1. TITLE PAGE

Vaccine Name and Compound Number:	BNT162 RNA-Based COVID-19 Vaccines, Compound Number: PF-07302048
Report Title:	Interim Report – Adolescent 6-Month Update: A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-CoV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals
Protocol Number:	Protocol C4591001
Sponsor:	BioNTech SE
Sponsor Agent:	Pfizer Inc
Phase of Development:	Phase 1/2/3
First Subject First Visit:	29 April 2020 (study start); 15 October 2020 (adolescent)
Primary Completion Date:	Not applicable
Data Cutoff Date:	02 September 2021
Serology Completion Dates:	29 October 2021
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 Other 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 Eleni Lagkadinou, MD, PhD Vice President, Clinical Development, BioNTech SE
Internal Reports Referenced:	C4591001 Booster Interim CSR: dated 23 August 2021 C4591001 6-Month Update Interim CSR: dated 29 April 2021 C4591001 Adolescent Interim CSR: dated 14 April 2021 C4591001 Final Analysis Interim CSR: dated 03 December 2020
Date of Current Version:	12 December 2021
Date(s) of Previous Report(s):	03 December 2021

GCP STATEMENT

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

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4. LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation	Definition
AE	adverse event
ACIP	Advisory Committee on Immunization Practices
AESI	adverse event of special interest
BDR	blinded data review
BMI	body mass index
CDC	Centers for Disease Control and Prevention (United States)
CI	confidence interval
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
EKG	electrocardiogram
GCP	Good Clinical Practice
GMC	geometric mean concentration
GMFR	geometric mean fold rise
GMR	geometric mean ratio
GMT	geometric mean titer
HBc Ab	hepatitis B core antibody
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCV	hepatitis C virus
HCV Ab	hepatitis C virus antibody
HIV	human immunodeficiency virus
ICD	informed consent document
ICH	International Council for Harmonisation
IEC	independent ethics committee
IgG	immunoglobulin G
IgM	immunoglobulin M
IRB	institutional review board
IRC	internal review committee
IRR	illness rate ratio
IRT	interactive response technology
IWR	interactive Web-based response
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
P2 S	SARS-CoV-2 full-length, P2 mutant, prefusion spike glycoprotein
PCR	polymerase chain reaction

Abbreviation	Definition
PD	protocol deviation
PT	preferred term
QA	quality assurance
QTL	quality tolerance limit
RCDC	reverse cumulative distribution curve
RDC	remote data capture
RNA	ribonucleic acid
SA	South Africa
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
VOC	variant of concern
VOI	variant of interest

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

This study was undertaken by Pfizer and BioNTech SE and conducted at 29 sites in the United States for adolescent participants 12 through 15 years of age as of the data cutoff date (02 September 2021) (Appendix 16.1.4.1). Due to live database and ongoing nature of the study, there is a discrepancy in the number of participants screened/randomized in Appendix 16.1.4.1 compared with the results tables.

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.

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.

No sites were terminated from the study to date.

7. INTRODUCTION

In December 2019, a pneumonia outbreak of unknown cause occurred in Wuhan, China. In January 2020, it became clear that a novel coronavirus was the underlying cause. On 11 March 2020, the WHO characterized the COVID-19 outbreak as a pandemic[1], which has

spread rapidly globally. A prophylactic, RNA-based SARS-CoV-2 vaccine provides one of the most flexible and fastest approaches available to immunize against COVID-19.[2,3]

This ongoing Phase 1/2/3 study is the registrational and pivotal study of the prophylactic BNT162b2 vaccine candidate against COVID-19 in healthy individuals ≥12 years of age that was initiated in April 2020.

This ongoing study has demonstrated the safety, tolerability, immunogenicity, and efficacy of BNT162b2 when administered as 2 doses of 30 µg given approximately 21 days apart, which was the basis of the current authorizations and approvals. Study C4591001 data supporting authorization or licensure for the 2-dose series in participants ≥12 years of age are summarized below:

- Phase 1 evaluated safety and immunogenicity results in healthy adult participants across dose levels of 2 vaccine candidates, BNT162b1 and BNT162b2. The Phase 1 reactogenicity and immunogenicity profiles, combined with available nonclinical animal study data, led to the selection of BNT162b2 at the 30-µg dose level to advance to Phase 2/3 evaluation.

- Phase 2/3 evaluated 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 a data cutoff date of 14 November 2020 were previously reported in the C4591001 Final Analysis Interim CSR, dated 03 December 2020. On 11 December 2020, the US FDA issued an EUA for use of BNT162b2 at 30 µg in individuals ≥16 years of age.

- For adolescents (12 through 15 years of age), immunobridging and safety (median ≥2 months follow-up) were compared with young adults 16 through 25 years of age were reported in the adolescent interim CSR, dated 14 April 2021. Immunogenicity data from adolescent (and young adult) participants showed robust neutralizing GMTs after vaccination with 2 doses of BNT162b2 at 30 µg. In addition, 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 for adolescents (12 through 15 years of age) showed estimated VE was 100.0% for cases reported from at least 7 days after Dose 2 in individuals without and with or without evidence of prior SARS-CoV-2 infection before and during vaccination regimen. On 10 May 2021, the US FDA issued an EUA for use in individuals 12 to 15 years of age. At present, there are currently no licensed vaccines to immunize against COVID-19 for individuals 12 to 15 years of age in the US.

