction	1 (0.0)	1 (0.0)
Bladder perforation	0	1 (0.0)
Bladder prolapse	5 (0.0)	5 (0.0)
Bladder spasm	4 (0.0)	2 (0.0)
Bladder stenosis	1 (0.0)	0
Calculus bladder	0	2 (0.0)
Calculus urinary	0	3 (0.0)
Chronic kidney disease	13 (0.1)	12 (0.1)
Cystitis glandularis	0	1 (0.0)
Cystitis interstitial	7 (0.1)	2 (0.0)
Dysuria	3 (0.0)	4 (0.0)
End stage renal disease	1 (0.0)	0
Glomerulonephritis membranous	0	1 (0.0)
Haematuria	4 (0.0)	10 (0.1)
Hydronephrosis	3 (0.0)	1 (0.0)
Hypercalciuria	3 (0.0)	1 (0.0)
Hypertonic bladder	35 (0.3)	33 (0.3)
IgA nephropathy	0	1 (0.0)
Incontinence	3 (0.0)	3 (0.0)
Lupus nephritis	0	1 (0.0)
Microalbuminuria	5 (0.0)	1 (0.0)
Micturition disorder	0	1 (0.0)
Micturition urgency	3 (0.0)	2 (0.0)
Mixed incontinence	1 (0.0)	0
Nephritis	0	1 (0.0)
Nephrolithiasis	163 (1.2)	162 (1.2)
Nephropathy	2 (0.0)	2 (0.0)
Nephrotic syndrome	1 (0.0)	2 (0.0)
Neurogenic bladder	0	2 (0.0)
Nocturia	11 (0.1)	10 (0.1)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Pollakiuria	4 (0.0)	6 (0.0)
Polyuria	0	1 (0.0)
Post streptococcal glomerulonephritis	1 (0.0)	0
Proteinuria	0	2 (0.0)
Reflux nephropathy	1 (0.0)	0
Renal atrophy	0	1 (0.0)
Renal colic	2 (0.0)	0
Renal cyst	4 (0.0)	6 (0.0)
Renal disorder	2 (0.0)	0
Renal failure	1 (0.0)	3 (0.0)
Renal impairment	1 (0.0)	2 (0.0)
Renal necrosis	0	1 (0.0)
Single functional kidney	1 (0.0)	0
Stress urinary incontinence	13 (0.1)	9 (0.1)
Trigonitis	1 (0.0)	0
Ureteral disorder	1 (0.0)	0
Ureteric stenosis	1 (0.0)	2 (0.0)
Urethral dilatation	0	1 (0.0)
Urethral disorder	0	2 (0.0)
Urethral prolapse	0	1 (0.0)
Urethral stenosis	3 (0.0)	2 (0.0)
Urge incontinence	4 (0.0)	1 (0.0)
Urinary hesitation	2 (0.0)	0
Urinary incontinence	17 (0.1)	14 (0.1)
Urinary retention	2 (0.0)	6 (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	754 (5.8)	749 (5.7)
Adenomyosis	7 (0.1)	9 (0.1)
Adnexa uteri cyst	1 (0.0)	0
Amenorrhoea	15 (0.1)	8 (0.1)
Anisomastia	1 (0.0)	1 (0.0)
Atrophic vulvovaginitis	4 (0.0)	3 (0.0)
Azoospermia	1 (0.0)	1 (0.0)
Bartholin's cyst	1 (0.0)	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Benign prostatic hyperplasia	31 (0.2)	39 (0.3)
Breast calcifications	1 (0.0)	0
Breast cyst	6 (0.0)	6 (0.0)
Breast enlargement	5 (0.0)	4 (0.0)
Breast mass	8 (0.1)	7 (0.1)
Breast pain	3 (0.0)	1 (0.0)
Breast swelling	1 (0.0)	0
Cervical cyst	2 (0.0)	0
Cervical dysplasia	13 (0.1)	12 (0.1)
Cervix disorder	0	1 (0.0)
Cystocele	0	1 (0.0)
Dysfunctional uterine bleeding	8 (0.1)	2 (0.0)
Dysmenorrhoea	66 (0.5)	79 (0.6)
Dyspareunia	4 (0.0)	2 (0.0)
Ectropion of cervix	1 (0.0)	0
Endometrial disorder	0	1 (0.0)
Endometrial hyperplasia	4 (0.0)	2 (0.0)
Endometrial thickening	1 (0.0)	0
Endometriosis	108 (0.8)	91 (0.7)
Epididymal cyst	1 (0.0)	2 (0.0)
Erectile dysfunction	56 (0.4)	80 (0.6)
Fallopian tube adhesion	0	1 (0.0)
Fallopian tube cyst	0	1 (0.0)
Fallopian tube disorder	0	1 (0.0)
Fallopian tube obstruction	1 (0.0)	5 (0.0)
Female genital tract fistula	0	1 (0.0)
Fibrocystic breast disease	14 (0.1)	9 (0.1)
Genital lesion	0	1 (0.0)
Genital rash	1 (0.0)	0
Gynaecomastia	5 (0.0)	7 (0.1)
Infertility	10 (0.1)	9 (0.1)
Infertility female	4 (0.0)	7 (0.1)
Infertility male	2 (0.0)	1 (0.0)
Lactation puerperal increased	0	1 (0.0)
Mastoptosis	0	1 (0.0)
Menometrorrhagia	3 (0.0)	1 (0.0)
Menopausal symptoms	13 (0.1)	21 (0.2)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Menorrhagia	109 (0.8)	94 (0.7)
Menstrual discomfort	1 (0.0)	0
Menstrual disorder	12 (0.1)	17 (0.1)
Menstruation irregular	32 (0.2)	23 (0.2)
Metrorrhagia	3 (0.0)	4 (0.0)
Micromastia	1 (0.0)	0
Oligomenorrhoea	2 (0.0)	2 (0.0)
Oligospermia	1 (0.0)	0
Ovarian cyst	61 (0.5)	67 (0.5)
Ovarian cyst ruptured	2 (0.0)	1 (0.0)
Ovarian failure	0	3 (0.0)
Ovarian haemorrhage	1 (0.0)	0
Ovarian mass	1 (0.0)	1 (0.0)
Ovarian rupture	1 (0.0)	1 (0.0)
Ovulation pain	0	1 (0.0)
Pelvic pain	4 (0.0)	1 (0.0)
Perineal cyst	0	1 (0.0)
Peyronie's disease	0	1 (0.0)
Polycystic ovaries	103 (0.8)	92 (0.7)
Polymenorrhoea	1 (0.0)	0
Postmenopausal haemorrhage	0	1 (0.0)
Premature menopause	9 (0.1)	4 (0.0)
Premenstrual dysphoric disorder	8 (0.1)	8 (0.1)
Premenstrual headache	0	1 (0.0)
Premenstrual syndrome	5 (0.0)	5 (0.0)
Prostatic calcification	0	1 (0.0)
Prostatic disorder	2 (0.0)	2 (0.0)
Prostatism	2 (0.0)	0
Prostatitis	4 (0.0)	2 (0.0)
Prostatomegaly	9 (0.1)	10 (0.1)
Rectocele	2 (0.0)	2 (0.0)
Sexual dysfunction	0	2 (0.0)
Testicular cyst	1 (0.0)	1 (0.0)
Testicular pain	2 (0.0)	0
Testicular swelling	0	1 (0.0)
Testicular torsion	4 (0.0)	5 (0.0)
Uterine adhesions	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Uterine cyst	2 (0.0)	1 (0.0)
Uterine disorder	2 (0.0)	1 (0.0)
Uterine enlargement	1 (0.0)	1 (0.0)
Uterine haemorrhage	7 (0.1)	8 (0.1)
Uterine malposition	1 (0.0)	2 (0.0)
Uterine mass	0	1 (0.0)
Uterine polyp	10 (0.1)	11 (0.1)
Uterine prolapse	11 (0.1)	6 (0.0)
Vaginal cyst	0	1 (0.0)
Vaginal discharge	0	1 (0.0)
Vaginal haemorrhage	3 (0.0)	2 (0.0)
Varicocele	11 (0.1)	9 (0.1)
Varicose veins pelvic	1 (0.0)	0
Vulval disorder	1 (0.0)	0
Vulvovaginal dryness	5 (0.0)	1 (0.0)
Vulvovaginal pain	1 (0.0)	0
Respiratory, thoracic and mediastinal disorders	1785 (13.7)	1818 (13.9)
Adenoidal hypertrophy	10 (0.1)	13 (0.1)
Allergic bronchitis	3 (0.0)	0
Allergic cough	1 (0.0)	3 (0.0)
Allergic pharyngitis	1 (0.0)	0
Allergic sinusitis	23 (0.2)	27 (0.2)
Apnoea	0	2 (0.0)
Asthma	860 (6.6)	853 (6.5)
Asthma exercise induced	61 (0.5)	34 (0.3)
Bronchial hyperreactivity	12 (0.1)	14 (0.1)
Bronchiectasis	1 (0.0)	2 (0.0)
Bronchitis chronic	13 (0.1)	7 (0.1)
Bronchospasm	7 (0.1)	5 (0.0)
Childhood asthma	10 (0.1)	16 (0.1)
Chronic obstructive pulmonary disease	36 (0.3)	36 (0.3)
Chronic respiratory failure	0	1 (0.0)
Cough	8 (0.1)	18 (0.1)
Cough variant asthma	0	2 (0.0)
Cystic lung disease	0	1 (0.0)
Dysphonia	0	2 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Dyspnoea	14 (0.1)	11 (0.1)
Dyspnoea exertional	0	2 (0.0)
Emphysema	4 (0.0)	8 (0.1)
Epistaxis	7 (0.1)	7 (0.1)
Glottal incompetence	0	1 (0.0)
Haemothorax	0	1 (0.0)
Hypoxia	0	1 (0.0)
Infantile apnoea	0	1 (0.0)
Laryngeal oedema	0	1 (0.0)
Laryngeal polyp	0	1 (0.0)
Laryngospasm	0	1 (0.0)
Nasal congestion	7 (0.1)	15 (0.1)
Nasal cyst	1 (0.0)	0
Nasal discomfort	1 (0.0)	0
Nasal obstruction	1 (0.0)	1 (0.0)
Nasal polyps	16 (0.1)	13 (0.1)
Nasal septum deviation	73 (0.6)	80 (0.6)
Nasal turbinate hypertrophy	1 (0.0)	5 (0.0)
Obliterative bronchiolitis	0	1 (0.0)
Oropharyngeal pain	4 (0.0)	5 (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)
Pharyngeal polyp	1 (0.0)	1 (0.0)
Pleural effusion	1 (0.0)	2 (0.0)
Pleurisy	1 (0.0)	3 (0.0)
Pneumonitis	0	1 (0.0)
Pneumothorax	8 (0.1)	9 (0.1)
Pneumothorax spontaneous	8 (0.1)	4 (0.0)
Pulmonary calcification	1 (0.0)	0
Pulmonary embolism	10 (0.1)	14 (0.1)
Pulmonary fibrosis	0	1 (0.0)
Pulmonary hypertension	1 (0.0)	1 (0.0)
Pulmonary mass	0	1 (0.0)
Pulmonary oedema	0	2 (0.0)
Reflux laryngitis	0	4 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Respiratory disorder	0	1 (0.0)
Respiratory failure	0	1 (0.0)
Respiratory tract congestion	0	1 (0.0)
Rhinitis allergic	540 (4.1)	530 (4.0)
Rhinitis perennial	17 (0.1)	18 (0.1)
Rhinorrhoea	4 (0.0)	1 (0.0)
Sinus congestion	14 (0.1)	9 (0.1)
Sinus disorder	1 (0.0)	7 (0.1)
Sinus pain	0	1 (0.0)
Sinus polyp	3 (0.0)	5 (0.0)
Sleep apnoea syndrome	216 (1.7)	222 (1.7)
Sneezing	0	1 (0.0)
Snoring	3 (0.0)	2 (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	9 (0.1)	11 (0.1)
Tonsillar inflammation	1 (0.0)	3 (0.0)
Tonsillolith	3 (0.0)	1 (0.0)
Upper airway resistance syndrome	1 (0.0)	0
Upper-airway cough syndrome	1 (0.0)	4 (0.0)
Vocal cord dysfunction	0	1 (0.0)
Vocal cord polyp	1 (0.0)	2 (0.0)
Vocal cord thickening	1 (0.0)	1 (0.0)
Wheezing	4 (0.0)	3 (0.0)
Skin and subcutaneous tissue disorders	903 (6.9)	968 (7.4)
Acanthosis	1 (0.0)	0
Acanthosis nigricans	2 (0.0)	2 (0.0)
Acne	281 (2.2)	273 (2.1)
Acne cystic	6 (0.0)	7 (0.1)
Actinic cheilitis	0	1 (0.0)
Actinic keratosis	3 (0.0)	9 (0.1)
Alopecia	64 (0.5)	66 (0.5)
Alopecia areata	2 (0.0)	4 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Androgenetic alopecia	8 (0.1)	23 (0.2)
Angioedema	1 (0.0)	1 (0.0)
Angiokeratoma	0	1 (0.0)
Cafe au lait spots	1 (0.0)	0
Chloasma	1 (0.0)	3 (0.0)
Chronic spontaneous urticaria	2 (0.0)	5 (0.0)
Cold urticaria	2 (0.0)	1 (0.0)
Cutaneous lupus erythematosus	0	1 (0.0)
Dandruff	3 (0.0)	4 (0.0)
Decubitus ulcer	0	1 (0.0)
Dermal cyst	14 (0.1)	10 (0.1)
Dermatitis	13 (0.1)	11 (0.1)
Dermatitis acneiform	0	1 (0.0)
Dermatitis allergic	4 (0.0)	6 (0.0)
Dermatitis atopic	35 (0.3)	29 (0.2)
Dermatitis contact	30 (0.2)	52 (0.4)
Dermatomyositis	1 (0.0)	0
Diabetic dermopathy	0	1 (0.0)
Diabetic foot	1 (0.0)	1 (0.0)
Diffuse alopecia	0	1 (0.0)
Drug eruption	18 (0.1)	20 (0.2)
Dry skin	5 (0.0)	4 (0.0)
Dyshidrotic eczema	1 (0.0)	5 (0.0)
Eczema	167 (1.3)	197 (1.5)
Eczema asteatotic	0	1 (0.0)
Eczema nummular	0	1 (0.0)
Erythema annulare	1 (0.0)	0
Granuloma annulare	1 (0.0)	2 (0.0)
Guttate psoriasis	0	1 (0.0)
Hand dermatitis	10 (0.1)	17 (0.1)
Henoch-Schonlein purpura	1 (0.0)	0
Hidradenitis	7 (0.1)	8 (0.1)
Hirsutism	6 (0.0)	3 (0.0)
Hyperhidrosis	16 (0.1)	7 (0.1)
Hyperkeratosis	6 (0.0)	1 (0.0)
Hypertrophic scar	1 (0.0)	0
Hypohidrosis	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Hypotrichosis	0	1 (0.0)
Idiopathic urticaria	5 (0.0)	0
Ingrowing nail	4 (0.0)	0
Ingrown hair	2 (0.0)	1 (0.0)
Intertrigo	1 (0.0)	0
Keloid scar	3 (0.0)	5 (0.0)
Keratosis pilaris	7 (0.1)	8 (0.1)
Lentigo	1 (0.0)	1 (0.0)
Lichen planus	1 (0.0)	1 (0.0)
Lichen sclerosus	2 (0.0)	3 (0.0)
Lichenification	0	1 (0.0)
Lichenoid keratosis	0	1 (0.0)
Madarosis	0	1 (0.0)
Mechanical urticaria	1 (0.0)	6 (0.0)
Miliaria	2 (0.0)	2 (0.0)
Nail bed disorder	0	1 (0.0)
Nail discolouration	1 (0.0)	0
Neurodermatitis	4 (0.0)	1 (0.0)
Night sweats	2 (0.0)	3 (0.0)
Palmoplantar keratoderma	1 (0.0)	0
Peau d'orange	0	1 (0.0)
Perioral dermatitis	1 (0.0)	1 (0.0)
Photodermatosis	1 (0.0)	2 (0.0)
Pityriasis	1 (0.0)	0
Pityriasis lichenoides et varioliformis acuta	0	1 (0.0)
Pityriasis rosea	1 (0.0)	0
Polymorphic light eruption	1 (0.0)	0
Precancerous skin lesion	2 (0.0)	0
Pruritus	3 (0.0)	3 (0.0)
Pruritus allergic	5 (0.0)	2 (0.0)
Pseudofolliculitis	0	1 (0.0)
Psoriasis	79 (0.6)	75 (0.6)
Rash	11 (0.1)	11 (0.1)
Rash pruritic	0	1 (0.0)
Rosacea	51 (0.4)	57 (0.4)
Seborrhoea	1 (0.0)	1 (0.0)
Seborrhoeic dermatitis	19 (0.1)	12 (0.1)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Sensitive skin	1 (0.0)	1 (0.0)
Skin atrophy	1 (0.0)	0
Skin discolouration	2 (0.0)	1 (0.0)
Skin disorder	1 (0.0)	1 (0.0)
Skin exfoliation	1 (0.0)	0
Skin hyperpigmentation	0	1 (0.0)
Skin hypertrophy	1 (0.0)	0
Skin irritation	1 (0.0)	0
Skin lesion	1 (0.0)	3 (0.0)
Skin maceration	0	1 (0.0)
Skin mass	1 (0.0)	0
Skin ulcer	1 (0.0)	1 (0.0)
Solar lentigo	2 (0.0)	0
Stevens-Johnson syndrome	1 (0.0)	0
Transient acantholytic dermatosis	1 (0.0)	0
Urticaria	33 (0.3)	50 (0.4)
Urticaria cholinergic	0	1 (0.0)
Urticaria chronic	0	3 (0.0)
Urticaria thermal	1 (0.0)	0
Vitiligo	11 (0.1)	11 (0.1)
Social circumstances	748 (5.7)	726 (5.5)
Alcohol use	13 (0.1)	9 (0.1)
Andropause	1 (0.0)	1 (0.0)
Bereavement	1 (0.0)	0
Blood donor	11 (0.1)	13 (0.1)
Celibacy	5 (0.0)	5 (0.0)
Corrective lens user	113 (0.9)	102 (0.8)
Denture wearer	2 (0.0)	0
Drug abuser	1 (0.0)	0
Electronic cigarette user	5 (0.0)	1 (0.0)
Ex-tobacco user	32 (0.2)	33 (0.3)
Eye prosthesis user	0	1 (0.0)
Familial risk factor	2 (0.0)	2 (0.0)
Hearing aid user	2 (0.0)	1 (0.0)
High risk sexual behaviour	0	2 (0.0)
Inadequate diet	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Menarche	0	2 (0.0)
Menopause	138 (1.1)	137 (1.0)
Multigravida	0	1 (0.0)
Multiparous	0	1 (0.0)
Organ donor	5 (0.0)	6 (0.0)
Orthodontic appliance user	1 (0.0)	0
Postmenopause	328 (2.5)	342 (2.6)
Social alcohol drinker	5 (0.0)	2 (0.0)
Substance use	21 (0.2)	13 (0.1)
Tobacco user	107 (0.8)	82 (0.6)
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	3976 (30.4)	3993 (30.5)
Abdominal exploration	2 (0.0)	0
Abdominal hernia repair	16 (0.1)	21 (0.2)
Abdominal operation	9 (0.1)	1 (0.0)
Abdominal panniculectomy	2 (0.0)	2 (0.0)
Abdominal wall operation	1 (0.0)	2 (0.0)
Abdominoplasty	38 (0.3)	38 (0.3)
Abortion induced	2 (0.0)	3 (0.0)
Abscess drainage	7 (0.1)	9 (0.1)
Acoustic neuroma removal	0	1 (0.0)
Adenoidectomy	69 (0.5)	65 (0.5)
Adenotonsillectomy	15 (0.1)	15 (0.1)
Adhesiolysis	0	1 (0.0)
Adrenalectomy	0	2 (0.0)
Alcohol rehabilitation	0	1 (0.0)
Amblyopia therapy	1 (0.0)	1 (0.0)
Amputation	0	1 (0.0)
Anal fissure excision	1 (0.0)	0
Anal fistula repair	4 (0.0)	4 (0.0)
Anal sphincterotomy	0	1 (0.0)
Angioplasty	3 (0.0)	3 (0.0)
Ankle arthroplasty	5 (0.0)	6 (0.0)
Ankle operation	31 (0.2)	38 (0.3)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Anorectal operation	4 (0.0)	3 (0.0)
Antibiotic prophylaxis	1 (0.0)	1 (0.0)
Antibiotic therapy	1 (0.0)	0
Antidepressant therapy	1 (0.0)	0
Antiviral prophylaxis	1 (0.0)	0
Aorta coarctation repair	0	1 (0.0)
Aortic aneurysm repair	0	1 (0.0)
Aortic valve repair	0	1 (0.0)
Aortic valve replacement	3 (0.0)	4 (0.0)
Apicectomy	0	1 (0.0)
Appendicectomy	328 (2.5)	309 (2.4)
Arm amputation	1 (0.0)	0
Arterial bypass operation	1 (0.0)	0
Arterial repair	0	1 (0.0)
Arterial therapeutic procedure	1 (0.0)	0
Arteriovenous fistula operation	2 (0.0)	0
Arthrodesis	5 (0.0)	5 (0.0)
Arthroscopic surgery	0	1 (0.0)
Arthrotomy	0	1 (0.0)
Artificial crown procedure	0	2 (0.0)
Artificial insemination	1 (0.0)	0
Astrocytoma surgery	1 (0.0)	0
Atrial septal defect repair	5 (0.0)	6 (0.0)
Axillary lymphadenectomy	2 (0.0)	2 (0.0)
Bartholin's cyst removal	3 (0.0)	1 (0.0)
Benign breast lump removal	14 (0.1)	9 (0.1)
Benign tumour excision	2 (0.0)	2 (0.0)
Bilateral orchidectomy	2 (0.0)	1 (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
Bladder lesion excision	0	1 (0.0)
Bladder neoplasm surgery	1 (0.0)	0
Bladder operation	1 (0.0)	1 (0.0)
Bladder repair	4 (0.0)	5 (0.0)
Blepharoplasty	2 (0.0)	2 (0.0)
Blood donation	1 (0.0)	5 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Bone cyst excision	5 (0.0)	3 (0.0)
Bone debridement	1 (0.0)	0
Bone graft	3 (0.0)	2 (0.0)
Bone lesion excision	14 (0.1)	14 (0.1)
Bone marrow donation	1 (0.0)	1 (0.0)
Bone operation	27 (0.2)	21 (0.2)
Botulinum toxin injection	0	2 (0.0)
Brain lobectomy	2 (0.0)	0
Brain operation	4 (0.0)	4 (0.0)
Brain tumour operation	1 (0.0)	0
Breast conserving surgery	22 (0.2)	27 (0.2)
Breast cyst excision	3 (0.0)	6 (0.0)
Breast operation	4 (0.0)	2 (0.0)
Breast prosthesis removal	4 (0.0)	0
Breast reconstruction	6 (0.0)	7 (0.1)
Breast tumour excision	2 (0.0)	1 (0.0)
Bunion operation	36 (0.3)	34 (0.3)
Burn operation	1 (0.0)	0
Bursa removal	0	2 (0.0)
Bursal operation	0	2 (0.0)
Caecopexy	0	1 (0.0)
Caesarean section	392 (3.0)	421 (3.2)
Cancer surgery	12 (0.1)	8 (0.1)
Capsulorrhaphy	1 (0.0)	0
Cardiac ablation	23 (0.2)	12 (0.1)
Cardiac operation	4 (0.0)	7 (0.1)
Cardiac pacemaker insertion	8 (0.1)	5 (0.0)
Cardiac pacemaker removal	0	2 (0.0)
Cardiac pacemaker replacement	0	1 (0.0)
Carotid endarterectomy	0	2 (0.0)
Carpal tunnel decompression	36 (0.3)	38 (0.3)
Cartilage operation	1 (0.0)	0
Cataract operation	11 (0.1)	13 (0.1)
Catheter placement	0	1 (0.0)
Central venous catheterisation	1 (0.0)	0
Cerebral cyst excision	0	1 (0.0)
Cerebral endovascular aneurysm repair	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Cervical conisation	0	1 (0.0)
Cervical laser therapy	1 (0.0)	0
Cervical polypectomy	2 (0.0)	0
Cervicectomy	0	2 (0.0)
Cervix cautery	1 (0.0)	0
Cervix cryotherapy	3 (0.0)	0
Chemical contraception	0	1 (0.0)
Chemotherapy	2 (0.0)	4 (0.0)
Chest tube insertion	3 (0.0)	3 (0.0)
Chest wall operation	0	1 (0.0)
Cholecystectomy	348 (2.7)	371 (2.8)
Cholecystostomy	0	1 (0.0)
Choledocholithotomy	0	1 (0.0)
Cholelithotomy	1 (0.0)	3 (0.0)
Cholesteatoma removal	0	3 (0.0)
Chondrectomy	1 (0.0)	1 (0.0)
Chondroplasty	25 (0.2)	28 (0.2)
Circumcision	7 (0.1)	10 (0.1)
Cleft lip repair	1 (0.0)	1 (0.0)
Cleft palate repair	3 (0.0)	2 (0.0)
Closed fracture manipulation	1 (0.0)	0
Coccygectomy	0	1 (0.0)
Cochlea implant	4 (0.0)	3 (0.0)
Colectomy	12 (0.1)	14 (0.1)
Colectomy total	1 (0.0)	1 (0.0)
Colon operation	3 (0.0)	2 (0.0)
Colostomy	1 (0.0)	0
Commissurotomy of pulmonary valve	1 (0.0)	0
Contact lens therapy	1 (0.0)	1 (0.0)
Continuous positive airway pressure	9 (0.1)	5 (0.0)
Contraception	14 (0.1)	17 (0.1)
Contraceptive implant	5 (0.0)	7 (0.1)
Corneal operation	0	1 (0.0)
Corneal transplant	4 (0.0)	4 (0.0)
Coronary angioplasty	1 (0.0)	1 (0.0)
Coronary arterial stent insertion	16 (0.1)	19 (0.1)
Coronary artery bypass	6 (0.0)	3 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Coronary artery surgery	1 (0.0)	1 (0.0)
Coronary revascularisation	0	1 (0.0)
Cranial nerve decompression	1 (0.0)	0
Cranial operation	4 (0.0)	4 (0.0)
Craniectomy	0	1 (0.0)
Cranioplasty	1 (0.0)	1 (0.0)
Craniotomy	3 (0.0)	1 (0.0)
Cryotherapy	2 (0.0)	1 (0.0)
Cyst drainage	1 (0.0)	0
Cyst removal	10 (0.1)	10 (0.1)
Cystocele repair	1 (0.0)	0
Dacryocystorhinostomy	1 (0.0)	0
Debridement	4 (0.0)	5 (0.0)
Decompressive craniectomy	0	1 (0.0)
Dental care	0	1 (0.0)
Dental implantation	3 (0.0)	8 (0.1)
Dental operation	4 (0.0)	2 (0.0)
Dental prosthesis placement	1 (0.0)	1 (0.0)
Detoxification	0	1 (0.0)
Diplopia correction	1 (0.0)	0
Diverticulectomy	1 (0.0)	2 (0.0)
Drug delivery device placement	1 (0.0)	0
Drug rehabilitation	1 (0.0)	1 (0.0)
Duodenal switch	0	2 (0.0)
Dupuytren's contracture operation	1 (0.0)	0
Ear operation	7 (0.1)	3 (0.0)
Ear tube insertion	23 (0.2)	27 (0.2)
Ear tube removal	1 (0.0)	3 (0.0)
Ectopic pregnancy termination	1 (0.0)	1 (0.0)
Elbow operation	10 (0.1)	10 (0.1)
Electrodesiccation	1 (0.0)	0
Endocervical curettage	1 (0.0)	0
Endodontic procedure	1 (0.0)	4 (0.0)
Endometrial ablation	74 (0.6)	77 (0.6)
Endometriosis ablation	2 (0.0)	7 (0.1)
Endoscopic sleeve gastroplasty	0	1 (0.0)
Enterorrhaphy	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Enterostomy	2 (0.0)	0
Epidermoid cyst excision	1 (0.0)	0
Epididymal cyst removal	1 (0.0)	0
Epididymal operation	1 (0.0)	0
Epiphysiodesis	1 (0.0)	0
Eustachian tube operation	1 (0.0)	2 (0.0)
Exeresis	5 (0.0)	2 (0.0)
Explorative laparotomy	2 (0.0)	1 (0.0)
External fixation of fracture	2 (0.0)	1 (0.0)
External nose lesion excision	1 (0.0)	0
Eye excision	2 (0.0)	1 (0.0)
Eye laser surgery	24 (0.2)	13 (0.1)
Eye muscle operation	3 (0.0)	5 (0.0)
Eye operation	10 (0.1)	14 (0.1)
Eyelid cyst removal	1 (0.0)	1 (0.0)
Eyelid operation	1 (0.0)	2 (0.0)
Face lift	2 (0.0)	1 (0.0)
Facet joint block	0	2 (0.0)
Facial lesion excision	0	1 (0.0)
Facial operation	1 (0.0)	1 (0.0)
Fallopian tube operation	0	1 (0.0)
Fascia release	2 (0.0)	2 (0.0)
Fascial operation	1 (0.0)	2 (0.0)
Fasciotomy	7 (0.1)	2 (0.0)
Female genital operation	1 (0.0)	0
Female sterilisation	424 (3.2)	468 (3.6)
Femoral derotation osteotomy	0	1 (0.0)
Femoral hernia repair	1 (0.0)	1 (0.0)
Finger amputation	3 (0.0)	7 (0.1)
Finger repair operation	3 (0.0)	2 (0.0)
Fistula repair	1 (0.0)	1 (0.0)
Foetal surgery	0	1 (0.0)
Foot amputation	1 (0.0)	1 (0.0)
Foot operation	23 (0.2)	16 (0.1)
Foraminotomy	1 (0.0)	0
Fracture reduction	2 (0.0)	2 (0.0)
Fracture treatment	72 (0.6)	74 (0.6)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Frontal sinus operation	1 (0.0)	0
Functional endoscopic sinus surgery	2 (0.0)	4 (0.0)
Gallbladder operation	4 (0.0)	3 (0.0)
Gastrectomy	58 (0.4)	71 (0.5)
Gastric banding	16 (0.1)	13 (0.1)
Gastric banding reversal	2 (0.0)	3 (0.0)
Gastric bypass	68 (0.5)	67 (0.5)
Gastric operation	2 (0.0)	5 (0.0)
Gastric stapling	0	1 (0.0)
Gastric ulcer surgery	0	1 (0.0)
Gastroenterostomy	1 (0.0)	0
Gastrointestinal surgery	2 (0.0)	1 (0.0)
Gastrointestinal ulcer management	1 (0.0)	0
Gastroplasty	0	3 (0.0)
Gastrostomy	1 (0.0)	0
Gastrostomy tube removal	1 (0.0)	0
Gender reassignment therapy	1 (0.0)	0
Gingival graft	2 (0.0)	6 (0.0)
Gingival operation	0	1 (0.0)
Glaucoma surgery	0	1 (0.0)
Haemangioma removal	2 (0.0)	3 (0.0)
Haematoma evacuation	0	1 (0.0)
Haemorrhoid operation	16 (0.1)	11 (0.1)
Haemostasis	1 (0.0)	0
Hair transplant	2 (0.0)	4 (0.0)
Hand repair operation	1 (0.0)	3 (0.0)
Heart valve replacement	2 (0.0)	0
Hepatectomy	0	1 (0.0)
Hepatitis B immunisation	0	1 (0.0)
Hernia diaphragmatic repair	2 (0.0)	0
Hernia hiatus repair	5 (0.0)	15 (0.1)
Hernia repair	55 (0.4)	52 (0.4)
High frequency ablation	2 (0.0)	1 (0.0)
Hip arthroplasty	21 (0.2)	21 (0.2)
Hip surgery	7 (0.1)	11 (0.1)
Hormone replacement therapy	4 (0.0)	2 (0.0)
Hospitalisation	1 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Hydrocele operation	1 (0.0)	4 (0.0)
Hysterectomy	521 (4.0)	498 (3.8)
Hysteropexy	0	1 (0.0)
Hysterosalpingectomy	0	1 (0.0)
Hysterosalpingo-oophorectomy	6 (0.0)	4 (0.0)
Hysterotomy	0	1 (0.0)
Ileectomy	0	1 (0.0)
Ileostomy	0	2 (0.0)
Immune tolerance induction	1 (0.0)	1 (0.0)
Immunoglobulin therapy	1 (0.0)	0
Implantable cardiac monitor insertion	0	3 (0.0)
Implantable defibrillator insertion	1 (0.0)	4 (0.0)
In vitro fertilisation	1 (0.0)	3 (0.0)
Incisional drainage	2 (0.0)	5 (0.0)
Incisional hernia repair	1 (0.0)	3 (0.0)
Influenza immunisation	0	1 (0.0)
Inguinal hernia repair	86 (0.7)	94 (0.7)
Injection	0	1 (0.0)
Inner ear operation	1 (0.0)	0
Internal fixation of fracture	6 (0.0)	6 (0.0)
Intervertebral disc operation	52 (0.4)	45 (0.3)
Intestinal operation	5 (0.0)	4 (0.0)
Intestinal resection	10 (0.1)	5 (0.0)
Intra-cerebral aneurysm operation	2 (0.0)	1 (0.0)
Intra-uterine contraceptive device insertion	29 (0.2)	31 (0.2)
Intramedullary rod insertion	1 (0.0)	1 (0.0)
Intraocular lens implant	3 (0.0)	3 (0.0)
Intrauterine contraception	26 (0.2)	34 (0.3)
Iridotomy	0	1 (0.0)
Jaw operation	15 (0.1)	18 (0.1)
Jejunostomy	0	1 (0.0)
Joint arthroplasty	2 (0.0)	4 (0.0)
Joint debridement	4 (0.0)	2 (0.0)
Joint dislocation reduction	4 (0.0)	6 (0.0)
Joint fluid drainage	1 (0.0)	0
Joint manipulation	0	1 (0.0)
Joint resurfacing surgery	2 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Joint stabilisation	0	1 (0.0)
Joint surgery	3 (0.0)	5 (0.0)
Keratomileusis	80 (0.6)	71 (0.5)
Keratotomy	0	1 (0.0)
Knee arthroplasty	32 (0.2)	34 (0.3)
Knee operation	72 (0.6)	73 (0.6)
Lacrimal duct procedure	1 (0.0)	3 (0.0)
Lacrimal gland operation	0	1 (0.0)
Laminaplasty	0	1 (0.0)
Laparoscopic surgery	4 (0.0)	2 (0.0)
Laparotomy	2 (0.0)	2 (0.0)
Large intestinal polypectomy	11 (0.1)	10 (0.1)
Large intestine operation	1 (0.0)	0
Laryngeal operation	1 (0.0)	0
Laryngeal polypectomy	0	1 (0.0)
Laryngoplasty	0	1 (0.0)
Laser therapy	1 (0.0)	0
Leg amputation	3 (0.0)	2 (0.0)
Lesion excision	1 (0.0)	1 (0.0)
Ligament operation	110 (0.8)	106 (0.8)
Limb operation	40 (0.3)	47 (0.4)
Limb reattachment surgery	1 (0.0)	0
Limb reconstructive surgery	0	1 (0.0)
Lipectomy	1 (0.0)	1 (0.0)
Lipoma excision	11 (0.1)	12 (0.1)
Liposuction	9 (0.1)	13 (0.1)
Lithotripsy	17 (0.1)	14 (0.1)
Liver transplant	0	1 (0.0)
Loop electrosurgical excision procedure	14 (0.1)	11 (0.1)
Lower oesophageal sphincter magnetic augmentation	1 (0.0)	0
Lung assist device therapy	1 (0.0)	0
Lung cyst removal	1 (0.0)	0
Lung lobectomy	2 (0.0)	3 (0.0)
Lung operation	0	2 (0.0)
Lymphadenectomy	4 (0.0)	6 (0.0)
Lymphoid tissue operation	1 (0.0)	0
Lymphoma operation	1 (0.0)	2 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Mammary ductectomy	0	1 (0.0)
Mammoplasty	163 (1.2)	147 (1.1)
Mass excision	2 (0.0)	1 (0.0)
Mastectomy	21 (0.2)	31 (0.2)
Mastoidectomy	1 (0.0)	4 (0.0)
Maxillofacial operation	4 (0.0)	1 (0.0)
Medical cannabis therapy	0	1 (0.0)
Medical device battery replacement	1 (0.0)	0
Medical device implantation	2 (0.0)	1 (0.0)
Medical device removal	5 (0.0)	3 (0.0)
Meningioma surgery	3 (0.0)	2 (0.0)
Meniscus operation	57 (0.4)	52 (0.4)
Meniscus removal	9 (0.1)	8 (0.1)
Metabolic surgery	34 (0.3)	34 (0.3)
Metatarsal excision	1 (0.0)	0
Micrographic skin surgery	5 (0.0)	13 (0.1)
Middle ear operation	1 (0.0)	0
Middle ear prosthesis insertion	0	1 (0.0)
Mitral valve repair	0	1 (0.0)
Mitral valve replacement	1 (0.0)	2 (0.0)
Mole excision	13 (0.1)	8 (0.1)
Muscle graft	0	1 (0.0)
Muscle operation	5 (0.0)	9 (0.1)
Myectomy	0	2 (0.0)
Myomectomy	17 (0.1)	18 (0.1)
Myopia correction	2 (0.0)	5 (0.0)
Myringotomy	7 (0.1)	10 (0.1)
Nail operation	5 (0.0)	1 (0.0)
Nasal operation	7 (0.1)	9 (0.1)
Nasal polypectomy	11 (0.1)	5 (0.0)
Nasal septal operation	82 (0.6)	75 (0.6)
Nasal sinus irrigation	0	1 (0.0)
Neck dissection	1 (0.0)	1 (0.0)
Neck surgery	8 (0.1)	3 (0.0)
Nephrectomy	8 (0.1)	10 (0.1)
Nephrostomy	0	2 (0.0)
Nerve block	3 (0.0)	2 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Nervous system neoplasm surgery	2 (0.0)	0
Neurectomy	5 (0.0)	7 (0.1)
Neuroprosthesis implantation	0	1 (0.0)
Neurosurgery	0	1 (0.0)
Oesophageal dilation procedure	2 (0.0)	3 (0.0)
Oesophageal lesion excision	0	1 (0.0)
Oesophagocardiomyotomy	0	2 (0.0)
Oesophagogastrectomy	1 (0.0)	0
Oesophagogastric fundoplasty	6 (0.0)	6 (0.0)
Oocyte harvest	2 (0.0)	1 (0.0)
Oophorectomy	25 (0.2)	34 (0.3)
Oophorectomy bilateral	23 (0.2)	18 (0.1)
Open reduction of fracture	32 (0.2)	29 (0.2)
Oral cavity neoplasm surgery	0	1 (0.0)
Oral contraception	1 (0.0)	0
Oral surgery	2 (0.0)	1 (0.0)
Orchidectomy	10 (0.1)	8 (0.1)
Orchidopexy	4 (0.0)	3 (0.0)
Orthognathic surgery	9 (0.1)	9 (0.1)
Orthopaedic procedure	3 (0.0)	4 (0.0)
Ossiculoplasty	0	1 (0.0)
Ostectomy	5 (0.0)	8 (0.1)
Osteotomy	6 (0.0)	6 (0.0)
Otoplasty	4 (0.0)	4 (0.0)
Ovarian cystectomy	17 (0.1)	23 (0.2)
Ovarian lesion excision	2 (0.0)	1 (0.0)
Ovarian neoplasm surgery	2 (0.0)	1 (0.0)
Ovarian operation	1 (0.0)	3 (0.0)
Ovariocentesis	0	1 (0.0)
Pancreatic stent placement	0	1 (0.0)
Pancreatic stent removal	0	1 (0.0)
Papilloma excision	5 (0.0)	1 (0.0)
Paranasal sinus polypectomy	2 (0.0)	7 (0.1)
Parathyroidectomy	3 (0.0)	1 (0.0)
Parotidectomy	3 (0.0)	2 (0.0)
Penis frenulectomy	1 (0.0)	0
Percutaneous coronary intervention	2 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Peripheral nerve decompression	7 (0.1)	5 (0.0)
Peripheral nerve destruction	0	2 (0.0)
Peripheral nerve neurostimulation	0	1 (0.0)
Peripheral nerve operation	2 (0.0)	10 (0.1)
Peripheral nerve transposition	2 (0.0)	3 (0.0)
Permanent contraceptive tubal implant	1 (0.0)	2 (0.0)
Pharyngeal operation	0	2 (0.0)
Pharyngeal polypectomy	1 (0.0)	0
Phlebectomy	2 (0.0)	4 (0.0)
Photorefractive keratectomy	5 (0.0)	7 (0.1)
Physiotherapy	0	2 (0.0)
Pilonidal sinus repair	11 (0.1)	15 (0.1)
Pituitary tumour removal	2 (0.0)	2 (0.0)
Plastic surgery	2 (0.0)	2 (0.0)
Plastic surgery to the face	5 (0.0)	3 (0.0)
Platelet rich plasma therapy	1 (0.0)	0
Pleural operation	0	2 (0.0)
Pleurectomy	0	1 (0.0)
Pleurodesis	1 (0.0)	0
Pneumocentesis	0	1 (0.0)
Polypectomy	3 (0.0)	4 (0.0)
Precancerous lesion excision	1 (0.0)	0
Preventive surgery	1 (0.0)	0
Prophylaxis against HIV infection	6 (0.0)	2 (0.0)
Prostatectomy	6 (0.0)	3 (0.0)
Prostatic urethral lift procedure	1 (0.0)	0
Prosthesis implantation	1 (0.0)	1 (0.0)
Psychotherapy	0	1 (0.0)
Pterygium operation	1 (0.0)	2 (0.0)
Ptosis repair	1 (0.0)	0
Pulmonary bullectomy	1 (0.0)	0
Pulmonary resection	2 (0.0)	0
Pulmonary valve replacement	0	1 (0.0)
Pyeloplasty	0	1 (0.0)
Pyloromyotomy	2 (0.0)	2 (0.0)
Pyloroplasty	2 (0.0)	5 (0.0)
Pylorus dilation procedure	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Radical hysterectomy	1 (0.0)	6 (0.0)
Radical prostatectomy	1 (0.0)	0
Radiculotomy	0	1 (0.0)
Radioactive iodine therapy	1 (0.0)	2 (0.0)
Radiotherapy	2 (0.0)	1 (0.0)
Radiotherapy to breast	1 (0.0)	2 (0.0)
Radiotherapy to thyroid	0	1 (0.0)
Rectal fistula repair	1 (0.0)	3 (0.0)
Rectal lesion excision	1 (0.0)	0
Rectal prolapse repair	1 (0.0)	1 (0.0)
Rectocele repair	2 (0.0)	0
Reduction of increased intracranial pressure	1 (0.0)	0
Removal of foreign body	3 (0.0)	9 (0.1)
Removal of foreign body from eye	0	1 (0.0)
Removal of foreign body from gastrointestinal tract	1 (0.0)	1 (0.0)
Removal of foreign body from joint	1 (0.0)	0
Removal of foreign body from rectum	1 (0.0)	0
Renal artery stent placement	0	1 (0.0)
Renal cyst excision	0	1 (0.0)
Renal stone removal	19 (0.1)	22 (0.2)
Renal surgery	1 (0.0)	7 (0.1)
Retinal operation	4 (0.0)	5 (0.0)
Retinopexy	7 (0.1)	3 (0.0)
Rhinoplasty	35 (0.3)	42 (0.3)
Rib excision	1 (0.0)	1 (0.0)
Rotator cuff repair	41 (0.3)	41 (0.3)
Salivary gland operation	0	4 (0.0)
Salivary gland resection	2 (0.0)	1 (0.0)
Salpingectomy	77 (0.6)	77 (0.6)
Salpingo-oophorectomy	1 (0.0)	2 (0.0)
Salpingo-oophorectomy bilateral	2 (0.0)	2 (0.0)
Salpingo-oophorectomy unilateral	3 (0.0)	0
Salpingoplasty	1 (0.0)	0
Salpingostomy	3 (0.0)	1 (0.0)
Sarcoma excision	0	2 (0.0)
Scar excision	1 (0.0)	7 (0.1)
Scleral buckling surgery	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Sclerotherapy	1 (0.0)	0
Scoliosis surgery	5 (0.0)	3 (0.0)
Sebaceous cyst excision	0	3 (0.0)
Seizure prophylaxis	1 (0.0)	0
Sesamoidectomy	1 (0.0)	1 (0.0)
Shoulder arthroplasty	6 (0.0)	3 (0.0)
Shoulder operation	58 (0.4)	30 (0.2)
Sigmoidectomy	1 (0.0)	2 (0.0)
Sinuplasty	2 (0.0)	5 (0.0)
Sinus antrostomy	1 (0.0)	0
Sinus operation	40 (0.3)	36 (0.3)
Skin cosmetic procedure	2 (0.0)	4 (0.0)
Skin cyst excision	4 (0.0)	1 (0.0)
Skin graft	8 (0.1)	8 (0.1)
Skin lesion removal	6 (0.0)	3 (0.0)
Skin neoplasm excision	29 (0.2)	35 (0.3)
Skin operation	5 (0.0)	2 (0.0)
Skull fracture treatment	0	2 (0.0)
Small intestinal resection	1 (0.0)	3 (0.0)
Small intestine operation	1 (0.0)	0
Soft tissue flap operation	0	1 (0.0)
Spermatic cord operation	1 (0.0)	0
Spinal cord operation	1 (0.0)	0
Spinal decompression	4 (0.0)	0
Spinal fracture treatment	3 (0.0)	0
Spinal fusion surgery	56 (0.4)	53 (0.4)
Spinal laminectomy	19 (0.1)	26 (0.2)
Spinal nerve stimulator implantation	5 (0.0)	5 (0.0)
Spinal operation	33 (0.3)	26 (0.2)
Splenectomy	8 (0.1)	9 (0.1)
Splenorrhaphy	1 (0.0)	0
Stapedectomy	2 (0.0)	0
Stem cell therapy	1 (0.0)	1 (0.0)
Stent placement	4 (0.0)	3 (0.0)
Sterilisation	13 (0.1)	6 (0.0)
Sterilisation reversal	3 (0.0)	1 (0.0)
Stoma closure	1 (0.0)	0