- Follow-up to 6 months after Dose 2 was provided in the C4591001 6-Month Update Interim CSR, dated 29 April 2021, and provided up to 6 months of additional safety, efficacy, and immunogenicity follow-up data. The report included analysis of safety during the blinded and post-unblinding (open-label) periods through 6 months post-Dose 2 for participants ≥16 years of age, and updated efficacy analysis based on all confirmed COVID-19 cases in participants ≥12 years of age that accrued in blinded follow-up to a

data cutoff date of 13 March 2021. On 23 August 2021, the US FDA granted licensure of COMIRNATY (BNT162b2) for individuals ≥16 years of age.

Based on a data cutoff date of 02 September 2021, this interim report for adolescent participants 12 to 15 years of age summarizes updated descriptive efficacy analyses from 7 days after Dose 2 during blinded placebo-controlled follow-up (Section 11.1) and the following safety data, as ordered:

- Blinded placebo-controlled follow-up period from Dose 1 to the date of unblinding for BNT162b2 and placebo participants, including new AEs that were reported after the EUA snapshot date (based on events on or after the data cutoff date of 13 March 2021) (Section 12.2.1)
- Open-label observational follow-up period of original BNT162b2 recipients from the date of unblinding to the data cutoff date (Section 12.2.2)
- Cumulative safety from Dose 1 to at least 6 months after Dose 2, inclusive of blinded data and open-label data for original BNT162b2 recipients, including new AEs that were reported after the EUA snapshot date (Section 12.2.3)
- Open-label observational follow-up period for original placebo recipients who then received BNT162b2 from the first dose of BNT162b2 to the data cutoff date (Section 12.2.4)

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 objectives, estimands, and endpoints presented in Table 1 are from Appendix 16.1.1, Protocol Amendment 18. This report summarizes safety and immunogenicity for adolescent participants only, as described in Section 7.

Study objectives and endpoint analyses that were either previously reported, or will be reported at a later time, are indicated with gray shading and per the ‘reference’ column in 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 are reported in the 6-month update interim CSR dated 29 April 2021. Efficacy data from 7 days after Dose 2 to the data cutoff date (13 March 2021) for participants 12 through 15 years of age only are reported in the adolescent interim CSR dated 14 April 2021.
To evaluate the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after the second dose in participants with and without evidence of infection before vaccination	In participants complying with the key protocol criteria (evaluable participants) at least 7 days after receipt of the second dose of study intervention: 100 × (1 – IRR) [ratio of active vaccine to placebo]	COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT	Interim data are reported in final analysis interim CSR dated 03 December 2020. Updated efficacy data are reported in the 6-month update interim CSR dated 29 April 2021. Efficacy data from 7 days after Dose 2 to the data cutoff date (13 March 2021) for participants 12 through 15 years of age only are reported in the adolescent interim CSR dated 14 April 2021.

Table 1. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
Primary Safety			
To define the safety profile of prophylactic BNT162b2 in the first 360 participants randomized (Phase 2)	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 to 7 days after the second dose • SAEs from Dose 1 to 7 days after the second dose	• Local reactions (pain at the injection site, redness, and swelling) • Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs	Interim data are reported in final analysis interim CSR dated 03 December 2020.
To define the safety profile of prophylactic BNT162b2 in all participants randomized in Phase 2/3	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 to 1 month after the second dose • SAEs from Dose 1 to 6 months after the second dose	• AEs • SAEs • In a subset of at least 6000 participants o Local reactions (pain at the injection site, redness, and swelling) o Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain)	Interim data are reported up to 1 month after Dose 2 and to the data cutoff date (14 November 2020) in final analysis interim CSR dated 03 December 2020. Cumulative interim data up to cutoff date (13 March 2021) are reported in the 6-month update interim CSR dated 29 April 2021. Interim adolescent 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 data cutoff date (13 March 2021) are reported in the adolescent interim CSR dated 14 April 2021.

Table 1. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
To define the safety profile of prophylactic BNT162b2 in participants 12 to 15 years of age in Phase 3	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 to 1 month after the second dose • SAEs from Dose 1 to 6 months after the second dose	• Local reactions (pain at the injection site, redness, and swelling) • Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs	Interim data are reported up to 1 month after Dose 2 and to the data cutoff date (13 March 2021) in the adolescent interim CSR dated 14 April 2021. Interim data for AEs and SAEs reported up to 6 months after Dose 2 and to the data cutoff date (02 September 2021) 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 the subset for evaluation of boostability and protection against emerging VOCs	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 to 1 month after the last dose • SAEs from Dose 1 to 5 or 6 months after the last dose	• Local reactions (pain at the injection site, redness, and swelling) • Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs	Interim data for BNT162b2 given as a third dose to BNT162b2-experienced participants only are reported up to 1 month after Dose 3 and to the data cutoff date (17 June 2021) in the booster interim CSR dated 23 August 2021.
To describe the safety and tolerability profile of BNT162b2 given as a third dose at least 6 months after the second dose of BNT162b2 (or BNT162b2$_{SA}$) for participants who received a third dose as part of protocol amendment 18	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting: • AEs from Dose 3 to 1 month after Dose 3 • SAEs from Dose 3 to 6 months after Dose 3	• AEs • SAEs	Interim data for BNT162b2 given as a third dose to BNT162b2-experienced participants only are reported up to 1 month after Dose 3 and to the data cutoff date (17 June 2021) in the booster interim CSR dated 23 August 2021.

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 at 30 µg compared to after 2 doses of BNT162b2, in the same individuals	GMR of reference strain NT 1 month after the third dose of BNT162b2 at 30 µg to 1 month after the second dose of BNT162b2 The difference in percentages of participants with seroresponse to the reference strain at 1 month after the third dose of BNT162b2 at 30 µg and 1 month after the second dose of BNT162b2	SARS-CoV-2 reference strain NTs in participants with no serological or virological evidence (up to 1 month after receipt of the third dose of BNT162b2 at 30 µg) of past SARS-CoV-2 infection	Interim data for BNT162b2 given as a third dose to BNT162b2-experienced participants are reported up to 1 month after Dose 3 and to the data cutoff date (17 June 2021) in the booster interim CSR dated 23 August 2021.
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 only are reported in the 6-month update interim CSR dated 29 April 2021. Updated efficacy data occurring from at least 7 days after the second dose for participants 12 through 15 years of age only are reported in the adolescent interim CSR dated 14 April 2021.
To evaluate the efficacy of prophylactic BNT162b2 against confirmed severe COVID-19 occurring from 7 days and from 14 days after the second dose in participants with and without evidence of infection before vaccination	In participants complying with the key protocol criteria (evaluable participants) • at least 7 days and • at least 14 days after receipt of the second dose of study intervention: 100 × (1 – IRR) [ratio of active vaccine to placebo]	Confirmed severe COVID-19 incidence per 1000 person-years of follow-up	Prespecified complete efficacy data are reported in final analysis interim CSR dated 03 December 2020. Updated efficacy data occurring from at least 7 days after the second dose only are reported in the 6-month update interim CSR dated 29 April 2021.

Table 1. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
			Updated efficacy data occurring from at least 7 days after the second dose for participants 12 through 15 years of age only are reported in the adolescent interim CSR dated 14 April 2021.
To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 (according to the CDC-defined symptoms) occurring from 7 days and from 14 days after the second dose in participants without evidence of infection before vaccination	In participants complying with the key protocol criteria (evaluable participants) • at least 7 days and • at least 14 days after receipt of the second dose of study intervention: 100 × (1 – IRR) [ratio of active vaccine to placebo]	COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT in participants with no serological or virological evidence (up to 7 days and up to 14 days after receipt of the second dose) of past SARS-CoV-2 infection	Prespecified complete efficacy data are reported in final analysis interim CSR dated 03 December 2020.
To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 (according to the CDC-defined symptoms) occurring from 7 days and from 14 days after the second dose in participants with and without evidence of infection before vaccination	In participants complying with the key protocol criteria (evaluable participants) • at least 7 days and • at least 14 days after receipt of the second dose of study intervention: 100 × (1 – IRR) [ratio of active vaccine to placebo]	COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT	Prespecified complete efficacy data are reported in final analysis interim CSR dated 03 December 2020.
To evaluate the efficacy of prophylactic BNT162b2 against non-S seroconversion to SARS-CoV-2 in participants without evidence of infection or confirmed COVID-19	In participants complying with the key protocol criteria (evaluable participants): 100 × (1 – IRR) [ratio of active vaccine to placebo]	Incidence of asymptomatic SARS-CoV-2 infection per 1000 person-years of follow-up based on N-binding antibody seroconversion in participants with no serological or virological evidence of past SARS-CoV-2 infection or confirmed COVID-19	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	Data will be reported at a later time.

Table 1. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
		the asymptomatic surveillance period) of past SARS-CoV-2 infection	
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	Interim data are reported in the adolescent interim CSR dated 14 April 2021.
BNT162b2-experienced participants			
To demonstrate the noninferiority of the anti-SA immune response after a third dose of BNT162b2 at 30 µg compared to the anti–reference strain immune response after 2 doses of BNT162b2, in the same individuals	GMR of SA NT 1 month after the third dose of BNT162b2 at 30 µg to the reference strain NT 1 month after the second dose of BNT162b2 The difference in percentages of participants with seroresponse to the SA strain at 1 month after the third dose of BNT162b2 at 30 µg and seroresponse to the reference strain at 1 month after the second dose of BNT162b2	SARS-CoV-2 SA and reference strain NTs in participants with no serological or virological evidence (up to 1 month after receipt of the third dose of BNT162b2 at 30 µg) of past SARS-CoV-2 infection	Data will be reported at a later time.
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.

Table 1. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
To descriptively compare the anti-SA immune response after 1 dose of BNT162b2$_{SA}$ and a third dose of BNT162b2 at 30 µg	GMR of SA NT 1 month after 1 dose of BNT162b2$_{SA}$ to 1 month after the third dose of BNT162b2 at 30 µg The difference in percentages of participants with seroresponse to the SA strain at 1 month after 1 dose of BNT162b2$_{SA}$ and 1 month after the third dose of BNT162b2 at 30 µg	SARS-CoV-2 SA NT in participants with no serological or virological evidence (up to 1 month after receipt of 1 dose of BNT162b2$_{SA}$ or the third dose of BNT162b2 at 30 µg) of past SARS-CoV-2 infection	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 BNT162b2$_{SA}$ and 1 month after the second dose of BNT162b2	SARS-CoV-2 SA NTs in participants with no serological or virological evidence (up to 1 month after receipt of the second dose of BNT162b2$_{SA}$ or BNT162b2 as appropriate) of past SARS-CoV-2 infection	Data will be reported at a later time.