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Stomach lesion excision	1 (0.0)	0
Strabismus correction	13 (0.1)	16 (0.1)
Subdural haematoma evacuation	1 (0.0)	0
Surgery	4 (0.0)	7 (0.1)
Surgical fixation of rib fracture	1 (0.0)	0
Suture insertion	2 (0.0)	2 (0.0)
Sympathectomy	0	1 (0.0)
Synovectomy	1 (0.0)	1 (0.0)
Synovial cyst removal	13 (0.1)	11 (0.1)
Talipes correction	1 (0.0)	4 (0.0)
Tarsal tunnel decompression	0	1 (0.0)
Temporomandibular joint surgery	6 (0.0)	1 (0.0)
Tendon graft	1 (0.0)	0
Tendon operation	3 (0.0)	6 (0.0)
Tendon sheath incision	7 (0.1)	6 (0.0)
Tendon transfer	3 (0.0)	3 (0.0)
Tenolysis	1 (0.0)	1 (0.0)
Tenonectomy	1 (0.0)	0
Tenoplasty	38 (0.3)	37 (0.3)
Tenotomy	6 (0.0)	7 (0.1)
Testes exploration	1 (0.0)	3 (0.0)
Testicular operation	1 (0.0)	1 (0.0)
Tetralogy of Fallot repair	2 (0.0)	1 (0.0)
Therapeutic aspiration	0	1 (0.0)
Therapeutic embolisation	1 (0.0)	0
Therapeutic nerve ablation	4 (0.0)	1 (0.0)
Therapeutic procedure	2 (0.0)	0
Thermal ablation	1 (0.0)	0
Thoracic operation	4 (0.0)	1 (0.0)
Thoracic outlet surgery	1 (0.0)	0
Thoracoplasty	2 (0.0)	2 (0.0)
Thoracotomy	1 (0.0)	1 (0.0)
Thrombectomy	2 (0.0)	0
Thymectomy	1 (0.0)	1 (0.0)
Thyroglossal cyst excision	1 (0.0)	0
Thyroid nodule removal	1 (0.0)	3 (0.0)
Thyroid operation	2 (0.0)	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Thyroidectomy	71 (0.5)	79 (0.6)
Toe amputation	4 (0.0)	8 (0.1)
Toe operation	4 (0.0)	10 (0.1)
Tongue tie operation	1 (0.0)	2 (0.0)
Tonsillectomy	399 (3.1)	361 (2.8)
Tooth extraction	8 (0.1)	12 (0.1)
Tooth repair	0	1 (0.0)
Trabeculectomy	0	1 (0.0)
Trabeculoplasty	0	1 (0.0)
Tracheal fistula repair	1 (0.0)	0
Tracheostomy	1 (0.0)	1 (0.0)
Transfusion	5 (0.0)	4 (0.0)
Transgender hormonal therapy	2 (0.0)	1 (0.0)
Transgender operation	2 (0.0)	0
Transplant	1 (0.0)	0
Transurethral incision of prostate	1 (0.0)	0
Transurethral prostatectomy	0	1 (0.0)
Tumour excision	3 (0.0)	0
Turbinectomy	5 (0.0)	8 (0.1)
Turbinoplasty	1 (0.0)	1 (0.0)
Tympanoplasty	11 (0.1)	13 (0.1)
Umbilical hernia repair	39 (0.3)	60 (0.5)
Umbilicoplasty	0	1 (0.0)
Ureteral stent insertion	2 (0.0)	6 (0.0)
Ureteral stent removal	0	1 (0.0)
Ureteric operation	2 (0.0)	2 (0.0)
Ureteric repair	0	2 (0.0)
Urethral dilation procedure	0	1 (0.0)
Urethral operation	4 (0.0)	3 (0.0)
Urethral repair	2 (0.0)	5 (0.0)
Urethral stent insertion	0	1 (0.0)
Urethrectomy	0	1 (0.0)
Urinary bladder suspension	15 (0.1)	15 (0.1)
Urinary tract operation	1 (0.0)	1 (0.0)
Urogenital fistula repair	0	1 (0.0)
Urostomy	1 (0.0)	0
Uterine cystectomy	1 (0.0)	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Uterine dilation and curettage	28 (0.2)	43 (0.3)
Uterine leiomyoma embolisation	1 (0.0)	0
Uterine operation	1 (0.0)	1 (0.0)
Uterine polypectomy	7 (0.1)	4 (0.0)
Uterine repair	1 (0.0)	0
Uterine tumour excision	1 (0.0)	0
Uvulectomy	1 (0.0)	1 (0.0)
Uvulopalatopharyngoplasty	6 (0.0)	4 (0.0)
Uvuloplasty	1 (0.0)	0
Vaginal fistula repair	0	1 (0.0)
Vaginal operation	2 (0.0)	2 (0.0)
Vaginal prolapse repair	1 (0.0)	0
Vaginal ring	1 (0.0)	0
Valvuloplasty cardiac	1 (0.0)	0
Varicocele repair	6 (0.0)	12 (0.1)
Varicose vein operation	5 (0.0)	6 (0.0)
Vascular graft	1 (0.0)	2 (0.0)
Vascular operation	1 (0.0)	2 (0.0)
Vascular stent insertion	2 (0.0)	3 (0.0)
Vasectomy	348 (2.7)	307 (2.3)
Vasectomy reversal	2 (0.0)	1 (0.0)
Venous reconstruction	0	1 (0.0)
Venous stent insertion	1 (0.0)	0
Ventricular drainage	1 (0.0)	0
Ventricular septal defect repair	1 (0.0)	1 (0.0)
Ventriculo-peritoneal shunt	1 (0.0)	3 (0.0)
Vertebroplasty	2 (0.0)	1 (0.0)
Vesicoureteral reflux surgery	0	1 (0.0)
Vestibular apparatus operation	0	1 (0.0)
Vision correction operation	4 (0.0)	1 (0.0)
Vitamin supplementation	1 (0.0)	0
Vitrectomy	0	2 (0.0)
Vocal cord nodule removal	1 (0.0)	1 (0.0)
Vocal cord operation	0	1 (0.0)
Vocal cord polypectomy	0	1 (0.0)
Vulval operation	1 (0.0)	1 (0.0)
Vulvectomy	2 (0.0)	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Weight control	2 (0.0)	0
Wisdom teeth removal	136 (1.0)	142 (1.1)
Wound closure	3 (0.0)	6 (0.0)
Wound treatment	2 (0.0)	0
Wrist surgery	15 (0.1)	24 (0.2)
Vascular disorders	1641 (12.6)	1673 (12.8)
Aortic aneurysm	2 (0.0)	1 (0.0)
Aortic arteriosclerosis	0	2 (0.0)
Aortic dilatation	2 (0.0)	1 (0.0)
Aortic disorder	0	1 (0.0)
Aortic stenosis	1 (0.0)	1 (0.0)
Arteriosclerosis	1 (0.0)	3 (0.0)
Arteriovenous fistula	1 (0.0)	0
Capillary fragility	0	1 (0.0)
Collateral circulation	0	1 (0.0)
Deep vein thrombosis	18 (0.1)	23 (0.2)
Embolism	1 (0.0)	1 (0.0)
Embolism venous	1 (0.0)	1 (0.0)
Erythromelalgia	1 (0.0)	0
Essential hypertension	24 (0.2)	16 (0.1)
Extremity necrosis	1 (0.0)	0
Fibromuscular dysplasia	0	1 (0.0)
Giant cell arteritis	0	1 (0.0)
Haematoma	1 (0.0)	1 (0.0)
Haemorrhage	0	1 (0.0)
Hot flush	48 (0.4)	60 (0.5)
Hypertension	1495 (11.4)	1507 (11.5)
Hypotension	5 (0.0)	6 (0.0)
Kawasaki's disease	1 (0.0)	0
Lymphoedema	3 (0.0)	0
May-Thurner syndrome	2 (0.0)	2 (0.0)
Orthostatic hypertension	1 (0.0)	0
Orthostatic hypotension	0	3 (0.0)
Peripheral arterial occlusive disease	1 (0.0)	1 (0.0)
Peripheral artery thrombosis	1 (0.0)	0
Peripheral vascular disorder	0	1 (0.0)