Table 1. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
To descriptively compare the anti-reference strain immune response after 2 doses of BNT162b2$_{SA}$ and after 2 doses of BNT162b2	GMR of reference strain NT 1 month after the second dose of BNT162b2$_{SA}$ to 1 month after the second dose of BNT162b2 The difference in percentages of participants with seroresponse to reference strain at 1 month after the second dose of BNT162b2$_{SA}$ and 1 month after the second dose of BNT162b2	SARS-CoV-2 reference strain NTs in participants with no serological or virological evidence (up to 1 month after receipt of the second dose of BNT162b2$_{SA}$ or BNT162b2 as appropriate) of past SARS-CoV-2 infection	Data will be reported at a later time.
Exploratory			
To describe the efficacy of prophylactic BNT162b2 against confirmed COVID-19 occurring from 7 days after the second dose through the blinded follow-up period in participants without, and with and without, evidence of infection before vaccination	In participants complying with the key protocol criteria (evaluable participants) after receipt of the second dose of study intervention: 100 × (1 – IRR) [ratio of active vaccine to placebo]	COVID-19 incidence per 1000 person-years of blinded follow-up based on central laboratory or locally confirmed NAAT	Interim data are reported in the 6-month update interim CSR dated 29 April 2021. Updated efficacy data from 7 days after Dose 2 through the blinded follow-up period for participants 12 through 15 years of age are provided in this CSR.
To describe the incidence of confirmed COVID-19 through the entire study follow-up period prior to receiving the third dose of BNT162b2 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 describe the incidence of confirmed COVID-19 after receiving the third dose of BNT162b2	In participants who received the third dose of BNT162b2: Incidence per 1000 person-years of follow-up	COVID-19 incidence per 1000 person-years of follow-up based on central laboratory or locally confirmed NAAT	Data will be reported at a later time.

Table 1. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
To evaluate the immune response over time to prophylactic BNT162b2 and persistence of immune response in participants with and without serological or virological evidence of SARS-CoV-2 infection before vaccination	GMC/GMT and GMFR at baseline and 1, 6, 12, and 24 months after completion of vaccination	• Full-length S-binding or S1-binding IgG levels • SARS-CoV-2 neutralizing titers	Interim data for Phase 2 (first 360 participants) only up to 1 month after Dose 2 are reported for S1-binding IgG levels and SARS-CoV-2 neutralizing titers in final analysis interim CSR dated 03 December 2020. GMTs and GMFRs of SARS-CoV-2 neutralizing titers up to 1 month after Dose 2 in participants 12 through 15 and 16 through 25 years of age are reported in the adolescent interim CSR dated 14 April 2021.
To describe the 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.

Table 1. Phase 2/3 Objectives, Estimands, and Endpoints

Objectives[a]	Estimands	Endpoints	Reference
To describe the safety, immunogenicity, and efficacy of prophylactic BNT162b2 in individuals with confirmed stable HIV disease		• All safety, immunogenicity, and efficacy endpoints described above	Safety data only in participants with confirmed stable HIV disease are reported in the 6-month update interim CSR dated 29 April 2021.
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 immune response to a third dose of BNT162b2 (at 30 µg or a lower dose of 5 µg or 10 µg) or a third or fourth dose of BNT162b2$_{SA}$	• GMTs at Dose 3 and subsequent time points • GMFRs from Dose 3 to subsequent time points	• SARS-CoV-2 reference strain NTs	Interim data for BNT162b2 30 µg given as a third dose to BNT162b2-experienced participants are reported in the booster interim CSR dated 23 August 2021.
To describe the cell-mediated immune response, and additional humoral immune response parameters, to the reference strain and SA in a subset of participants: • 7 days and 1 and 6 months after BNT162b2$_{SA}$ given as 1 or 2 doses to BNT162b2-experienced participants • 7 days and 1 and 6 months after BNT162b2$_{SA}$ given as 2 doses to BNT162b2-naïve participants • 7 days and 1 and 6 months after BNT162b2 given as a third dose to BNT162b2-experienced participants			Data will be reported at a later time.

a. HIV-positive participants in Phase 3 were not included in analyses of the objectives, with the exception of the specific exploratory objective.
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. The study evaluated the safety, tolerability, and immunogenicity of 3 different SARS-CoV-2 RNA vaccine candidates against COVID-19 and the Phase 2/3 efficacy of 1 selected candidate based on Phase 1 results:

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

To facilitate rapid review of data in real time, Pfizer and BioNTech 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.

Boostability and Variant Strain Evaluations

Immunogenicity and safety evaluations of boostability were conducted in a subset of Phase 3 participants at selected sites in the US who received a third dose of BNT162b2 at 30 µg at least 6 months after their second dose, and results are reported in the booster interim CSR dated 23 August 2021. Evaluations of boostability in Phase 1 participants and a further subset of Phase 3 participants receiving a third, lower, dose of BNT162b2 at 5 or 10 µg will be reported at a later time.

Evaluations of VOC strains of SARS-CoV-2 (in participants who receive a SARS-CoV-2 variant encoding vaccine that encodes the Beta variant originally identified in South Africa

[BNT162b2$_{SA}$] as a third dose) are not included in this report and will be reported at a later time.

Refer to Appendix 16.1.1, Protocol Section 4.1.1 for further details on the booster (Dose 3) for Phase 1, and Appendix 16.1.1, Protocol Section 4.1.2 for further details on the booster (Dose 3) 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 to be unblinded in stages once all ongoing participants either had been individually unblinded or had concluded their 6-month post–Dose 2 or post-Dose 3 study visit, in the following sequence:

- Phase 1 (after Visit 8 [6-month post-Dose 2 visit]).
- Phase 2/3, ≥16 years of age (after Visit 4 [6-month post-Dose 2 visit]).
- Phase 3, 12 through 15 years of age (after Visit 4 [6-month post-Dose 2 visit]).
- Original Phase 3 participants rerandomized to assess boostability and protection against emerging VOCs (after Visit 306) (data not included in this report).

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

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

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

9.1.1. Phase 1

Phase 1 safety follow-up is ongoing, and participants are expected to participate for up to a maximum of approximately 26 months.

Refer to Appendix 16.1.1, Protocol Section 4.1.1 for further details on the Phase 1 study design.

9.1.2. Phase 2/3

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 360 Phase 2 participants. Enrollment continued during Phase 2 and these participants were 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 to 15 years of age stratum comprised up to approximately 2000 participants enrolled at selected investigational sites. It was planned to enroll a minimum of 40% of participants in the >55 years of age stratum. Participants in Phase 3 were randomized 1:1 to receive either active vaccine or placebo.

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

At the time of the final analysis of efficacy (CSR dated 03 December 2020), relatively few participants 12 to 15 years of age had enrolled in the study, and no COVID-19 cases in this age group accrued at that time. In the adolescent interim CSR dated 14 April 2021, noninferiority of immune response to prophylactic BNT162b2 in participants 12 to 15 years of age to response in participants 16 to 25 years of age was assessed based on the GMR of SARS-CoV-2 neutralizing titers using a 1.5-fold margin and reported in the adolescent interim CSR dated 14 April 2021 and in an EUA amendment, which supported issuance of the EUA for use in individuals 12 to 15 years of age. Additionally, the adolescent interim CSR also presented updated descriptive efficacy analyses for participants 12 to 15 years of age, based on confirmed cases COVID-19 reported from at least 7 days after Dose 2 through the data cutoff date (13 March 2021), with an observed VE of 100% irrespective of evidence of prior infection with SARS-CoV-2. No severe COVID-19 cases were reported in this age group, based on either protocol definition (ie, per FDA criteria) or per CDC criteria for severity.

Updated efficacy analyses during the blinded placebo-controlled follow-up period were conducted on cases accrued up to the data cutoff date of 13 March 2021 to evaluate duration of protection and reported in the 6-month update interim CSR dated 29 April 2021, which presented these analyses of all confirmed COVID-19 cases and any cases meeting protocol- and CDC-defined criteria for severe cases.

It is planned that participants would participate in the study for approximately 26 months from the time of enrollment.

This interim report for participants 12 to 15 years of age includes updated efficacy analyses from 7 days after Dose 2 and safety analyses up to 6 months after Dose 2 and to the data cutoff date (02 September 2021).

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 1 (selected) candidate, in healthy individuals. Boostability is being assessed in a subset of Phase 3 participants, including with a prototype vaccine that targets a SARS-CoV-2 VOC.

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 was also assessed.

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

9.3. Participant Selection

9.3.1. Inclusion Criteria

Participants were eligible to be included in the study only if all of the following criteria applied:

Age and Sex:

1. Male or female participants between the ages of 18 and 55 years, inclusive, and 65 and 85 years, inclusive (Phase 1), or ≥12 years (Phase 2/3), at randomization.

For the boostability and protection-against-VOCs subset:

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

- Newly enrolled participants enrolled to receive 2 doses of BNT162b2$_{SA}$; male or female participants between the ages of 18 and 55 years, inclusive, at enrollment.

- Existing participants enrolled to receive a third dose of BNT162b2 at 5 or 10 µg; male or female participants ≥18 years at rerandomization.

Note that participants <18 years of age could not be enrolled in the EU.

- Refer to Appendix 4 for reproductive criteria for male (Appendix 16.1.1, Protocol Section 10.4.1) and female (Appendix 16.1.1, Protocol Section 10.4.2) participants.

Type of Participant and Disease Characteristics:

2. Participants who were willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures.

3. Healthy participants who were determined by medical history, physical examination (if required), and clinical judgment of the investigator to be eligible for inclusion in the study.

Note: Healthy participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, could be included. Specific criteria for Phase 3 participants with known stable infection with HIV, HCV, or HBV can be found in Appendix 16.1.1, Protocol Section 10.8.

4. **Phase 2/3 only:** Participants who, in the judgment of the investigator, were at higher risk for acquiring COVID-19 (including, but not limited to, use of mass transportation, relevant demographics, and frontline essential workers).

5. **Boostability and protection-against-VOCs existing participant subset only:** Participants who provided a serum sample at Visit 3, with Visit 3 occurring within the protocol-specified window.

Informed Consent:

6. Capable of giving personal signed informed consent/have parent(s)/legal guardian capable of giving signed informed consent as described in Appendix 16.1.1, Protocol Appendix 1, which included compliance with the requirements and restrictions listed in the ICD and in the protocol.

9.3.2. Exclusion Criteria

Participants were excluded from the study if any of the following criteria applied:

Medical Conditions:

1. Other medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that increased the risk of study participation or, in the investigator's judgment, made the participant inappropriate for the study.

2. **Phases 1 and 2 only:** Known infection with HIV, HCV, or HBV.