14.4. Medical History – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=13069) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=13095) n[b] (%)
Peripheral venous disease	4 (0.0)	9 (0.1)
Phlebosclerosis	1 (0.0)	0
Prehypertension	2 (0.0)	1 (0.0)
Raynaud's phenomenon	17 (0.1)	14 (0.1)
Subclavian artery aneurysm	1 (0.0)	0
Subclavian vein thrombosis	1 (0.0)	1 (0.0)
Thrombosis	7 (0.1)	10 (0.1)
Varicose vein	21 (0.2)	32 (0.2)
Vena cava thrombosis	1 (0.0)	0
Venous thrombosis	2 (0.0)	0
Venous thrombosis limb	0	2 (0.0)
White coat hypertension	8 (0.1)	2 (0.0)

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: 28MAR2021 (14:29)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/admh_s002_all_1655_saf

14.5. Immunogenicity Blood Samples Drawn – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset)

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=280) n[b] (%)	16-25 Years (N[a]=280) n[b] (%)	12-15 Years (N[a]=50) n[b] (%)	16-25 Years (N[a]=50) n[b] (%)
Randomized	280 (100.0)	280 (100.0)	50 (100.0)	50 (100.0)
Not vaccinated	0	0	0	0
Blood sample drawn	280 (100.0)	280 (100.0)	50 (100.0)	50 (100.0)
Vaccinated at Dose 1	280 (100.0)	280 (100.0)	50 (100.0)	50 (100.0)
Blood sample drawn before Dose 1[c]	279 (99.6)	280 (100.0)	50 (100.0)	50 (100.0)
Not obtained	1 (0.4)	0	0	0
Vaccinated at Dose 2	279 (99.6)	280 (100.0)	50 (100.0)	50 (100.0)
Blood sample drawn 1 month after Dose 2[c]				
<28 Days	2 (0.7)	5 (1.8)	0	0
28 to 35 Days	271 (96.8)	255 (91.1)	49 (98.0)	45 (90.0)
>35 Days	6 (2.1)	15 (5.4)	1 (2.0)	4 (8.0)
Not obtained	0	5 (1.8)	0	1 (2.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Protocol-specified time frame.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (00:54)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adsl s001 imm bld ped rand