3. History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s).

4. Receipt of medications intended to prevent COVID-19.

5. Previous clinical (based on COVID-19 symptoms/signs alone, if a SARS-CoV-2 NAAT result was not available) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID-19.

6. **Phase 1 only:** Individuals at high risk for severe COVID-19, including those with any of the following risk factors:

- Hypertension
- Diabetes mellitus
- Chronic pulmonary disease
- Asthma
- Current vaping or smoking
- History of chronic smoking within the prior year
- Chronic liver disease
- Stage 3 or worse chronic kidney disease (glomerular filtration rate <60 mL/min/1.73 m^2)
- Resident in a long-term facility
- BMI >30 kg/m^2
- Anticipating the need for immunosuppressive treatment within the next 6 months

7. **Phase 1 only:** Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel).

8. Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination.

9. **Phase 1 only:** Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention, including but not limited to: systemic or cutaneous lupus erythematosus, autoimmune arthritis/rheumatoid arthritis, Guillain-Barré syndrome, multiple sclerosis, Sjögren's syndrome, idiopathic thrombocytopenia purpura,

glomerulonephritis, autoimmune thyroiditis, giant cell arteritis (temporal arteritis), psoriasis, and insulin-dependent diabetes mellitus (type 1).

10. Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection.

11. Women who are pregnant or breastfeeding.

Prior/Concomitant Therapy:

12. Previous vaccination with any coronavirus vaccine.

13. Individuals who received treatment with immunosuppressive therapy, including cytotoxic agents or systemic corticosteroids, eg, for cancer or an autoimmune disease, or planned receipt throughout the study. If systemic corticosteroids were administered short term (<14 days) for treatment of an acute illness, participants should not have been enrolled into the study until corticosteroid therapy had been discontinued for at least 28 days before study intervention administration. Inhaled/nebulized (except for participants in Phase 1 – see exclusion criterion 14), intra-articular, intrabursal, or topical (skin or eyes) corticosteroids were permitted.

14. **Phase 1 only:** Regular receipt of inhaled/nebulized corticosteroids.

15. Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study.

Prior/Concurrent Clinical Study Experience:

16. Participation in other studies involving study intervention within 28 days prior to study entry through and including 28 days after the last dose of study intervention, with the exception of non-Pfizer interventional studies for prevention of COVID 19, which are prohibited throughout study participation.

17. Previous participation in other studies involving study intervention containing lipid nanoparticles.

Diagnostic Assessments:

18. **Phase 1 only:** Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit.

19. **Phase 1 only:** Any screening hematology and/or blood chemistry laboratory value that meets the definition of a ≥ Grade 1 abnormality.

Note: With the exception of bilirubin, participants with any stable Grade 1 abnormalities (according to the toxicity grading scale) may be considered eligible at the discretion of the investigator. (Note: A “stable” Grade 1 laboratory abnormality is defined as a report of Grade

1 on an initial blood sample that remains ≤ Grade 1 upon repeat testing on a second sample from the same participant.)

20. **Phase 1 only:** Positive test for HIV, HBsAg, HBc Abs, or HCV Abs at the screening visit.

21. **Phase 1 only:** SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention.

Other Exclusions:

Investigator site staff or Pfizer/BioNTech employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members.

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:

- BNT162b2 (BNT162 RNA-LNP vaccine containing modRNA that encodes the 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 other planned or ongoing study intervention(s) and study intervention administration that will be reported at a later time.

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.

Table 2. Investigational Product Lot Numbers – Interim – Adolescent 6-Month Update

Investigational Product	Manufacturer	Vendor Lot Number (Manufacturer)	Lot Number[a] (Pfizer)
BNT162b2 (30 µg)	BioNTech	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	PA2074300/P220395-0022L
		ED3938	PA2074300/P220395-0023L
		EE3813	NC2075485/P220395-0068L
		EE3813	NC2075485/P220395-0074L
		EE3813	NC2075485/P220395-0077L
		EE3813	PA2074838/P220395-0020L
		EE3813	PA2074838/P220395-0024L
		ER9449Z	PA2096794/P220395-0079L
		ER9449Z	PA2096794/P220395-0082L
		EE8493Y	PA2087473/P220395-0073L
		EJ0553Z	PA2085061/P220395-0070L
Placebo (normal saline 0.9% sodium chloride solution)	Pfizer	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/P220395-0055L
		DK2074;20-002221	PA2069407/P220395-0062L
		DK2074;20-002221	PA2069407/P220395-0065L
Diluent (normal saline 0.9% sodium chloride solution)	Pfizer	DK2074	20-002221
		DK1589	20-001776
		DK1589	20-001592

Note: C4591001 End of Study Information and Quality Control (QC) Record for Study Drug Appendix (Section D) dated 08Oct2021 was used to create this table.
a. Lot number assigned to the investigational product or diluent by Pfizer Global Clinical Supply.
Protocol C4591001 Investigational Product Lot Numbers Table – Interim – Adolescent 6-Month Update, Final, Version 1.0, 15Oct2021.

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. Sponsor staff and all personnel directly involved in study conduct were 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 study was to be unblinded in stages once all ongoing participants either had been individually unblinded or had concluded their 6-month post–Dose 2 or post-Dose 3 study visit, as follows:

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

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

Refer to Appendix 16.1.1, Protocol Section 6.3.2 for details on blinding of the site personnel, Protocol Section 6.3.3 for details on blinding of Pfizer and BioNTech personnel, 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

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

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

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

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

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 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 in the adolescent interm CSR, dated 14 April 2021.

In this report, updated descriptive efficacy analyses for participants 12 through 15 years of age accrued during blinded placebo-controlled follow-up are summarized up to a data cutoff date of 02 September 2021.

Immunogenicity evaluations in participants 12 through 15 years of age are not included in

this interim report. The immune response to BNT162b2 30 µg in adolescents 12 through 15 years of age was previously reported to be noninferior (and in fact exceeded) the immune response in young adults 16 through 25 years of age (ie, successful immunobridging), as detailed in the adolescent interim report dated 14 April 2021.

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

There are no new e-diary data presented in this report (previously reported in the adolescent interim CSR, dated 14 April 2021).

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, prior to protocol amendment 16 (28 May 2021), 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.

When the total number of severe cases was 20 or less, stopping rules 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).

For those participants who originally received placebo but went on to receive BNT162b2 at Vaccinations 3 and 4, AEs were collected from the time the participant provided informed consent (for receipt of Vaccinations 3 and 4) through and including Visit 103 (1-month follow-up after Vaccination 4). SAEs were collected from the time the participant provided informed consent (for receipt of Vaccinations 3 and 4) to approximately 6 months after the second dose of BNT162b2 (Visit 104).

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

9.5.2.4. Events of Special Interest

Myocarditis and pericarditis were included as AESIs in Protocol Amendment 18 (07 September 2021).

Pfizer also 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 in the reported safety dataset were also reviewed and summarized (Section 12.3.4).

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. For the time period applicable to this interim report, there were 2 audits conducted for sites that enrolled adolescent participants (Appendix 16.1.8).

Refer to the final analysis interim CSR dated 03 December 2020 for previously reported data quality issues. There were none reported in the adolescent CSR dated 14 April 2021, or in the 6-month update interim CSR dated 29 April 2021.

9.7. Statistical Methods Planned in the Protocol

9.7.1. Statistical and Analytical Plans

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 other planned analysis sets to be reported at a later time.

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.
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

In Phase 3, approximately 2,000 participants enrolled were anticipated to be 12 to 15 years of age based on regulatory requirements for the safety database.

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) VE 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).

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 (adolescent interim CSR, dated 14 April 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 were also performed.

In this report, 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 02 September 2021. In addition to the protocol definition of severe COVID-19, supportive analyses using the CDC definition of severe COVID-19 were 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

Immunogenicity evaluations in participants 12-15 years of age are not included in this interim report.

In the adolescent interim report dated 14 April 2021, the GMR of SARS-CoV-2 50% neutralizing titers in adolescents 12-15 years of age to those in young adults 16-25 years of age and 2-sided 95% CIs were provided at 1 month after Dose 2 for noninferiority assessment. The immune response to BNT162b2 30 µg in SARS-CoV-2 50% neutralizing titers in adolescents 12-15 years of age was noninferior (and in fact exceeded) the immune response in young aduts 16-25 years of age (ie, successful immunobridging).

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

9.7.5. Safety Analysis

The primary safety objective was evaluated by descriptive summary statistics for local reactions, systemic events, and AEs/SAEs for each vaccine group. There are no new reactogenicity data in this report (previously reported in the adolescent interim CSR, dated 14 April 2021).

Descriptive summary statistics included counts and percentages of participants with the indicated endpoint and the associated Clopper-Pearson 2-sided 95% CIs. Incidence rates accounted for differential follow-up time and the associated 2-sided 95% CI were also provided.

The safety analysis is described in Appendix 16.1.1, Protocol Section 9.4.3, and Appendix 16.1.9, SAP Section 6.1.1 (primary).

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

Statistical analyses for participants 12 through 15 years of age were described for the following data in the adolescent interim CSR dated 14 April 2021:

- 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 were included for comparative purposes and did not include a full independent safety evaluation (these will be reported separately).

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

Statistical analyses for participants 12 through 15 years of age are reported for the following data in this CSR:

- Complete safety analysis at 6 months after Dose 2 for adolescent participants in Phase 3; and analysis of available safety results up to the data cutoff date for this report.

- Updated descriptive efficacy analysis for participants 12 through 15 years of age during the blinded placebo-controlled follow-up period based on the data cutoff date of 02 September 2021.

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 v7.0 (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 CSR dated 03 December 2020 and Section 9.8 of the adolescent interim CSR dated 14 April 2021. Changes in study conduct or planned analysis not noted in the protocol or SAP in this interim CSR were as follows:

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

- Per regulatory request, ad hoc safety tables were generated which summarized new AEs reported after the EUA snapshot date (based on events on or after a data cutoff date of 13 March 2021) for the blinded placebo-controlled and open-label follow-up periods.

10. STUDY PARTICIPANTS

10.1. Disposition of Participants – Participants 12 Through 15 Years of Age

10.1.1. Blinded Placebo-Controlled Follow-Up Period

During the blinded placebo-controlled follow-up period, there were 3 (0.3%) participants in the BNT162b2 group and 14 (1.2%) participants in the placebo group who discontinued from the vaccination period (Dose 1 to 1 month after Dose 2) (Table 4). Most participants completed the visit at 1 month after Dose 2 (≥97.0%). Few participants in the BNT162b2 and placebo groups were withdrawn from the study (0.4% and 1.2%, respectively), and all were because of withdrawal by the participant, withdrawal by parent/guardian, or they were lost to follow-up.