14.6. E-Diary Transmission – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years n[a] (%)	16-25 Years n[a] (%)	12-15 Years n[a] (%)	16-25 Years n[a] (%)
Vaccinated at Dose 1[b]	1131	537	1129	561
E-diary				
Not transmitted[c]	4 (0.4)	6 (1.1)	2 (0.2)	8 (1.4)
Transmitted[d]				
Day 1	1081 (95.6)	506 (94.2)	1066 (94.4)	514 (91.6)
Day 2	1089 (96.3)	509 (94.8)	1073 (95.0)	519 (92.5)
Day 3	1048 (92.7)	485 (90.3)	1056 (93.5)	515 (91.8)
Day 4	1025 (90.6)	478 (89.0)	1011 (89.5)	503 (89.7)
Day 5	1012 (89.5)	472 (87.9)	1002 (88.8)	492 (87.7)
Day 6	991 (87.6)	474 (88.3)	1002 (88.8)	484 (86.3)
Day 7	1006 (88.9)	476 (88.6)	989 (87.6)	476 (84.8)
All 7 days[e]	718 (63.5)	347 (64.6)	695 (61.6)	343 (61.1)
Vaccinated at Dose 2[b]	1124	525	1117	535
E-diary				
Not transmitted[c]	27 (2.4)	35 (6.7)	39 (3.5)	39 (7.3)
Transmitted[d]				
Day 1	852 (75.8)	377 (71.8)	785 (70.3)	348 (65.0)
Day 2	984 (87.5)	437 (83.2)	879 (78.7)	406 (75.9)
Day 3	959 (85.3)	419 (79.8)	904 (80.9)	428 (80.0)
Day 4	913 (81.2)	418 (79.6)	907 (81.2)	431 (80.6)
Day 5	917 (81.6)	421 (80.2)	909 (81.4)	433 (80.9)
Day 6	930 (82.7)	414 (78.9)	923 (82.6)	425 (79.4)
Day 7	925 (82.3)	412 (78.5)	912 (81.6)	426 (79.6)
All 7 days[e]	463 (41.2)	217 (41.3)	414 (37.1)	201 (37.6)

14.6. E-Diary Transmission – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years n[a] (%)	16-25 Years n[a] (%)	12-15 Years n[a] (%)	16-25 Years n[a] (%)

Note: Human immunodeficiency virus (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. 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 ped saf

14.7. E-Diary Transmission (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)
Vaccinated at Dose 1[b]	2982	2997
E-diary		
Not transmitted[c]	46 (1.5)	50 (1.7)
Transmitted[d]		
Day 1	2812 (94.3)	2775 (92.6)
Day 2	2804 (94.0)	2770 (92.4)
Day 3	2716 (91.1)	2771 (92.5)
Day 4	2685 (90.0)	2707 (90.3)
Day 5	2658 (89.1)	2705 (90.3)
Day 6	2665 (89.4)	2662 (88.8)
Day 7	2657 (89.1)	2676 (89.3)
All 7 days[e]	2005 (67.2)	2005 (66.9)
Vaccinated at Dose 2[b]	2924	2923
E-diary		
Not transmitted[c]	201 (6.9)	199 (6.8)
Transmitted[d]		
Day 1	2245 (76.8)	2120 (72.5)
Day 2	2511 (85.9)	2324 (79.5)
Day 3	2445 (83.6)	2390 (81.8)
Day 4	2426 (83.0)	2415 (82.6)
Day 5	2429 (83.1)	2419 (82.8)
Day 6	2446 (83.7)	2425 (83.0)
Day 7	2414 (82.6)	2442 (83.5)
All 7 days[e]	1517 (51.9)	1376 (47.1)

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: 28MAR2021 (12:24)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adce_s200_trns_1655_saf

14.8. Concomitant Vaccines Received From After Dose 1 Through 1 Month After Dose 2 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

Vaccine[b]	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N[a]=1131)	16-25 Years (N[a]=536)	12-15 Years (N[a]=1129)	16-25 Years (N[a]=561)
	n[c] (%)	n[c] (%)	n[c] (%)	n[c] (%)
Any concomitant vaccine	15 (1.3)	17 (3.2)	8 (0.7)	18 (3.2)
ANTHRAX VACCINE	0	0	0	1 (0.2)
HPV VACCINE	2 (0.2)	2 (0.4)	4 (0.4)	1 (0.2)
HPV VACCINE VLP RL1 4V (YEAST)	1 (0.1)	0	0	0
INFLUENZA VACCINE	8 (0.7)	13 (2.4)	4 (0.4)	10 (1.8)
INFLUENZA VACCINE INACT SPLIT 3V	0	0	0	2 (0.4)
INFLUENZA VACCINE INACT SPLIT 4V	2 (0.2)	1 (0.2)	1 (0.1)	1 (0.2)
MENINGOCOCCAL VACCINE	1 (0.1)	1 (0.2)	0	1 (0.2)
MENINGOCOCCAL VACCINE A/C/Y/W CONJ (CRM197)	0	1 (0.2)	0	2 (0.4)
MENINGOCOCCAL VACCINE A/C/Y/W CONJ (DIP TOX)	1 (0.1)	1 (0.2)	0	1 (0.2)
MENINGOCOCCAL VACCINE B RFHBP/NADA/NHBA OMV	0	1 (0.2)	0	1 (0.2)

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 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adcm_s001_vax_1m2_ped_saf

14.9. Concomitant Vaccines Received After Dose 1 – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

Vaccine[b]	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12995)	Placebo (N[a]=13026)
	n[c] (%)	n[c] (%)
Any concomitant vaccine	1291 (9.9)	1562 (12.0)
ANTHRAX VACCINE	0	1 (0.0)
CHOLERA VACCINE	0	1 (0.0)
COVID-19 VACCINE	3 (0.0)	56 (0.4)
COVID-19 VACCINE INACT (VERO)	4 (0.0)	6 (0.0)
COVID-19 VACCINE INACT (VERO) HB02	1 (0.0)	1 (0.0)
COVID-19 VACCINE MRNA (MRNA 1273)	8 (0.1)	71 (0.5)
COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)	0	3 (0.0)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 5-COMPONENT;TETANUS VACCINE TOXOID	2 (0.0)	2 (0.0)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	15 (0.1)	16 (0.1)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE;TETANUS VACCINE TOXOID	0	1 (0.0)
DIPHTHERIA VACCINE TOXOID;TETANUS VACCINE TOXOID	4 (0.0)	1 (0.0)
DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE	1 (0.0)	4 (0.0)
DIPHTHERIA VACCINE;TETANUS VACCINE	0	1 (0.0)
HEPATITIS A VACCINE	4 (0.0)	4 (0.0)
HEPATITIS A VACCINE;HEPATITIS B VACCINE	1 (0.0)	0
HEPATITIS B VACCINE	10 (0.1)	13 (0.1)
HEPATITIS VACCINES	1 (0.0)	0
HIB VACCINE CONJ	1 (0.0)	0
HPV VACCINE	7 (0.1)	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)
INFLUENZA VACCINE	1053 (8.1)	1195 (9.2)
INFLUENZA VACCINE INACT SAG 3V	19 (0.1)	17 (0.1)
INFLUENZA VACCINE INACT SAG 4V	17 (0.1)	13 (0.1)
INFLUENZA VACCINE INACT SPLIT 3V	25 (0.2)	22 (0.2)
INFLUENZA VACCINE INACT SPLIT 4V	99 (0.8)	117 (0.9)
INFLUENZA VACCINE LIVE REASSORT 4V	0	1 (0.0)
INFLUENZA VACCINE RHA 3V (BACULOVIRUS)	1 (0.0)	0
INFLUENZA VACCINE RHA 4V (BACULOVIRUS)	10 (0.1)	10 (0.1)

14.9. Concomitant Vaccines Received After Dose 1 – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

Vaccine[b]	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12995)	Placebo (N[a]=13026)
	n[c] (%)	n[c] (%)
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 (0.1)	5 (0.0)
MENINGOCOCCAL VACCINE	2 (0.0)	5 (0.0)
MENINGOCOCCAL VACCINE A/C/Y/W	1 (0.0)	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)
PNEUMOCOCCAL VACCINE	5 (0.0)	10 (0.1)
PNEUMOCOCCAL VACCINE CONJ 13V (CRM197)	0	1 (0.0)
PNEUMOCOCCAL VACCINE POLYSACCH	2 (0.0)	1 (0.0)
PNEUMOCOCCAL VACCINE POLYSACCH 23V	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	15 (0.1)	16 (0.1)
TETANUS VACCINE TOXOID	4 (0.0)	0
TYPHOID VACCINE	1 (0.0)	2 (0.0)
VARICELLA ZOSTER VACCINE	19 (0.1)	13 (0.1)
VARICELLA ZOSTER VACCINE LIVE (OKA/MERCK)	0	1 (0.0)
VARICELLA ZOSTER VACCINE RGE (CHO)	9 (0.1)	16 (0.1)
YELLOW FEVER VACCINE	0	2 (0.0)
YELLOW FEVER VACCINE LIVE (17D-204)	1 (0.0)	0

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: 28MAR2021 (14:47)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adsl_fu_1655_saf

Immunogenicity

14.10. Summary of Geometric Mean Titers, by Baseline SARS-CoV-2 Status – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
			12-15 Years		16-25 Years		12-15 Years		16-25 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMT[d] (95% CI[d])	n[c]	GMT[d] (95% CI[d])	n[c]	GMT[d] (95% CI[d])	n[c]	GMT[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	ALL	155	11.2 (10.3, 12.3)	136	10.5 (9.9, 11.2)	29	11.2 (8.9, 14.0)	24	10.0 (10.0, 10.0)
		POS	8	54.1 (19.7, 148.7)	5	38.6 (6.4, 232.9)	1	251.0 (NE, NE)	0	NE (NE, NE)
		NEG	146	10.3 (9.7, 10.9)	131	10.0 (10.0, 10.0)	27	10.0 (10.0, 10.0)	24	10.0 (10.0, 10.0)
	2/1 Month	ALL	207	1283.0 (1139.6, 1444.5)	185	730.8 (646.7, 825.8)	36	15.1 (10.7, 21.4)	32	10.7 (9.3, 12.4)
		POS	10	2342.2 (1308.7, 4191.8)	8	1439.2 (727.1, 2848.7)	2	191.0 (1.2, 30873.6)	1	10.0 (NE, NE)
		NEG	192	1239.2 (1096.6, 1400.5)	177	708.7 (626.4, 802.0)	33	13.1 (9.7, 17.7)	31	10.8 (9.3, 12.5)

Abbreviations: COVID-19 = coronavirus disease 2019; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; NE = not estimable; NEG = negative;
NT50 = 50% neutralizing titer; POS = positive; Prevax = before vaccination; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. POS = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. NEG = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19. ALL = irrespective of baseline SARS-CoV-2 status, including missing baseline status.
c. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
d. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:54)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adva_s001_gm_ped_eval

14.11. Summary of Geometric Mean Titers, by Baseline SARS-CoV-2 Status – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 All-Available Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
			12-15 Years		16-25 Years		12-15 Years		16-25 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMT[d] (95% CI[d])	n[c]	GMT[d] (95% CI[d])	n[c]	GMT[d] (95% CI[d])	n[c]	GMT[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	ALL	156	11.2 (10.2, 12.3)	140	10.5 (9.9, 11.1)	29	11.2 (8.9, 14.0)	25	10.0 (10.0, 10.0)
		POS	8	54.1 (19.7, 148.7)	5	38.6 (6.4, 232.9)	1	251.0 (NE, NE)	0	NE (NE, NE)
		NEG	147	10.3 (9.7, 10.9)	135	10.0 (10.0, 10.0)	27	10.0 (10.0, 10.0)	25	10.0 (10.0, 10.0)
	2/1 Month	ALL	208	1284.4 (1141.4, 1445.2)	190	726.3 (643.9, 819.1)	36	15.1 (10.7, 21.4)	34	10.7 (9.3, 12.2)
		POS	10	2342.2 (1308.7, 4191.8)	8	1439.2 (727.1, 2848.7)	2	191.0 (1.2, 30873.6)	1	10.0 (NE, NE)
		NEG	193	1240.9 (1098.7, 1401.5)	182	704.7 (624.1, 795.9)	33	13.1 (9.7, 17.7)	33	10.7 (9.3, 12.3)

Abbreviations: COVID-19 = coronavirus disease 2019; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; NE = not estimable; NEG = negative;
NT50 = 50% neutralizing titer; POS = positive; Prevax = before vaccination; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. POS = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. NEG = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19. ALL = irrespective of baseline SARS-CoV-2 status, including missing baseline status.
c. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
d. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:54)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adva_s001_gm_ped_aai

14.12. Summary of Geometric Mean Fold Rise From Before Vaccination to Each Subsequent Time Point, by Baseline SARS-CoV-2 Status – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 All-Available Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
			12-15 Years		16-25 Years		12-15 Years		16-25 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	ALL	155	118.5 (101.7, 138.0)	139	70.3 (60.7, 81.5)	29	1.4 (1.0, 1.9)	25	1.1 (0.9, 1.3)
		POS	8	47.6 (26.4, 86.0)	5	47.1 (3.1, 721.4)	1	1.1 (NE, NE)	0	NE (NE, NE)
		NEG	146	125.2 (107.2, 146.3)	134	71.4 (62.2, 81.9)	27	1.4 (1.0, 2.0)	25	1.1 (0.9, 1.3)

Abbreviations: COVID-19 = coronavirus disease 2019; GMFR = geometric mean fold rise; LLOQ = lower limit of quantitation;
NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; NE = not estimable; NEG = negative;
NT50 = 50% neutralizing titer; POS = positive; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. POS = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. NEG = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19. ALL = irrespective of baseline SARS-CoV-2 status, including missing baseline status.
c. n = Number of subjects with valid and determinate assay results for the specified assay both prevaccination time points and at the given dose/sampling time point.
d. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (06:15)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adva_s002_gmfr_ped_aai

Local Reactions

14.13. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]												
	Any	1127	65 (5.8)	(4.5, 7.3)	531	34 (6.4)	(4.5, 8.8)	1127	12 (1.1)	(0.6, 1.9)	553	5 (0.9)	(0.3, 2.1)
	Mild	1127	44 (3.9)	(2.9, 5.2)	531	25 (4.7)	(3.1, 6.9)	1127	11 (1.0)	(0.5, 1.7)	553	4 (0.7)	(0.2, 1.8)
	Moderate	1127	20 (1.8)	(1.1, 2.7)	531	7 (1.3)	(0.5, 2.7)	1127	1 (0.1)	(0.0, 0.5)	553	1 (0.2)	(0.0, 1.0)
	Severe	1127	1 (0.1)	(0.0, 0.5)	531	2 (0.4)	(0.0, 1.4)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Swelling[d]												
	Any	1127	78 (6.9)	(5.5, 8.6)	531	44 (8.3)	(6.1, 11.0)	1127	11 (1.0)	(0.5, 1.7)	553	6 (1.1)	(0.4, 2.3)
	Mild	1127	55 (4.9)	(3.7, 6.3)	531	31 (5.8)	(4.0, 8.2)	1127	9 (0.8)	(0.4, 1.5)	553	3 (0.5)	(0.1, 1.6)
	Moderate	1127	23 (2.0)	(1.3, 3.0)	531	12 (2.3)	(1.2, 3.9)	1127	2 (0.2)	(0.0, 0.6)	553	3 (0.5)	(0.1, 1.6)
	Severe	1127	0	(0.0, 0.3)	531	1 (0.2)	(0.0, 1.0)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Pain at the injection site[e]												
	Any	1127	971 (86.2)	(84.0, 88.1)	531	443 (83.4)	(80.0, 86.5)	1127	263 (23.3)	(20.9, 25.9)	553	88 (15.9)	(13.0, 19.2)
	Mild	1127	467 (41.4)	(38.5, 44.4)	531	204 (38.4)	(34.3, 42.7)	1127	227 (20.1)	(17.8, 22.6)	553	81 (14.6)	(11.8, 17.9)
	Moderate	1127	493 (43.7)	(40.8, 46.7)	531	227 (42.7)	(38.5, 47.1)	1127	36 (3.2)	(2.2, 4.4)	553	7 (1.3)	(0.5, 2.6)
	Severe	1127	11 (1.0)	(0.5, 1.7)	531	12 (2.3)	(1.2, 3.9)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)

14.13. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any local reaction[f]	1127	976 (86.6)	(84.5, 88.5)	531	445 (83.8)	(80.4, 86.8)	1127	271 (24.0)	(21.6, 26.7)	553	91 (16.5)	(13.5, 19.8)
2	Redness[d]												
	Any	1097	55 (5.0)	(3.8, 6.5)	488	28 (5.7)	(3.8, 8.2)	1078	10 (0.9)	(0.4, 1.7)	496	1 (0.2)	(0.0, 1.1)
	Mild	1097	29 (2.6)	(1.8, 3.8)	488	18 (3.7)	(2.2, 5.8)	1078	8 (0.7)	(0.3, 1.5)	496	1 (0.2)	(0.0, 1.1)
	Moderate	1097	26 (2.4)	(1.6, 3.5)	488	9 (1.8)	(0.8, 3.5)	1078	2 (0.2)	(0.0, 0.7)	496	0	(0.0, 0.7)
	Severe	1097	0	(0.0, 0.3)	488	1 (0.2)	(0.0, 1.1)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Swelling[d]												
	Any	1097	54 (4.9)	(3.7, 6.4)	488	33 (6.8)	(4.7, 9.4)	1078	6 (0.6)	(0.2, 1.2)	496	1 (0.2)	(0.0, 1.1)
	Mild	1097	36 (3.3)	(2.3, 4.5)	488	23 (4.7)	(3.0, 7.0)	1078	4 (0.4)	(0.1, 0.9)	496	1 (0.2)	(0.0, 1.1)
	Moderate	1097	18 (1.6)	(1.0, 2.6)	488	10 (2.0)	(1.0, 3.7)	1078	2 (0.2)	(0.0, 0.7)	496	0	(0.0, 0.7)
	Severe	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Pain at the injection site[e]												
	Any	1097	866 (78.9)	(76.4, 81.3)	488	378 (77.5)	(73.5, 81.1)	1078	193 (17.9)	(15.7, 20.3)	496	60 (12.1)	(9.4, 15.3)
	Mild	1097	466 (42.5)	(39.5, 45.5)	488	202 (41.4)	(37.0, 45.9)	1078	164 (15.2)	(13.1, 17.5)	496	53 (10.7)	(8.1, 13.7)
	Moderate	1097	393 (35.8)	(33.0, 38.7)	488	169 (34.6)	(30.4, 39.0)	1078	29 (2.7)	(1.8, 3.8)	496	7 (1.4)	(0.6, 2.9)
	Severe	1097	7 (0.6)	(0.3, 1.3)	488	7 (1.4)	(0.6, 2.9)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Any local reaction[f]	1097	872 (79.5)	(77.0, 81.8)	488	381 (78.1)	(74.1, 81.7)	1078	198 (18.4)	(16.1, 20.8)	496	62 (12.5)	(9.7, 15.7)

14.13. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Any dose	Redness[d]												
	Any	1131	97 (8.6)	(7.0, 10.4)	535	55 (10.3)	(7.8, 13.2)	1129	18 (1.6)	(0.9, 2.5)	555	5 (0.9)	(0.3, 2.1)
	Mild	1131	55 (4.9)	(3.7, 6.3)	535	37 (6.9)	(4.9, 9.4)	1129	15 (1.3)	(0.7, 2.2)	555	4 (0.7)	(0.2, 1.8)
	Moderate	1131	41 (3.6)	(2.6, 4.9)	535	15 (2.8)	(1.6, 4.6)	1129	3 (0.3)	(0.1, 0.8)	555	1 (0.2)	(0.0, 1.0)
	Severe	1131	1 (0.1)	(0.0, 0.5)	535	3 (0.6)	(0.1, 1.6)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Swelling[d]												
	Any	1131	104 (9.2)	(7.6, 11.0)	535	61 (11.4)	(8.8, 14.4)	1129	13 (1.2)	(0.6, 2.0)	555	7 (1.3)	(0.5, 2.6)
	Mild	1131	69 (6.1)	(4.8, 7.7)	535	44 (8.2)	(6.0, 10.9)	1129	10 (0.9)	(0.4, 1.6)	555	4 (0.7)	(0.2, 1.8)
	Moderate	1131	35 (3.1)	(2.2, 4.3)	535	16 (3.0)	(1.7, 4.8)	1129	3 (0.3)	(0.1, 0.8)	555	3 (0.5)	(0.1, 1.6)
	Severe	1131	0	(0.0, 0.3)	535	1 (0.2)	(0.0, 1.0)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Pain at the injection site[e]												
	Any	1131	1023 (90.5)	(88.6, 92.1)	535	468 (87.5)	(84.4, 90.2)	1129	341 (30.2)	(27.5, 33.0)	555	121 (21.8)	(18.4, 25.5)
	Mild	1131	394 (34.8)	(32.1, 37.7)	535	168 (31.4)	(27.5, 35.5)	1129	283 (25.1)	(22.6, 27.7)	555	108 (19.5)	(16.2, 23.0)
	Moderate	1131	612 (54.1)	(51.2, 57.0)	535	282 (52.7)	(48.4, 57.0)	1129	58 (5.1)	(3.9, 6.6)	555	13 (2.3)	(1.3, 4.0)
	Severe	1131	17 (1.5)	(0.9, 2.4)	535	18 (3.4)	(2.0, 5.3)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Any local reaction[f]	1131	1028 (90.9)	(89.1, 92.5)	535	471 (88.0)	(85.0, 90.7)	1129	349 (30.9)	(28.2, 33.7)	555	125 (22.5)	(19.1, 26.2)

14.13. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

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 sev ped saf

14.14. Onset Days for Local Reactions – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Local Reaction	12-15 Years	16-25 Years	12-15 Years	16-25 Years
1	Redness				
	n[a]	65	34	12	5
	Mean (SD)	2.4 (0.82)	2.4 (1.05)	1.8 (1.11)	1.8 (1.30)
	Median	2.0	2.0	1.5	1.0
	Min, max	(1, 4)	(1, 5)	(1, 4)	(1, 4)
	Swelling				
	n[a]	78	44	11	6
	Mean (SD)	1.9 (0.85)	2.2 (1.02)	1.6 (1.21)	1.3 (0.82)
	Median	2.0	2.0	1.0	1.0
	Min, max	(1, 5)	(1, 5)	(1, 4)	(1, 3)
	Pain at the injection site				
	n[a]	971	443	263	88
	Mean (SD)	1.4 (0.55)	1.4 (0.51)	1.3 (0.84)	1.5 (1.05)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 7)	(1, 4)	(1, 7)	(1, 7)
	Any local reaction[b]				
	n[a]	976	445	271	91
	Mean (SD)	1.4 (0.56)	1.4 (0.51)	1.4 (0.87)	1.5 (1.06)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 7)	(1, 4)	(1, 7)	(1, 7)
2	Redness				
	n[a]	55	28	10	1
	Mean (SD)	2.5 (0.84)	2.6 (0.79)	1.2 (0.42)	1.0 (NE)
	Median	2.0	3.0	1.0	1.0
	Min, max	(1, 5)	(1, 4)	(1, 2)	(1, 1)
	Swelling				
	n[a]	54	33	6	1
	Mean (SD)	2.1 (0.96)	2.0 (0.98)	2.8 (2.86)	3.0 (NE)
	Median	2.0	2.0	1.0	3.0
	Min, max	(1, 4)	(1, 4)	(1, 7)	(3, 3)
	Pain at the injection site				
	n[a]	866	378	193	60
	Mean (SD)	1.4 (0.61)	1.4 (0.62)	1.5 (1.14)	1.6 (1.06)

14.14. Onset Days for Local Reactions – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Local Reaction	12-15 Years	16-25 Years	12-15 Years	16-25 Years
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 6)	(1, 6)	(1, 7)	(1, 6)
	Any local reaction[b]				
	n[a]	872	381	198	62
	Mean (SD)	1.4 (0.62)	1.4 (0.63)	1.5 (1.08)	1.6 (1.06)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 6)	(1, 6)	(1, 7)	(1, 6)

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified reaction was reported.
a. n = Number of subjects reporting the specified reaction, with each subject counted only once per reaction.
b. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 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 ped saf

14.15. Duration (Days) From First to Last Day of Local Reactions – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Local Reaction	12-15 Years	16-25 Years	12-15 Years	16-25 Years
1	Redness				
	n[a]	65	34	12	5
	Mean (SD)	2.4 (2.26)	1.8 (0.97)	1.3 (0.62)	1.2 (0.45)
	Median	2.0	2.0	1.0	1.0
	Min, max	(1, 16)	(1, 5)	(1, 3)	(1, 2)
	Swelling				
	n[a]	78	44	11	6
	Mean (SD)	1.9 (1.10)	2.0 (1.50)	1.7 (1.35)	1.3 (0.82)
	Median	2.0	1.0	1.0	1.0
	Min, max	(1, 5)	(1, 7)	(1, 5)	(1, 3)
	Pain at the injection site				
	n[a]	971	443	263	88
	Mean (SD)	2.4 (1.35)	2.3 (1.37)	2.0 (1.75)	1.5 (1.27)
	Median	2.0	2.0	1.0	1.0
	Min, max	(1, 10)	(1, 9)	(1, 10)	(1, 11)
2	Redness				
	n[a]	55	28	10	1
	Mean (SD)	1.8 (0.88)	1.9 (1.43)	1.7 (1.16)	1.0 (NE)
	Median	2.0	1.5	1.0	1.0
	Min, max	(1, 5)	(1, 8)	(1, 4)	(1, 1)
	Unknown[b]	1	0	0	0
	Swelling				
	n[a]	54	33	6	1
	Mean (SD)	1.6 (0.93)	2.2 (1.69)	1.5 (0.55)	3.0 (NE)
	Median	1.0	2.0	1.5	3.0
	Min, max	(1, 5)	(1, 7)	(1, 2)	(3, 3)
	Pain at the injection site				
	n[a]	866	378	193	60
	Mean (SD)	2.5 (1.38)	2.8 (4.31)	1.8 (1.44)	2.2 (4.45)
	Median	2.0	2.0	1.0	1.0
	Min, max	(1, 11)	(1, 70)	(1, 8)	(1, 35)
	Unknown[b]	3	3	0	0

14.15. Duration (Days) From First to Last Day of Local Reactions – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Local Reaction	12-15 Years	16-25 Years	12-15 Years	16-25 Years

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported reaction to the resolution of the last reported reaction, inclusive. 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_ped_saf

14.16. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 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	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)
	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)

14.16. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 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])
	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)

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: 28MAR2021 (14:46)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 EUA 1655/adce s010 lr 1655 saf

14.17. Onset Days for Local Reactions (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
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)

14.17. Onset Days for Local Reactions (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

		Vaccine Group (as Administered)	
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)

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: 30MAR2021 (08:23)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 EUA 1655/adce s050 lr onset 1655 saf

14.18. Duration (Days) From First to Last Day of Local Reactions (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
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

14.18. Duration (Days) From First to Last Day of Local Reactions (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

		Vaccine Group (as Administered)	
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: 30MAR2021 (08:22)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 EUA 1655/adce s030 lr dur 1655 saf

Systemic Events

14.19. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever												
	≥38.0°C	1127	114 (10.1)	(8.4, 12.0)	531	39 (7.3)	(5.3, 9.9)	1127	12 (1.1)	(0.6, 1.9)	553	8 (1.4)	(0.6, 2.8)
	≥38.0°C to 38.4°C	1127	74 (6.6)	(5.2, 8.2)	531	24 (4.5)	(2.9, 6.7)	1127	8 (0.7)	(0.3, 1.4)	553	5 (0.9)	(0.3, 2.1)
	>38.4°C to 38.9°C	1127	29 (2.6)	(1.7, 3.7)	531	12 (2.3)	(1.2, 3.9)	1127	2 (0.2)	(0.0, 0.6)	553	2 (0.4)	(0.0, 1.3)
	>38.9°C to 40.0°C	1127	10 (0.9)	(0.4, 1.6)	531	3 (0.6)	(0.1, 1.6)	1127	2 (0.2)	(0.0, 0.6)	553	1 (0.2)	(0.0, 1.0)
	>40.0°C	1127	1 (0.1)	(0.0, 0.5)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Fatigue[d]												
	Any	1127	677 (60.1)	(57.1, 62.9)	531	318 (59.9)	(55.6, 64.1)	1127	457 (40.6)	(37.7, 43.5)	553	213 (38.5)	(34.4, 42.7)
	Mild	1127	278 (24.7)	(22.2, 27.3)	531	134 (25.2)	(21.6, 29.2)	1127	250 (22.2)	(19.8, 24.7)	553	118 (21.3)	(18.0, 25.0)
	Moderate	1127	384 (34.1)	(31.3, 36.9)	531	173 (32.6)	(28.6, 36.7)	1127	199 (17.7)	(15.5, 20.0)	553	89 (16.1)	(13.1, 19.4)
	Severe	1127	15 (1.3)	(0.7, 2.2)	531	11 (2.1)	(1.0, 3.7)	1127	8 (0.7)	(0.3, 1.4)	553	6 (1.1)	(0.4, 2.3)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Headache[d]												
	Any	1127	623 (55.3)	(52.3, 58.2)	531	286 (53.9)	(49.5, 58.2)	1127	396 (35.1)	(32.3, 38.0)	553	205 (37.1)	(33.0, 41.2)
	Mild	1127	361 (32.0)	(29.3, 34.8)	531	151 (28.4)	(24.6, 32.5)	1127	256 (22.7)	(20.3, 25.3)	553	138 (25.0)	(21.4, 28.8)

14.19. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	1127	251 (22.3)	(19.9, 24.8)	531	124 (23.4)	(19.8, 27.2)	1127	131 (11.6)	(9.8, 13.6)	553	63 (11.4)	(8.9, 14.3)
	Severe	1127	11 (1.0)	(0.5, 1.7)	531	11 (2.1)	(1.0, 3.7)	1127	9 (0.8)	(0.4, 1.5)	553	4 (0.7)	(0.2, 1.8)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Chills[d]												
	Any	1127	311 (27.6)	(25.0, 30.3)	531	133 (25.0)	(21.4, 29.0)	1127	109 (9.7)	(8.0, 11.5)	553	47 (8.5)	(6.3, 11.1)
	Mild	1127	195 (17.3)	(15.1, 19.6)	531	91 (17.1)	(14.0, 20.6)	1127	82 (7.3)	(5.8, 9.0)	553	31 (5.6)	(3.8, 7.9)
	Moderate	1127	111 (9.8)	(8.2, 11.7)	531	37 (7.0)	(5.0, 9.5)	1127	25 (2.2)	(1.4, 3.3)	553	15 (2.7)	(1.5, 4.4)
	Severe	1127	5 (0.4)	(0.1, 1.0)	531	5 (0.9)	(0.3, 2.2)	1127	2 (0.2)	(0.0, 0.6)	553	1 (0.2)	(0.0, 1.0)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Vomiting[e]												
	Any	1127	31 (2.8)	(1.9, 3.9)	531	9 (1.7)	(0.8, 3.2)	1127	10 (0.9)	(0.4, 1.6)	553	9 (1.6)	(0.7, 3.1)
	Mild	1127	30 (2.7)	(1.8, 3.8)	531	9 (1.7)	(0.8, 3.2)	1127	8 (0.7)	(0.3, 1.4)	553	8 (1.4)	(0.6, 2.8)
	Moderate	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	2 (0.2)	(0.0, 0.6)	553	0	(0.0, 0.7)
	Severe	1127	1 (0.1)	(0.0, 0.5)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	1 (0.2)	(0.0, 1.0)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Diarrhea[f]												
	Any	1127	90 (8.0)	(6.5, 9.7)	531	57 (10.7)	(8.2, 13.7)	1127	82 (7.3)	(5.8, 9.0)	553	62 (11.2)	(8.7, 14.1)
	Mild	1127	77 (6.8)	(5.4, 8.5)	531	50 (9.4)	(7.1, 12.2)	1127	72 (6.4)	(5.0, 8.0)	553	49 (8.9)	(6.6, 11.5)
	Moderate	1127	13 (1.2)	(0.6, 2.0)	531	7 (1.3)	(0.5, 2.7)	1127	10 (0.9)	(0.4, 1.6)	553	13 (2.4)	(1.3, 4.0)
	Severe	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)

14.19. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	New or worsened muscle pain[d]												
	Any	1127	272 (24.1)	(21.7, 26.7)	531	143 (26.9)	(23.2, 30.9)	1127	148 (13.1)	(11.2, 15.2)	553	78 (14.1)	(11.3, 17.3)
	Mild	1127	125 (11.1)	(9.3, 13.1)	531	67 (12.6)	(9.9, 15.7)	1127	88 (7.8)	(6.3, 9.5)	553	51 (9.2)	(6.9, 11.9)
	Moderate	1127	145 (12.9)	(11.0, 15.0)	531	71 (13.4)	(10.6, 16.6)	1127	60 (5.3)	(4.1, 6.8)	553	27 (4.9)	(3.2, 7.0)
	Severe	1127	2 (0.2)	(0.0, 0.6)	531	5 (0.9)	(0.3, 2.2)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	New or worsened joint pain[d]												
	Any	1127	109 (9.7)	(8.0, 11.5)	531	70 (13.2)	(10.4, 16.4)	1127	77 (6.8)	(5.4, 8.5)	553	28 (5.1)	(3.4, 7.2)
	Mild	1127	66 (5.9)	(4.6, 7.4)	531	38 (7.2)	(5.1, 9.7)	1127	50 (4.4)	(3.3, 5.8)	553	17 (3.1)	(1.8, 4.9)
	Moderate	1127	42 (3.7)	(2.7, 5.0)	531	29 (5.5)	(3.7, 7.7)	1127	27 (2.4)	(1.6, 3.5)	553	11 (2.0)	(1.0, 3.5)
	Severe	1127	1 (0.1)	(0.0, 0.5)	531	3 (0.6)	(0.1, 1.6)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Any systemic event[g]	1127	877 (77.8)	(75.3, 80.2)	531	403 (75.9)	(72.0, 79.5)	1127	636 (56.4)	(53.5, 59.4)	553	311 (56.2)	(52.0, 60.4)
	Use of antipyretic or pain medication[h]	1127	413 (36.6)	(33.8, 39.5)	531	167 (31.5)	(27.5, 35.6)	1127	111 (9.8)	(8.2, 11.7)	553	62 (11.2)	(8.7, 14.1)
2	Fever												
	≥38.0°C	1097	215 (19.6)	(17.3, 22.1)	488	84 (17.2)	(14.0, 20.9)	1078	7 (0.6)	(0.3, 1.3)	496	2 (0.4)	(0.0, 1.4)

14.19. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	≥38.0°C to 38.4°C	1097	107 (9.8)	(8.1, 11.7)	488	45 (9.2)	(6.8, 12.1)	1078	5 (0.5)	(0.2, 1.1)	496	1 (0.2)	(0.0, 1.1)
	>38.4°C to 38.9°C	1097	83 (7.6)	(6.1, 9.3)	488	32 (6.6)	(4.5, 9.1)	1078	1 (0.1)	(0.0, 0.5)	496	0	(0.0, 0.7)
	>38.9°C to 40.0°C	1097	25 (2.3)	(1.5, 3.3)	488	7 (1.4)	(0.6, 2.9)	1078	1 (0.1)	(0.0, 0.5)	496	1 (0.2)	(0.0, 1.1)
	>40.0°C	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Fatigue[d]												
	Any	1097	726 (66.2)	(63.3, 69.0)	488	320 (65.6)	(61.2, 69.8)	1078	264 (24.5)	(21.9, 27.2)	496	115 (23.2)	(19.5, 27.2)
	Mild	1097	232 (21.1)	(18.8, 23.7)	488	98 (20.1)	(16.6, 23.9)	1078	133 (12.3)	(10.4, 14.5)	496	51 (10.3)	(7.8, 13.3)
	Moderate	1097	468 (42.7)	(39.7, 45.7)	488	199 (40.8)	(36.4, 45.3)	1078	127 (11.8)	(9.9, 13.9)	496	62 (12.5)	(9.7, 15.7)
	Severe	1097	26 (2.4)	(1.6, 3.5)	488	23 (4.7)	(3.0, 7.0)	1078	4 (0.4)	(0.1, 0.9)	496	2 (0.4)	(0.0, 1.4)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Headache[d]												
	Any	1097	708 (64.5)	(61.6, 67.4)	488	297 (60.9)	(56.4, 65.2)	1078	263 (24.4)	(21.9, 27.1)	496	118 (23.8)	(20.1, 27.8)
	Mild	1097	302 (27.5)	(24.9, 30.3)	488	119 (24.4)	(20.6, 28.4)	1078	169 (15.7)	(13.6, 18.0)	496	67 (13.5)	(10.6, 16.8)
	Moderate	1097	384 (35.0)	(32.2, 37.9)	488	157 (32.2)	(28.0, 36.5)	1078	93 (8.6)	(7.0, 10.5)	496	46 (9.3)	(6.9, 12.2)
	Severe	1097	22 (2.0)	(1.3, 3.0)	488	21 (4.3)	(2.7, 6.5)	1078	1 (0.1)	(0.0, 0.5)	496	5 (1.0)	(0.3, 2.3)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Chills[d]												
	Any	1097	455 (41.5)	(38.5, 44.5)	488	195 (40.0)	(35.6, 44.5)	1078	73 (6.8)	(5.3, 8.4)	496	22 (4.4)	(2.8, 6.6)
	Mild	1097	221 (20.1)	(17.8, 22.6)	488	82 (16.8)	(13.6, 20.4)	1078	52 (4.8)	(3.6, 6.3)	496	17 (3.4)	(2.0, 5.4)

14.19. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	1097	214 (19.5)	(17.2, 22.0)	488	101 (20.7)	(17.2, 24.6)	1078	21 (1.9)	(1.2, 3.0)	496	5 (1.0)	(0.3, 2.3)
	Severe	1097	20 (1.8)	(1.1, 2.8)	488	12 (2.5)	(1.3, 4.3)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Vomiting[e]												
	Any	1097	29 (2.6)	(1.8, 3.8)	488	13 (2.7)	(1.4, 4.5)	1078	12 (1.1)	(0.6, 1.9)	496	9 (1.8)	(0.8, 3.4)
	Mild	1097	25 (2.3)	(1.5, 3.3)	488	10 (2.0)	(1.0, 3.7)	1078	11 (1.0)	(0.5, 1.8)	496	5 (1.0)	(0.3, 2.3)
	Moderate	1097	4 (0.4)	(0.1, 0.9)	488	3 (0.6)	(0.1, 1.8)	1078	1 (0.1)	(0.0, 0.5)	496	4 (0.8)	(0.2, 2.1)
	Severe	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Diarrhea[f]												
	Any	1097	65 (5.9)	(4.6, 7.5)	488	39 (8.0)	(5.7, 10.8)	1078	43 (4.0)	(2.9, 5.3)	496	26 (5.2)	(3.5, 7.6)
	Mild	1097	59 (5.4)	(4.1, 6.9)	488	32 (6.6)	(4.5, 9.1)	1078	38 (3.5)	(2.5, 4.8)	496	21 (4.2)	(2.6, 6.4)
	Moderate	1097	6 (0.5)	(0.2, 1.2)	488	5 (1.0)	(0.3, 2.4)	1078	5 (0.5)	(0.2, 1.1)	496	5 (1.0)	(0.3, 2.3)
	Severe	1097	0	(0.0, 0.3)	488	2 (0.4)	(0.0, 1.5)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	New or worsened muscle pain[d]												
	Any	1097	355 (32.4)	(29.6, 35.2)	488	199 (40.8)	(36.4, 45.3)	1078	90 (8.3)	(6.8, 10.2)	496	48 (9.7)	(7.2, 12.6)
	Mild	1097	152 (13.9)	(11.9, 16.0)	488	93 (19.1)	(15.7, 22.8)	1078	51 (4.7)	(3.5, 6.2)	496	29 (5.8)	(4.0, 8.3)
	Moderate	1097	197 (18.0)	(15.7, 20.4)	488	97 (19.9)	(16.4, 23.7)	1078	37 (3.4)	(2.4, 4.7)	496	18 (3.6)	(2.2, 5.7)
	Severe	1097	6 (0.5)	(0.2, 1.2)	488	9 (1.8)	(0.8, 3.5)	1078	2 (0.2)	(0.0, 0.7)	496	1 (0.2)	(0.0, 1.1)

14.19. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	New or worsened joint pain[d]												
	Any	1097	173 (15.8)	(13.7, 18.1)	488	107 (21.9)	(18.3, 25.9)	1078	51 (4.7)	(3.5, 6.2)	496	20 (4.0)	(2.5, 6.2)
	Mild	1097	91 (8.3)	(6.7, 10.1)	488	49 (10.0)	(7.5, 13.1)	1078	30 (2.8)	(1.9, 3.9)	496	14 (2.8)	(1.6, 4.7)
	Moderate	1097	78 (7.1)	(5.7, 8.8)	488	54 (11.1)	(8.4, 14.2)	1078	21 (1.9)	(1.2, 3.0)	496	6 (1.2)	(0.4, 2.6)
	Severe	1097	4 (0.4)	(0.1, 0.9)	488	4 (0.8)	(0.2, 2.1)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Any systemic event[g]	1097	904 (82.4)	(80.0, 84.6)	488	396 (81.1)	(77.4, 84.5)	1078	439 (40.7)	(37.8, 43.7)	496	183 (36.9)	(32.6, 41.3)
	Use of antipyretic or pain medication[h]	1097	557 (50.8)	(47.8, 53.8)	488	223 (45.7)	(41.2, 50.2)	1078	95 (8.8)	(7.2, 10.7)	496	59 (11.9)	(9.2, 15.1)
Any dose	Fever												
	≥38.0°C	1131	275 (24.3)	(21.8, 26.9)	535	113 (21.1)	(17.7, 24.8)	1129	17 (1.5)	(0.9, 2.4)	555	9 (1.6)	(0.7, 3.1)
	≥38.0°C to 38.4°C	1131	141 (12.5)	(10.6, 14.5)	535	63 (11.8)	(9.2, 14.8)	1129	11 (1.0)	(0.5, 1.7)	555	6 (1.1)	(0.4, 2.3)
	>38.4°C to 38.9°C	1131	100 (8.8)	(7.3, 10.6)	535	40 (7.5)	(5.4, 10.0)	1129	3 (0.3)	(0.1, 0.8)	555	2 (0.4)	(0.0, 1.3)
	>38.9°C to 40.0°C	1131	33 (2.9)	(2.0, 4.1)	535	10 (1.9)	(0.9, 3.4)	1129	3 (0.3)	(0.1, 0.8)	555	1 (0.2)	(0.0, 1.0)
	>40.0°C	1131	1 (0.1)	(0.0, 0.5)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)

14.19. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Fatigue[d]												
	Any	1131	876 (77.5)	(74.9, 79.9)	535	403 (75.3)	(71.4, 78.9)	1129	538 (47.7)	(44.7, 50.6)	555	240 (43.2)	(39.1, 47.5)
	Mild	1131	239 (21.1)	(18.8, 23.6)	535	104 (19.4)	(16.2, 23.1)	1129	266 (23.6)	(21.1, 26.1)	555	114 (20.5)	(17.3, 24.1)
	Moderate	1131	597 (52.8)	(49.8, 55.7)	535	267 (49.9)	(45.6, 54.2)	1129	260 (23.0)	(20.6, 25.6)	555	119 (21.4)	(18.1, 25.1)
	Severe	1131	40 (3.5)	(2.5, 4.8)	535	32 (6.0)	(4.1, 8.3)	1129	12 (1.1)	(0.6, 1.8)	555	7 (1.3)	(0.5, 2.6)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Headache[d]												
	Any	1131	854 (75.5)	(72.9, 78.0)	535	386 (72.1)	(68.1, 75.9)	1129	506 (44.8)	(41.9, 47.8)	555	243 (43.8)	(39.6, 48.0)
	Mild	1131	324 (28.6)	(26.0, 31.4)	535	140 (26.2)	(22.5, 30.1)	1129	303 (26.8)	(24.3, 29.5)	555	147 (26.5)	(22.9, 30.4)
	Moderate	1131	499 (44.1)	(41.2, 47.1)	535	216 (40.4)	(36.2, 44.7)	1129	194 (17.2)	(15.0, 19.5)	555	87 (15.7)	(12.8, 19.0)
	Severe	1131	31 (2.7)	(1.9, 3.9)	535	30 (5.6)	(3.8, 7.9)	1129	9 (0.8)	(0.4, 1.5)	555	9 (1.6)	(0.7, 3.1)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Chills[d]												
	Any	1131	557 (49.2)	(46.3, 52.2)	535	256 (47.9)	(43.5, 52.2)	1129	159 (14.1)	(12.1, 16.3)	555	60 (10.8)	(8.4, 13.7)
	Mild	1131	257 (22.7)	(20.3, 25.3)	535	117 (21.9)	(18.4, 25.6)	1129	114 (10.1)	(8.4, 12.0)	555	41 (7.4)	(5.4, 9.9)
	Moderate	1131	276 (24.4)	(21.9, 27.0)	535	123 (23.0)	(19.5, 26.8)	1129	43 (3.8)	(2.8, 5.1)	555	18 (3.2)	(1.9, 5.1)
	Severe	1131	24 (2.1)	(1.4, 3.1)	535	16 (3.0)	(1.7, 4.8)	1129	2 (0.2)	(0.0, 0.6)	555	1 (0.2)	(0.0, 1.0)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Vomiting[e]												
	Any	1131	59 (5.2)	(4.0, 6.7)	535	21 (3.9)	(2.4, 5.9)	1129	21 (1.9)	(1.2, 2.8)	555	16 (2.9)	(1.7, 4.6)
	Mild	1131	54 (4.8)	(3.6, 6.2)	535	18 (3.4)	(2.0, 5.3)	1129	18 (1.6)	(0.9, 2.5)	555	11 (2.0)	(1.0, 3.5)

14.19. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	1131	4 (0.4)	(0.1, 0.9)	535	3 (0.6)	(0.1, 1.6)	1129	3 (0.3)	(0.1, 0.8)	555	4 (0.7)	(0.2, 1.8)
	Severe	1131	1 (0.1)	(0.0, 0.5)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	1 (0.2)	(0.0, 1.0)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Diarrhea[f]												
	Any	1131	141 (12.5)	(10.6, 14.5)	535	81 (15.1)	(12.2, 18.5)	1129	106 (9.4)	(7.8, 11.2)	555	75 (13.5)	(10.8, 16.6)
	Mild	1131	123 (10.9)	(9.1, 12.8)	535	67 (12.5)	(9.8, 15.6)	1129	91 (8.1)	(6.5, 9.8)	555	57 (10.3)	(7.9, 13.1)
	Moderate	1131	18 (1.6)	(0.9, 2.5)	535	12 (2.2)	(1.2, 3.9)	1129	15 (1.3)	(0.7, 2.2)	555	18 (3.2)	(1.9, 5.1)
	Severe	1131	0	(0.0, 0.3)	535	2 (0.4)	(0.0, 1.3)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	New or worsened muscle pain[d]												
	Any	1131	477 (42.2)	(39.3, 45.1)	535	261 (48.8)	(44.5, 53.1)	1129	196 (17.4)	(15.2, 19.7)	555	103 (18.6)	(15.4, 22.0)
	Mild	1131	187 (16.5)	(14.4, 18.8)	535	108 (20.2)	(16.9, 23.8)	1129	110 (9.7)	(8.1, 11.6)	555	62 (11.2)	(8.7, 14.1)
	Moderate	1131	282 (24.9)	(22.4, 27.6)	535	139 (26.0)	(22.3, 29.9)	1129	84 (7.4)	(6.0, 9.1)	555	40 (7.2)	(5.2, 9.7)
	Severe	1131	8 (0.7)	(0.3, 1.4)	535	14 (2.6)	(1.4, 4.4)	1129	2 (0.2)	(0.0, 0.6)	555	1 (0.2)	(0.0, 1.0)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	New or worsened joint pain[d]												
	Any	1131	229 (20.2)	(17.9, 22.7)	535	141 (26.4)	(22.7, 30.3)	1129	107 (9.5)	(7.8, 11.3)	555	42 (7.6)	(5.5, 10.1)
	Mild	1131	122 (10.8)	(9.0, 12.7)	535	61 (11.4)	(8.8, 14.4)	1129	63 (5.6)	(4.3, 7.1)	555	26 (4.7)	(3.1, 6.8)
	Moderate	1131	102 (9.0)	(7.4, 10.8)	535	73 (13.6)	(10.9, 16.8)	1129	44 (3.9)	(2.8, 5.2)	555	16 (2.9)	(1.7, 4.6)

14.19. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	1131	5 (0.4)	(0.1, 1.0)	535	7 (1.3)	(0.5, 2.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Any systemic event[g]	1131	1026 (90.7)	(88.9, 92.3)	535	472 (88.2)	(85.2, 90.8)	1129	726 (64.3)	(61.4, 67.1)	555	343 (61.8)	(57.6, 65.9)
	Use of antipyretic or pain medication[h]	1131	664 (58.7)	(55.8, 61.6)	535	279 (52.1)	(47.8, 56.5)	1129	176 (15.6)	(13.5, 17.8)	555	95 (17.1)	(14.1, 20.5)

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.
Note: Subject C4591001 1077 10771278 (13 years of age) experienced systemic events, including a temperature of 40.4°C, on the day of Dose 2. Since these events were recorded as adverse events and not in the e-diary, they do not appear in this table.
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_sev_ped_saf

14.20. Onset Days for Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Systemic Event	12-15 Years	16-25 Years	12-15 Years	16-25 Years
1	Fever (≥38.0°C)				
	n[a]	114	39	12	8
	Mean (SD)	2.1 (0.37)	2.4 (1.29)	3.6 (2.02)	3.0 (2.00)
	Median	2.0	2.0	3.0	2.5
	Min, max	(1, 5)	(1, 7)	(1, 7)	(1, 7)
	Fatigue				
	n[a]	677	318	457	213
	Mean (SD)	1.8 (0.99)	1.9 (1.15)	2.0 (1.49)	2.3 (1.63)
	Median	2.0	2.0	1.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Headache				
	n[a]	623	286	396	205
	Mean (SD)	2.1 (1.21)	2.2 (1.37)	2.4 (1.69)	2.4 (1.58)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Chills				
	n[a]	311	133	109	47
	Mean (SD)	2.1 (1.00)	2.2 (1.19)	2.9 (1.75)	2.9 (1.91)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Vomiting				
	n[a]	31	9	10	9
	Mean (SD)	3.0 (1.67)	3.4 (2.13)	3.0 (1.83)	3.2 (1.48)
	Median	2.0	2.0	2.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 6)	(1, 5)
	Diarrhea				
	n[a]	90	57	82	62
	Mean (SD)	3.7 (1.79)	3.2 (1.48)	3.6 (1.85)	3.5 (1.81)
	Median	3.0	3.0	3.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	New or worsened muscle pain				
	n[a]	272	143	148	78
	Mean (SD)	2.1 (1.08)	2.2 (1.11)	2.5 (1.68)	3.0 (1.69)

14.20. Onset Days for Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Systemic Event	12-15 Years	16-25 Years	12-15 Years	16-25 Years
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	New or worsened joint pain				
	n[a]	109	70	77	28
	Mean (SD)	2.5 (1.41)	2.5 (1.32)	3.0 (1.92)	3.4 (1.79)
	Median	2.0	2.0	2.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Any systemic event[b]				
	n[a]	877	403	636	311
	Mean (SD)	1.8 (1.01)	1.8 (1.06)	1.9 (1.38)	2.1 (1.40)
	Median	2.0	2.0	1.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Use of antipyretic or pain medication				
	n[a]	413	167	111	62
	Mean (SD)	2.1 (0.91)	2.2 (1.03)	3.3 (1.93)	3.5 (1.90)
	Median	2.0	2.0	3.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
2	Fever (≥38.0°C)				
	n[a]	215	84	7	2
	Mean (SD)	2.0 (0.31)	2.0 (0.54)	3.0 (2.45)	1.5 (0.71)
	Median	2.0	2.0	2.0	1.5
	Min, max	(1, 4)	(1, 6)	(1, 7)	(1, 2)
	Fatigue				
	n[a]	726	320	264	115
	Mean (SD)	1.8 (0.67)	1.8 (0.79)	2.1 (1.59)	2.4 (1.48)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Headache				
	n[a]	708	297	263	118
	Mean (SD)	1.9 (0.66)	2.0 (0.92)	2.5 (1.68)	2.7 (1.83)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Chills				
	n[a]	455	195	73	22

14.20. Onset Days for Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Systemic Event	12-15 Years	16-25 Years	12-15 Years	16-25 Years
	Mean (SD)	2.0 (0.80)	1.9 (0.53)	2.8 (1.96)	3.0 (1.73)
	Median	2.0	2.0	2.0	3.0
	Min, max	(1, 7)	(1, 4)	(1, 7)	(1, 7)
	Vomiting				
	n[a]	29	13	12	9
	Mean (SD)	2.4 (1.12)	2.3 (0.85)	4.1 (1.62)	3.4 (2.35)
	Median	2.0	2.0	4.0	3.0
	Min, max	(1, 7)	(2, 5)	(2, 7)	(1, 7)
	Diarrhea				
	n[a]	65	39	43	26
	Mean (SD)	3.1 (1.55)	3.0 (1.48)	3.7 (2.06)	3.8 (1.97)
	Median	3.0	3.0	4.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	New or worsened muscle pain				
	n[a]	355	199	90	48
	Mean (SD)	2.1 (0.83)	2.0 (0.72)	2.7 (1.90)	2.8 (1.66)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	New or worsened joint pain				
	n[a]	173	107	51	20
	Mean (SD)	2.1 (0.77)	2.0 (0.68)	2.9 (1.81)	3.8 (2.07)
	Median	2.0	2.0	2.0	4.0
	Min, max	(1, 6)	(1, 7)	(1, 7)	(1, 7)
	Any systemic event[b]				
	n[a]	904	396	439	183
	Mean (SD)	1.8 (0.77)	1.8 (0.88)	2.3 (1.70)	2.3 (1.46)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Use of antipyretic or pain medication				
	n[a]	557	223	95	59
	Mean (SD)	2.0 (0.69)	2.0 (0.93)	3.2 (2.04)	3.0 (1.49)
	Median	2.0	2.0	3.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)

14.20. Onset Days for Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Systemic Event	12-15 Years	16-25 Years	12-15 Years	16-25 Years

Note: Day of onset is the first day the specified event was reported.
Note: Subject C4591001 1077 10771278 (13 years of age) experienced systemic events, including a temperature of 40.4°C, on the day of Dose 2. Since these events were recorded as adverse events and not in the electronic diary (e-diary), they do not appear in this table.
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 ped saf

14.21. Duration (Days) From First to Last Day of Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Systemic Event	12-15 Years	16-25 Years	12-15 Years	16-25 Years
1	Fever (≥38.0°C)				
	n[a]	114	39	12	8
	Mean (SD)	1.1 (0.45)	1.1 (0.52)	1.7 (1.37)	1.9 (2.27)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 4)	(1, 4)	(1, 5)	(1, 7)
	Unknown[b]	0	0	0	1
	Fatigue				
	n[a]	677	318	457	213
	Mean (SD)	2.5 (3.20)	2.4 (2.08)	3.1 (2.92)	3.0 (2.67)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 45)	(1, 11)	(1, 22)	(1, 15)
	Unknown[b]	0	0	2	3
	Headache				
	n[a]	623	286	396	205
	Mean (SD)	2.4 (2.27)	2.5 (2.51)	2.7 (2.55)	2.9 (3.17)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 24)	(1, 25)	(1, 21)	(1, 22)
	Unknown[b]	0	0	1	2
	Chills				
	n[a]	311	133	109	47
	Mean (SD)	1.6 (1.48)	1.5 (1.28)	2.6 (2.87)	2.3 (1.82)
	Median	1.0	1.0	1.0	2.0
	Min, max	(1, 15)	(1, 8)	(1, 22)	(1, 7)
	Unknown[b]	1	1	2	1
	Vomiting				
	n[a]	31	9	10	9
	Mean (SD)	1.2 (0.88)	1.6 (1.33)	1.1 (0.32)	1.6 (1.13)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 5)	(1, 5)	(1, 2)	(1, 4)
	Diarrhea				
	n[a]	90	57	82	62
	Mean (SD)	1.6 (1.25)	1.7 (1.62)	1.7 (1.52)	1.7 (1.42)

14.21. Duration (Days) From First to Last Day of Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Systemic Event	12-15 Years	16-25 Years	12-15 Years	16-25 Years
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 7)	(1, 9)	(1, 8)	(1, 7)
	New or worsened muscle pain				
	n[a]	272	143	148	78
	Mean (SD)	1.7 (1.28)	1.8 (1.65)	2.4 (3.02)	1.8 (1.95)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 9)	(1, 10)	(1, 22)	(1, 13)
	Unknown[b]	0	1	0	1
	New or worsened joint pain				
	n[a]	109	70	77	28
	Mean (SD)	1.6 (1.33)	1.7 (2.83)	2.2 (2.88)	2.7 (2.60)
	Median	1.0	1.0	1.0	1.5
	Min, max	(1, 8)	(1, 24)	(1, 22)	(1, 12)
	Use of antipyretic or pain medication				
	n[a]	413	167	111	62
	Mean (SD)	1.6 (1.37)	1.7 (1.57)	2.1 (2.32)	3.2 (4.16)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 20)	(1, 10)	(1, 19)	(1, 23)
	Unknown[b]	0	0	1	2
2	Fever (≥38.0°C)				
	n[a]	215	84	7	2
	Mean (SD)	1.0 (0.37)	1.1 (0.28)	3.0 (4.86)	1.0 (NE)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 6)	(1, 2)	(1, 14)	(1, 1)
	Unknown[b]	1	0	0	1
	Fatigue				
	n[a]	726	320	264	115
	Mean (SD)	2.1 (1.92)	2.2 (2.44)	2.8 (3.06)	3.3 (4.38)
	Median	1.0	1.0	2.0	2.0
	Min, max	(1, 23)	(1, 28)	(1, 37)	(1, 38)
	Unknown[b]	4	3	2	4
	Headache				
	n[a]	708	297	263	118

14.21. Duration (Days) From First to Last Day of Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Systemic Event	12-15 Years	16-25 Years	12-15 Years	16-25 Years
	Mean (SD)	2.1 (2.16)	2.1 (2.42)	2.5 (2.39)	3.5 (5.64)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 36)	(1, 24)	(1, 23)	(1, 35)
	Unknown[b]	6	1	3	3
	Chills				
	n[a]	455	195	73	22
	Mean (SD)	1.5 (1.07)	1.3 (0.91)	2.1 (1.90)	2.0 (1.41)
	Median	1.0	1.0	1.0	2.0
	Min, max	(1, 9)	(1, 11)	(1, 8)	(1, 6)
	Unknown[b]	1	1	1	1
	Vomiting				
	n[a]	29	13	12	9
	Mean (SD)	1.0 (0.19)	1.2 (0.38)	1.4 (0.90)	1.6 (1.67)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 2)	(1, 2)	(1, 4)	(1, 6)
	Diarrhea				
	n[a]	65	39	43	26
	Mean (SD)	2.1 (4.38)	1.4 (0.94)	1.5 (1.04)	4.4 (7.70)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 35)	(1, 5)	(1, 5)	(1, 33)
	Unknown[b]	1	0	1	1
	New or worsened muscle pain				
	n[a]	355	199	90	48
	Mean (SD)	1.6 (1.49)	1.6 (1.82)	2.1 (1.84)	2.3 (2.04)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 17)	(1, 23)	(1, 9)	(1, 9)
	Unknown[b]	1	1	0	0
	New or worsened joint pain				
	n[a]	173	107	51	20
	Mean (SD)	1.5 (1.26)	1.6 (2.75)	2.7 (2.61)	2.2 (1.81)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 8)	(1, 28)	(1, 12)	(1, 8)
	Unknown[b]	2	2	0	0

14.21. Duration (Days) From First to Last Day of Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Systemic Event	12-15 Years	16-25 Years	12-15 Years	16-25 Years
	Use of antipyretic or pain medication				
	n[a]	557	223	95	59
	Mean (SD)	1.6 (1.37)	1.8 (2.64)	1.9 (2.61)	2.1 (2.28)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 12)	(1, 28)	(1, 23)	(1, 15)
	Unknown[b]	3	0	2	2

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported event to the resolution of the last reported event, inclusive. 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.
Note: Subject C4591001 1077 10771278 (13 years of age) experienced systemic events, including a temperature of 40.4°C, on the day of Dose 2. Since these events were recorded as adverse events and not in the e-diary, they do not appear in this table.
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 (02:57)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_s040_se_dur_ped_saf

14.22. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 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	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)
	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)

14.22. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 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])
	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)
	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)

14.22. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 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])
	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]						
	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						

14.22. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 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])
	≥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)
	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)

14.22. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 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])
	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)

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: 28MAR2021 (17:20)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adce_s020_se_1655_saf

14.23. Onset Days for Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
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)

14.23. Onset Days for Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

		Vaccine Group (as Administered)	
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		

14.23. Onset Days for Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

		Vaccine Group (as Administered)	
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)

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: 30MAR2021 (08:28)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adce_s060_se_onset_1655_saf

14.24. Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
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

14.24. Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

		Vaccine Group (as Administered)	
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		

14.24. Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

		Vaccine Group (as Administered)	
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

14.24. Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

		Vaccine Group (as Administered)	
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: 28MAR2021 (18:13)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adce_s040_se_dur_1655_saf

Adverse Events

14.25. 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 16-55 Years of Age – Safety Population

	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)
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)
Iron deficiency anaemia	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Leukocytosis	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)
Lymphadenitis	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)
Thrombocytosis	0	(0.0, 0.0)	1 (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)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Atrial fibrillation	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	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)
Myocardial infarction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia	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)
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)
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)
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 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)

14.25. 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 16-55 Years of Age – Safety Population

	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])
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)
Myocarditis	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 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 cystic kidney disease	1 (0.0)	(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)
Ear discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Deafness unilateral	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Allergic otitis media	0	(0.0, 0.0)	1 (0.0)	(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)
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)
Meniere's disease	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)
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)
Autoimmune thyroiditis	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)
Hypogonadism	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)
Eye pain	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Eye irritation	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Blepharitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Chalazion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Conjunctivitis allergic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.25. 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 16-55 Years of Age – Safety Population

	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	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Photophobia	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Vision blurred	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Asthenopia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye pruritus	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)
Lacrimation increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitreous detachment	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitreous floaters	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)
Blepharospasm	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 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)
Diplopia	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 allergy	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)
Glaucoma	1 (0.0)	(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 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)

14.25. 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 16-55 Years of Age – Safety Population

	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])
Gastritis	2 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Dental caries	5 (0.0)	(0.0, 0.1)	4 (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)
Constipation	3 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
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)
Dysphagia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Gastrointestinal disorder	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Gingival pain	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haemorrhoids	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Rectal haemorrhage	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Stomatitis	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Tooth impacted	1 (0.0)	(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)
Cheilitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Food poisoning	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Inguinal hernia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Large intestine polyp	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Lip swelling	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Noninfective gingivitis	2 (0.0)	(0.0, 0.1)	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)
Umbilical hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal distension	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)
Acute abdomen	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)
Diverticular perforation	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)
Diverticulum intestinal haemorrhagic	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	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)

14.25. 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 16-55 Years of Age – Safety Population

	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])
Gastritis erosive	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 discomfort	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)
Haematochezia	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)
Hypoaesthesia teeth	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)
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)
Mouth ulceration	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)
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)
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)
Pancreatic failure	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)
Peptic ulcer	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)
Salivary gland mucocoele	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)
Swollen tongue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Teething	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)
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)

14.25. 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 16-55 Years of Age – Safety Population

	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])
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)
Chest pain	10 (0.1)	(0.0, 0.1)	10 (0.1)	(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)
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)
Injection site oedema	10 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Chest discomfort	4 (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)
Feeling hot	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site induration	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Oedema peripheral	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Swelling face	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Injection site reaction	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Feeling abnormal	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site discomfort	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Injection site papule	3 (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)
Application site pain	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 discolouration	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site haemorrhage	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 nodule	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)
Sensation of foreign body	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Thirst	1 (0.0)	(0.0, 0.0)	1 (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 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)

14.25. 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 16-55 Years of Age – Safety Population

	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	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)
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)
Illness	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 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 rash	1 (0.0)	(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)
Nodule	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)
Swelling	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)
Vaccination site pain	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 bruise	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)
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)
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)
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)
Hypersensitivity	2 (0.0)	(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)
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)
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)

14.25. 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 16-55 Years of Age – Safety Population

	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])
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)
Ear infection	6 (0.0)	(0.0, 0.1)	9 (0.1)	(0.0, 0.1)
Rhinitis	5 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Conjunctivitis	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Otitis media	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Cystitis	2 (0.0)	(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)
Hordeolum	3 (0.0)	(0.0, 0.1)	7 (0.1)	(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)
Diverticulitis	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Gingivitis	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Otitis externa	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Gastroenteritis	2 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Tooth abscess	5 (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)
Nasopharyngitis	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tonsillitis	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Acute sinusitis	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Folliculitis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Oral herpes	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Pharyngitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Skin infection	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
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)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Furuncle	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
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)
Otitis media acute	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Periodontitis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.25. 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 16-55 Years of Age – Safety Population

	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])
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)
Anal abscess	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bacterial vaginosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Chronic sinusitis	2 (0.0)	(0.0, 0.1)	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)
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)
Influenza	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Localised infection	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
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)
Paronychia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pustule	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinusitis bacterial	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (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)
Abscess neck	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acarodermatitis	0	(0.0, 0.0)	1 (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)
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)
COVID-19	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carbuncle	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)
Conjunctivitis bacterial	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)
Dermatitis infected	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)
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)

14.25. 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 16-55 Years of Age – Safety Population

	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])
Hepatitis A	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)
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)
Onychomycosis	1 (0.0)	(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 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)
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)
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)
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)
Puncture site infection	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)
Soft tissue infection	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)
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)
Trichomoniasis	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)
Exposure during pregnancy	10 (0.1)	(0.0, 0.1)	19 (0.1)	(0.1, 0.2)
Ligament sprain	10 (0.1)	(0.0, 0.1)	15 (0.1)	(0.1, 0.2)
Contusion	8 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)

14.25. 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 16-55 Years of Age – Safety Population

	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])
Road traffic accident	8 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Skin laceration	8 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Muscle strain	6 (0.0)	(0.0, 0.1)	6 (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)
Procedural pain	6 (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)
Arthropod bite	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Skin abrasion	3 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Concussion	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Facial bones fracture	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Ligament rupture	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Meniscus injury	3 (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)
Animal bite	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Epicondylitis	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 rupture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Thermal burn	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Ankle fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Arthropod sting	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bone contusion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(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)
Head injury	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint dislocation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ligament injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Procedural dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Radius fracture	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Tendon injury	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)
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)
Clavicle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.25. 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 16-55 Years of Age – Safety Population

	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])
Colon 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)
Fibula 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 in eye	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hand fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury	0	(0.0, 0.0)	1 (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)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during breast feeding	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)
Overdose	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 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)
Scar	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Soft tissue injury	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)
Stab wound	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Upper limb fracture	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	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)

14.25. 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 16-55 Years of Age – Safety Population

	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])
Blood pressure increased	3 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
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)
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)
Low density lipoprotein increased	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Mammogram abnormal	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alanine aminotransferase increased	1 (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 creatinine increased	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 glucose increased	0	(0.0, 0.0)	1 (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 testosterone decreased	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)
Electrocardiogram QT prolonged	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)
SARS-CoV-2 antibody test positive	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	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)
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)
Dyslipidaemia	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	4 (0.0)	(0.0, 0.1)	3 (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)
Glucose tolerance impaired	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Dehydration	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Gout	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Hyperglycaemia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
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)
Insulin resistance	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.25. 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 16-55 Years of Age – Safety Population

	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])
Obesity	2 (0.0)	(0.0, 0.1)	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)
Diabetic ketoacidosis	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)
Hypertriglyceridaemia	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)
Impaired fasting glucose	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)
Vitamin B12 deficiency	1 (0.0)	(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)
Musculoskeletal chest pain	9 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	4 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Tendonitis	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Muscle contracture	4 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Muscular weakness	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Bursitis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Plantar fasciitis	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Flank pain	3 (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)
Rotator cuff syndrome	2 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Costochondritis	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint swelling	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
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)
Osteoarthritis	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.0)	3 (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)
Joint range of motion decreased	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.25. 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 16-55 Years of Age – Safety Population

	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	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)
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)
Bone pain	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Coccydynia	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Metatarsalgia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovial cyst	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, 0.1)
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)
Bone swelling	0	(0.0, 0.0)	1 (0.0)	(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)
Intervertebral disc degeneration	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 effusion	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)
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)
Musculoskeletal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteitis	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)
Osteochondrosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteoporosis	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)
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)
Spinal osteoarthritis	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)
Spondylitis	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)
Temporomandibular joint syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tendon pain	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)

14.25. 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 16-55 Years of Age – Safety Population

	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])
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	14 (0.1)	(0.1, 0.2)	12 (0.1)	(0.0, 0.2)
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)
Fibroadenoma of breast	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Malignant melanoma	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Acrochordon	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)
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)
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)
Colon adenoma	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)
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)
Ovarian germ cell teratoma benign	1 (0.0)	(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)
Migraine	21 (0.2)	(0.1, 0.2)	9 (0.1)	(0.0, 0.1)
Sciatica	8 (0.1)	(0.0, 0.1)	8 (0.1)	(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)
Syncope	9 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dysgeusia	9 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Lethargy	7 (0.1)	(0.0, 0.1)	5 (0.0)	(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)
Burning sensation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tremor	4 (0.0)	(0.0, 0.1)	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)
Parosmia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.25. 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 16-55 Years of Age – Safety Population

	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])
Radiculopathy	2 (0.0)	(0.0, 0.1)	1 (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)
Nerve compression	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Restless legs syndrome	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sinus headache	2 (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)
Ageusia	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)
Aphasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerebral capillary telangiectasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	1 (0.0)	(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)
Dystonia	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)
Hemiplegic migraine	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)
Idiopathic intracranial hypertension	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)
Migraine with aura	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)
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraparesis	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)
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)
Taste disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Trigeminal neuralgia	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, 0.1)
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	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)

14.25. 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 16-55 Years of Age – Safety Population

	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])
Attention deficit hyperactivity disorder	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Anxiety disorder	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Irritability	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Depressed mood	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Panic attack	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Abnormal dreams	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Alcohol withdrawal syndrome	1 (0.0)	(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)
Disorientation	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
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)
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)
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 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)
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)
Schizophrenia	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)
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)
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)
Acute kidney injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Costovertebral angle tenderness	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)
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)

14.25. 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 16-55 Years of Age – Safety Population

	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])
Urinary bladder polyp	0	(0.0, 0.0)	1 (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)
Amenorrhoea	2 (0.0)	(0.0, 0.1)	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)
Menorrhagia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Breast cyst	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Breast mass	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)
Erectile dysfunction	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
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)
Prostatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Uterine haemorrhage	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)
Adenomyosis	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)
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)
Genital erythema	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)
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)
Pruritus genital	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)
Testicular pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine inflammation	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)

14.25. 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 16-55 Years of Age – Safety Population

	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])
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)
Rhinitis allergic	11 (0.1)	(0.0, 0.2)	9 (0.1)	(0.0, 0.1)
Rhinorrhoea	11 (0.1)	(0.0, 0.2)	8 (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)
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)
Epistaxis	1 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Throat irritation	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Asthma exercise induced	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dysphonia	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Productive cough	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Respiratory tract congestion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Sneezing	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Wheezing	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
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)
Bronchospasm	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dry throat	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)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Reflux laryngitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sleep apnoea syndrome	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)
Chronic obstructive pulmonary disease	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)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	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)

14.25. 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 16-55 Years of Age – Safety Population

	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])
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)
Pleuritic pain	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 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)
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)
Hyperhidrosis	18 (0.1)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Pruritus	9 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.2)
Urticaria	11 (0.1)	(0.0, 0.2)	8 (0.1)	(0.0, 0.1)
Dermatitis contact	7 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.2)
Night sweats	9 (0.1)	(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)
Erythema	5 (0.0)	(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)
Rash maculo-papular	4 (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)
Dermatitis allergic	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)
Angioedema	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Rash papular	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)
Dermatitis	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, 0.1)
Seborrhoeic dermatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
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)
Blister	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 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)
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)

14.25. 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 16-55 Years of Age – Safety Population

	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])
Ecchymosis	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)
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)
Macule	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mechanical urticaria	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)
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)
Psoriasis	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)
Urticaria contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
High risk sexual behaviour	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menopause	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)
Dental implantation	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Tooth extraction	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)
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)
Gingival operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Medical device implantation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
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)
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)
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)

14.25. 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 16-55 Years of Age – Safety Population

	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])
Flushing	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Haematoma	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Deep vein thrombosis	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Varicose vein	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypotension	2 (0.0)	(0.0, 0.1)	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)	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)
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: 29MAR2021 (15:30)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adae_s130_all_pd2_1655_saf

14.26. 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 16-55 Years of Age – Safety Population

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])
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)
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)
Acute myocardial infarction	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)
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)
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)
Conjunctivitis allergic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Eye pain	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)
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)
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)
Ocular hyperaemia	1 (0.0)	(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)

14.26. 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 16-55 Years of Age – Safety Population

	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])
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)
Abdominal discomfort	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
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)
Gastrooesophageal reflux disease	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Aphthous ulcer	2 (0.0)	(0.0, 0.1)	1 (0.0)	(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)
Dysphagia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Odynophagia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toothache	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal distension	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)
Dry mouth	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)
Flatulence	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)
Gastrointestinal disorder	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)
Hiatus hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia oral	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Irritable bowel syndrome	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)
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)
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)
Chills	198 (1.5)	(1.3, 1.7)	43 (0.3)	(0.2, 0.4)

14.26. 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 16-55 Years of Age – Safety Population

	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])
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)
Chest pain	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Influenza like illness	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site oedema	6 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Chest discomfort	2 (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)
Injection site warmth	3 (0.0)	(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 discomfort	2 (0.0)	(0.0, 0.1)	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 haemorrhage	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)
Oedema peripheral	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
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)
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)
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 discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site haematoma	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)
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)
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)

14.26. 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 16-55 Years of Age – Safety Population

	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	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)
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)
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)
Cholecystitis acute	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)
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)
Food allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seasonal allergy	1 (0.0)	(0.0, 0.0)	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)
Ear infection	2 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Sinusitis	1 (0.0)	(0.0, 0.0)	3 (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)	2 (0.0)	(0.0, 0.1)
Otitis media	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Tooth infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
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)
Cystitis	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)
Otitis externa	1 (0.0)	(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)
Vulvovaginal mycotic 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)
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)
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)
Herpes simplex	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes zoster	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.26. 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 16-55 Years of Age – Safety Population

	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])
Hordeolum	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)
Oral fungal infection	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)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngitis	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)
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)
Skin infection	0	(0.0, 0.0)	1 (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)
Tooth abscess	0	(0.0, 0.0)	1 (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)
Exposure during pregnancy	2 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Fall	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)
Muscle strain	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)
Contusion	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Ligament rupture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Animal bite	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)
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)
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)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.26. 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 16-55 Years of Age – Safety Population

	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])
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)
Muscle rupture	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)
Radius 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)
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)
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)
Heart rate increased	1 (0.0)	(0.0, 0.0)	2 (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 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)
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)
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)
Hypoglycaemia	0	(0.0, 0.0)	1 (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)
Insulin resistance	1 (0.0)	(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 D deficiency	0	(0.0, 0.0)	1 (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)

14.26. 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 16-55 Years of Age – Safety Population

	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])
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)
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)
Flank pain	1 (0.0)	(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)
Pain in jaw	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Bursitis	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)
Intervertebral disc protrusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint stiffness	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)
Muscle contracture	0	(0.0, 0.0)	1 (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)
Muscular weakness	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)
Musculoskeletal stiffness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periarthritis	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)
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)
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)
Colon adenoma	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)
Meningioma	1 (0.0)	(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)
Migraine	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
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)

14.26. 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 16-55 Years of Age – Safety Population

	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])
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)
Hypoaesthesia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Syncope	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Presyncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tension headache	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tremor	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Disturbance in attention	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)
Migraine without aura	1 (0.0)	(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)
Parosmia	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)
Sciatica	0	(0.0, 0.0)	1 (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)
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)
Irritability	3 (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)
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)
Disorientation	1 (0.0)	(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)
Panic attack	0	(0.0, 0.0)	1 (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)
Haematuria	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Pollakiuria	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.1)	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)
Dysuria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.26. 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 16-55 Years of Age – Safety Population

	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])
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	7 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Pelvic pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cyst	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)
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)
Erectile dysfunction	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)
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)
Testicular pain	0	(0.0, 0.0)	1 (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)
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)
Rhinorrhoea	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
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)
Upper-airway cough syndrome	2 (0.0)	(0.0, 0.1)	1 (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)
Throat irritation	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)
Asthma	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 exertional	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Epistaxis	1 (0.0)	(0.0, 0.0)	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)
Sneezing	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wheezing	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.26. 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 16-55 Years of Age – Safety Population

	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)
Hyperhidrosis	8 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Pruritus	1 (0.0)	(0.0, 0.0)	10 (0.1)	(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)
Night sweats	3 (0.0)	(0.0, 0.1)	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)
Erythema	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash pruritic	1 (0.0)	(0.0, 0.0)	1 (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)
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)
Rash maculo-papular	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	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
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)
Hot flush	2 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Hypertension	4 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Haematoma	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)
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: 28MAR2021 (13:28)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adae_s130_d17d_1655_saf

14.27. 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 16-55 Years of Age – Safety Population

	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)
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)
Neutropenia	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	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)
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)
Arteriospasm coronary	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)
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)
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)
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)
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)
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)
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)

14.27. 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 16-55 Years of Age – Safety Population

	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])
Eye irritation	2 (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)
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)
Eyelid oedema	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)
Photophobia	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)
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)
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)
Dyspepsia	3 (0.0)	(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)
Flatulence	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Odynophagia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Abdominal discomfort	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Aphthous ulcer	2 (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)
Tooth impacted	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal pain lower	0	(0.0, 0.0)	1 (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)
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)
Gastrooesophageal reflux disease	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)
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)

14.27. 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 16-55 Years of Age – Safety Population

	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])
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 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)
Retching	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stomatitis	0	(0.0, 0.0)	1 (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 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)
Injection site induration	3 (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)
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)
Feeling hot	2 (0.0)	(0.0, 0.1)	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 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)
Oedema peripheral	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)

14.27. 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 16-55 Years of Age – Safety Population

	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])
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)
Chest discomfort	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 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)
Injection site injury	0	(0.0, 0.0)	1 (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 reaction	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)
Non-cardiac chest 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)
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)
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)
Rhinitis	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.1)
Tooth infection	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)
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)
Pharyngitis streptococcal	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, 0.1)
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)
Conjunctivitis	1 (0.0)	(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)
Fungal skin infection	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)

14.27. 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 16-55 Years of Age – Safety Population

	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])
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)
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)
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)
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)
Sinusitis	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)
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)
Exposure during pregnancy	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
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)
Administration related reaction	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)
Craniocerebral injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fall	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fibula fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint dislocation	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)
Meniscus 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)
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 laceration	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)

14.27. 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 16-55 Years of Age – Safety Population

	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])
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 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 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)
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)
Mammogram abnormal	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	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)
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)
Vitamin D deficiency	1 (0.0)	(0.0, 0.0)	1 (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)
Polydipsia	1 (0.0)	(0.0, 0.0)	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)
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)
Muscle spasms	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)
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)

14.27. 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 16-55 Years of Age – Safety Population

	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])
Intervertebral disc protrusion	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
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)
Musculoskeletal discomfort	2 (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)
Axillary mass	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)
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)
Metatarsalgia	0	(0.0, 0.0)	1 (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)
Periarthritis	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)
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)
Tendonitis	1 (0.0)	(0.0, 0.0)	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)
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)
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)
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)
Lethargy	3 (0.0)	(0.0, 0.1)	1 (0.0)	(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)
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)
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)

14.27. 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 16-55 Years of Age – Safety Population

	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])
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)
Syncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tremor	2 (0.0)	(0.0, 0.1)	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)
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)
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)
Motor dysfunction	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)
Neuropathy peripheral	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)
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)
PSYCHIATRIC DISORDERS	12 (0.1)	(0.0, 0.2)	13 (0.1)	(0.1, 0.2)
Anxiety	4 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.1)
Insomnia	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)
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)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Generalised anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Irritability	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)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.1)
Pollakiuria	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysuria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematuria	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	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)

14.27. 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 16-55 Years of Age – Safety Population

	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])
Metrorrhagia	2 (0.0)	(0.0, 0.1)	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)
Pruritus genital	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)
Upper-airway cough syndrome	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)
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)
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)
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)
Dyspnoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Epistaxis	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)
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)
Respiratory tract congestion	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)
Throat irritation	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)
Upper respiratory tract congestion	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)

14.27. 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 16-55 Years of Age – Safety Population

	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])
Urticaria	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Erythema	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Rash pruritic	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Rash papular	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Skin lesion	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alopecia	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)
Cold sweat	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis contact	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)
Eczema	1 (0.0)	(0.0, 0.0)	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)
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 erythematous	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)
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)
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)
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)
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: 30MAR2021 (11:52)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 EUA 1655/adae s130 d27d 1655 saf

14.28. 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 16-55 Years of Age – Safety Population

	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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
Genitourinary chlamydia infection	0	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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 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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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)	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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.28. 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 16-55 Years of Age – Safety Population

	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])
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)
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: 28MAR2021 (13:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 EUA 1655/adae s131 all exp 1655 saf

14.29. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N[a]=1131)		16-25 Years (N[a]=536)		12-15 Years (N[a]=1129)		16-25 Years (N[a]=561)	
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	33 (2.9)	(2.0, 4.1)	33 (6.2)	(4.3, 8.5)	21 (1.9)	(1.2, 2.8)	12 (2.1)	(1.1, 3.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	7 (0.6)	(0.2, 1.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Lymphadenopathy	7 (0.6)	(0.2, 1.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
EYE DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Eyelid rash	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
GASTROINTESTINAL DISORDERS	11 (1.0)	(0.5, 1.7)	2 (0.4)	(0.0, 1.3)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
Nausea	5 (0.4)	(0.1, 1.0)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Diarrhoea	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
Abdominal pain	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Aphthous ulcer	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Lip swelling	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Mouth swelling	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Oral mucosal blistering	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Vomiting	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	15 (1.3)	(0.7, 2.2)	19 (3.5)	(2.1, 5.5)	9 (0.8)	(0.4, 1.5)	9 (1.6)	(0.7, 3.0)
Injection site pain	7 (0.6)	(0.2, 1.3)	10 (1.9)	(0.9, 3.4)	7 (0.6)	(0.2, 1.3)	2 (0.4)	(0.0, 1.3)
Fatigue	7 (0.6)	(0.2, 1.3)	7 (1.3)	(0.5, 2.7)	3 (0.3)	(0.1, 0.8)	3 (0.5)	(0.1, 1.6)
Pyrexia	5 (0.4)	(0.1, 1.0)	7 (1.3)	(0.5, 2.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Chills	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Injection site erythema	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)
Injection site swelling	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)
Injection site bruising	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Injection site discomfort	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Injection site hyperaesthesia	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Pain	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Peripheral swelling	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Decreased appetite	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)

14.29. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N^a=1131)		16-25 Years (N^a=536)		12-15 Years (N^a=1129)		16-25 Years (N^a=561)	
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])
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	3 (0.3)	(0.1, 0.8)	10 (1.9)	(0.9, 3.4)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
Myalgia	3 (0.3)	(0.1, 0.8)	6 (1.1)	(0.4, 2.4)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
Arthralgia	0	(0.0, 0.3)	3 (0.6)	(0.1, 1.6)	0	(0.0, 0.3)	0	(0.0, 0.7)
Back pain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Musculoskeletal discomfort	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
NERVOUS SYSTEM DISORDERS	5 (0.4)	(0.1, 1.0)	12 (2.2)	(1.2, 3.9)	5 (0.4)	(0.1, 1.0)	4 (0.7)	(0.2, 1.8)
Headache	3 (0.3)	(0.1, 0.8)	11 (2.1)	(1.0, 3.6)	3 (0.3)	(0.1, 0.8)	3 (0.5)	(0.1, 1.6)
Dizziness	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
Migraine	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Presyncope	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
PSYCHIATRIC DISORDERS	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Anxiety	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Disorientation	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
Oropharyngeal pain	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Rhinorrhoea	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)	7 (0.6)	(0.2, 1.3)	0	(0.0, 0.7)
Urticaria	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	4 (0.4)	(0.1, 0.9)	0	(0.0, 0.7)
Rash	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Rash maculo-papular	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.
Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).
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 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 1md2 rel ped saf

14.30. 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 16-55 Years of Age – Safety Population

	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)
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)
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)
Ear pain	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)
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)
Tympanic membrane perforation	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)
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)
Photophobia	2 (0.0)	(0.0, 0.1)	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)
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)
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	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Abdominal pain upper	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)

14.30. 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 16-55 Years of Age – Safety Population

	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])
Abdominal discomfort	4 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Aphthous ulcer	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Dyspepsia	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Flatulence	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Dry mouth	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Gingival pain	2 (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)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal distension	1 (0.0)	(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)
Faeces soft	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)
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)
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)
Odynophagia	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)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toothache	1 (0.0)	(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)

14.30. 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 16-55 Years of Age – Safety Population

	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 oedema	10 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Axillary pain	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Feeling hot	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site induration	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Injection site reaction	3 (0.0)	(0.0, 0.1)	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)
Injection site discomfort	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site papule	3 (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 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)
Injection site discolouration	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Injection site haematoma	1 (0.0)	(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 mass	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)
Application site erythema	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)
Illness	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 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 rash	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)
Nodule	0	(0.0, 0.0)	1 (0.0)	(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)
Shoulder injury related to vaccine administration	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)

14.30. 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 16-55 Years of Age – Safety Population

	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])
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)
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)
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)
Oral candidiasis	1 (0.0)	(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)
Procedural pain	4 (0.0)	(0.0, 0.1)	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)
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 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)
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)
SARS-CoV-2 antibody test positive	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	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)
Gout	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	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)

14.30. 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 16-55 Years of Age – Safety Population

	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])
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)
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)
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)
Musculoskeletal discomfort	3 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Musculoskeletal stiffness	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Muscle twitching	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)
Tendonitis	2 (0.0)	(0.0, 0.1)	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)
Costochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Flank pain	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)
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)
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)
Musculoskeletal pain	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)
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)
Paraesthesia	9 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Somnolence	5 (0.0)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Lethargy	7 (0.1)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Dysgeusia	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Migraine	8 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
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)
Tension headache	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)

14.30. 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 16-55 Years of Age – Safety Population

	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])
Tremor	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)
Hyperaesthesia	3 (0.0)	(0.0, 0.1)	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)
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)
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	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)
Migraine without 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	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)
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)
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)
Depression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Irritability	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)
RENAL AND URINARY DISORDERS	1 (0.0)	(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)
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)
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)
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)

14.30. 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 16-55 Years of Age – Safety Population

	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])
Nasal congestion	8 (0.1)	(0.0, 0.1)	8 (0.1)	(0.0, 0.1)
Cough	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.1)
Rhinorrhoea	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Sinus congestion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
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)
Dyspnoea	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Oropharyngeal discomfort	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)
Pharyngeal swelling	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Productive cough	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)
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 obstruction	1 (0.0)	(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)
Pruritus	3 (0.0)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Night sweats	9 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
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)
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)
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)
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)
Cold sweat	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)
Fixed eruption	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 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)

14.30. 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 16-55 Years of Age – Safety Population

	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])
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)
VASCULAR DISORDERS	10 (0.1)	(0.0, 0.1)	7 (0.1)	(0.0, 0.1)
Hot flush	3 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Flushing	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
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: 30MAR2021 (17:36)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 EUA 1655/adae s130 1md2 rel 1655 saf

14.31. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 1, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N[a]=1131)		16-25 Years (N[a]=536)		12-15 Years (N[a]=1129)		16-25 Years (N[a]=561)	
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	0	(0.0, 0.3)	0	(0.0, 0.7)	4 (0.4)	(0.1, 0.9)	2 (0.4)	(0.0, 1.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 0.3)	0	(0.0, 0.7)	3 (0.3)	(0.1, 0.8)	2 (0.4)	(0.0, 1.3)
Injection site pain	0	(0.0, 0.3)	0	(0.0, 0.7)	3 (0.3)	(0.1, 0.8)	1 (0.2)	(0.0, 1.0)
Injection site erythema	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Vessel puncture site pain	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.3)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Dizziness	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Headache	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)

Note: MedDRA (v23.1) coding dictionary applied.
Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).
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 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_immd_vax1_ped_saf

14.32. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N[a]=1124)		16-25 Years (N[a]=523)		12-15 Years (N[a]=1117)		16-25 Years (N[a]=535)	
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	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.1)	3 (0.3)	(0.1, 0.8)	2 (0.4)	(0.0, 1.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.1)	2 (0.2)	(0.0, 0.6)	2 (0.4)	(0.0, 1.3)
Injection site pain	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Fatigue	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
Chills	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Injection site bruising	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Injection site hyperaesthesia	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.1)	0	(0.0, 0.3)	0	(0.0, 0.7)
NERVOUS SYSTEM DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Dizziness	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Rash maculo-papular	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)

Note: MedDRA (v23.1) coding dictionary applied.
Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).
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 each dose 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 (04:22)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 immd vax2 ped saf

14.33. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N^a=1131)		16-25 Years (N^a=536)		12-15 Years (N^a=1129)		16-25 Years (N^a=561)	
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	7 (0.6)	(0.2, 1.3)	9 (1.7)	(0.8, 3.2)	2 (0.2)	(0.0, 0.6)	3 (0.5)	(0.1, 1.6)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)
Abdominal pain	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (0.2)	(0.0, 0.6)	4 (0.7)	(0.2, 1.9)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Pyrexia	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Fatigue	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Injection site erythema	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Injection site pain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Injection site swelling	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
INFECTIONS AND INFESTATIONS	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Appendicitis	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Otitis externa	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
Flail chest	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Patella fracture	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Arthralgia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Back pain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Myalgia	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
NERVOUS SYSTEM DISORDERS	2 (0.2)	(0.0, 0.6)	2 (0.4)	(0.0, 1.3)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Headache	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Migraine	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
PSYCHIATRIC DISORDERS	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Depression	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Anxiety	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)

14.33. Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N^a=1131)	16-25 Years (N^a=536)	12-15 Years (N^a=1129)	16-25 Years (N^a=561)
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.
Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.
Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).
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 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_1md2_sev_ped_saf

14.34. Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N^a=1131)		16-25 Years (N^a=536)		12-15 Years (N^a=1129)		16-25 Years (N^a=561)	
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 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Pyrexia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
INFECTIONS AND INFESTATIONS	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Appendicitis	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Focal peritonitis	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.
Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).
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 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_1md2_life_ped_saf

14.35. 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 16-55 Years of Age – Safety Population

	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)
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)
Neutropenia	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	3 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.1)
Acute coronary syndrome	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 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 fibrillation	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)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinnitus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
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)
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)
Abdominal pain	4 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
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)
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)
Gastrooesophageal reflux disease	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)
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)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Small intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

14.35. 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 16-55 Years of Age – Safety Population

	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)
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)
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)
Bile duct stone	1 (0.0)	(0.0, 0.0)	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, 0.1)	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)
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 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)
COVID-19	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)
Infected bite	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)
Otitis externa	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
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)
Road traffic accident	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)

14.35. 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 16-55 Years of Age – Safety Population

	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])
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)
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)
Facial bones fracture	1 (0.0)	(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)
Hip 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)
Ligament sprain	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)
Spinal cord injury cervical	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)	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)
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)
Hypoglycaemia	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	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)
Costochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle contracture	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)

14.35. 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 16-55 Years of Age – Safety Population

	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])
Musculoskeletal chest pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neck pain	0	(0.0, 0.0)	1 (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)
Adenocarcinoma gastric	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	23 (0.2)	(0.1, 0.3)	15 (0.1)	(0.1, 0.2)
Headache	15 (0.1)	(0.1, 0.2)	8 (0.1)	(0.0, 0.1)
Migraine	3 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness	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)
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)
Subarachnoid haemorrhage	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)	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)
Anxiety	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)
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)
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)
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)
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)

14.35. 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 16-55 Years of Age – Safety Population

	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])
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
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 embolism	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinorrhoea	0	(0.0, 0.0)	1 (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)
Urticaria	1 (0.0)	(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)
Aortic stenosis	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: 29MAR2021 (18:22)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 EUA 1655/adae s130 1md2 sev 1655 saf

14.36. 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 16-55 Years of Age – Safety Population

	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)
Arrhythmia supraventricular	1 (0.0)	(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 infarction	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)
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)
Diverticular perforation	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)
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)
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)
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)
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)
Toxicity to various agents	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)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Hemiplegic migraine	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)
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)

14.36. 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 16-55 Years of Age – Safety Population

	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])
Respiratory arrest	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: 29MAR2021 (18:35)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adae_s130_1md2_life_1655_saf

14.37. 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 16-55 Years of Age – Safety Population

	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)
CARDIAC DISORDERS	8 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Acute myocardial infarction	2 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Atrial fibrillation	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)
Acute left ventricular failure	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)
Bradycardia	1 (0.0)	(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 infarction	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)
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)
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)
Abdominal pain	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)
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)
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)
Pancreatitis acute	0	(0.0, 0.0)	1 (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)
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)
Non-cardiac chest 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)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

14.37. 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 16-55 Years of Age – Safety Population

	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])
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)
Bile duct stone	1 (0.0)	(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)
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)
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)
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)
Anal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis 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)
Postoperative wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
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)
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)
Facial bones fracture	1 (0.0)	(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)
Hip fracture	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)
Overdose	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)
Road traffic accident	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)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	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)

14.37. 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 16-55 Years of Age – Safety Population

	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])
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)
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)
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)
Chronic myeloid leukaemia	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)
Malignant melanoma	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)
NERVOUS SYSTEM DISORDERS	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Syncope	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	1 (0.0)	(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)
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)
Depression suicidal	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)
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)
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)

14.37. 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 16-55 Years of Age – Safety Population

	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])
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)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.1)
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 embolism	1 (0.0)	(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)
Aortic stenosis	0	(0.0, 0.0)	1 (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: 29MAR2021 (15:02)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adae_s130_ser_all_pd2_1655_saf

14.38. 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 16-55 Years of Age – Safety Population

	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)
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)

14.38. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.38. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.38. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.38. 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 16-55 Years of Age – Safety Population

	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])
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)
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)

14.38. 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 16-55 Years of Age – Safety Population

	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])
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)

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: 29MAR2021 (17:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adae_s131_sae_exp_1655_saf

14.39. 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 16-55 Years of Age – Safety Population

	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)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vertigo	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
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)
Diverticular perforation	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)
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)
Death	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)
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)
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)
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)
Metastases to central nervous system	1 (0.0)	(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)

14.39. 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 16-55 Years of Age – Safety Population

	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	2 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Amnesia	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)
Paraparesis	0	(0.0, 0.0)	1 (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)
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)
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)

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 (18:52)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 EUA 1655/adae s130 1md2 wd 1655 saf

SUPPLEMENTAL FIGURES

None

SUBJECT NARRATIVES (12 THROUGH 15 YEARS OF AGE)

Primary Reason for Narrative	Subject Number
Safety-Related Subject Withdrawal	Subject C4591001 1006 10061272 Subject C4591001 1147 11471327
Appendicitis	Subject C4591001 1007 10071581 Subject C4591001 1147 11471281
Lymphadenopathy	Subject C4591001 1007 10071497 Subject C4591001 1007 10071615 Subject C4591001 1007 10071651 Subject C4591001 1009 10091231 Subject C4591001 1009 10091342 Subject C4591001 1016 10161344 Subject C4591001 1126 11261263 Subject C4591001 1131 11311287 Subject C4591001 1142 11421385 Subject C4591001 1152 11521683 Subject C4591001 1152 11521704
Other Serious Adverse Event	Subject C4591001 1007 10071620 Subject C4591001 1039 10391326 Subject C4591001 1123 11231507 Subject C4591001 1270 12701222
Adverse Events With Numerical Imbalance Between Vaccine Groups	Subject C4591001 1006 10061245 Subject C4591001 1007 10071585 Subject C4591001 1008 10081928 Subject C4591001 1039 10391337 Subject C4591001 1044 10441373 Subject C4591001 1126 11261268
COVID-19 Case (Severe and/or Multiple)	Subject C4591001 1270 12701237

15. REFERENCES

None