10.1.2. Open-Label Follow-Up Period

Individuals have been unblinded as they became locally eligible and wished to know their vaccine assignment to confirm prior vaccination with BNT162b2 (if randomized to this group), or to receive BNT162b2 (if randomized to placebo). Participants who originally received BNT162b2 continued to be followed in an open-label manner. Participants who originally received placebo were offered BNT162b2 vaccination (Doses 3 and 4 [first and second dose of BNT162b2 30 µg, respectively]) and thereafter followed in an open-label manner.

Most participants in the BNT162b2 (98.1%) and placebo (97.0%) groups completed the 1 month post-Dose 2 visit before unblinding (Table 4).

A total of 4 (0.4%) original BNT162b2 adolescent participants received Dose 1 of BNT162b2 during the blinded placebo-controlled follow-up period and then received Dose 2 of BNT162b2 30 µg during the open-label follow-up period (when they were unblinded) (Table 4). There were 45 (4.0%) participants withdrawn from the study (Table 4), and most were because of other reasons (21 of 23 participants were enrolled into Study C4591031 to evaluate a booster dose of BNT162b2) (Appendix 16.2.1).

During the open-label follow-up period, most participants originally randomized to the placebo group received Doses 3 and 4 (89.4% and 87.8%, first and second dose of BNT162b2 30 µg, respectively). There were 47 (4.2%) participants who were withdrawn from the study after unblinding and before Dose 3. There were few participants in this group (who received at least the first dose of BNT162b2 30 µg) who were withdrawn from the study (0.5%), and most were because of withdrawals by the participant, or they were lost to follow-up (Table 4).

Table 4. Disposition of All Randomized Subjects – Phase 2/3 Subjects 12 Through 15 Years of Age

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1134) n[b] (%)	Placebo (N[a]=1130) n[b] (%)	Total (N[a]=2264) n[b] (%)
Randomized	1134 (100.0)	1130 (100.0)	2264 (100.0)
Not vaccinated	3 (0.3)	1 (0.1)	4 (0.2)
Original blinded placebo-controlled follow-up period			
Vaccinated	1131 (99.7)	1129 (99.9)	2260 (99.8)
Dose 1	1131 (99.7)	1129 (99.9)	2260 (99.8)
Dose 2	1124 (99.1)	1117 (98.8)	2241 (99.0)
Discontinued from original blinded placebo-controlled vaccination period[c]	3 (0.3)	14 (1.2)	17 (0.8)
Reason for discontinuation			
No longer meets eligibility criteria	0	7 (0.6)	7 (0.3)
Protocol deviation	0	2 (0.2)	2 (0.1)
Adverse event	1 (0.1)	0	1 (0.0)
Physician decision	1 (0.1)	0	1 (0.0)
Withdrawal by subject	0	1 (0.1)	1 (0.0)
Withdrawal by parent/guardian	0	1 (0.1)	1 (0.0)
Other	1 (0.1)	3 (0.3)	4 (0.2)
Unblinded before 1-month post–Dose 2 visit	12 (1.1)	21 (1.9)	33 (1.5)
Completed 1-month post–Dose 2 visit	1113 (98.1)	1096 (97.0)	2209 (97.6)
Withdrawn from the study	5 (0.4)	14 (1.2)	19 (0.8)
Withdrawn after Dose 1 and before Dose 2	0	0	0
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	0	3 (0.3)	3 (0.1)
Withdrawn after 1-month post–Dose 2 visit	5 (0.4)	11 (1.0)	16 (0.7)
Reason for withdrawal from the study			
Withdrawal by subject	1 (0.1)	7 (0.6)	8 (0.4)
Withdrawal by parent/guardian	1 (0.1)	5 (0.4)	6 (0.3)
Lost to follow-up	3 (0.3)	2 (0.2)	5 (0.2)
Open-label follow-up period			
Originally randomized to BNT162b2	1107 (97.6)		
Received Dose 2/unplanned dose	4 (0.4)		
Completed 1-month post–Dose 2 visit	15 (1.3)		
Completed 6-month post–Dose 2 visit	1065 (93.9)		
Withdrawn from the study	45 (4.0)		
Withdrawn before 6-month post–Dose 2 visit	25 (2.2)		
Withdrawn after 6-month post–Dose 2 visit	20 (1.8)		
Reason for withdrawal from the study			
Withdrawal by subject	7 (0.6)		

Table 4. Disposition of All Randomized Subjects – Phase 2/3 Subjects 12 Through 15 Years of Age

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1134) n[b] (%)	Placebo (N[a]=1130) n[b] (%)	Total (N[a]=2264) n[b] (%)
Withdrawal by parent/guardian	7 (0.6)		
Lost to follow-up	6 (0.5)		
Protocol deviation	1 (0.1)		
No longer meets eligibility criteria	1 (0.1)		
Other	23 (2.0)		
Originally randomized to placebo		1108 (98.1)	
Withdrawn from the study after unblinding and before Dose 3		47 (4.2)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		1010 (89.4)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		992 (87.8)	
Discontinued from open-label vaccination period[d]		5 (0.4)	
Reason for discontinuation from open-label vaccination period			
Protocol deviation		4 (0.4)	
Withdrawal by subject		1 (0.1)	
Completed 1-month post–Dose 4 visit		933 (82.6)	
Withdrawn from the study		6 (0.5)	
Withdrawn after Dose 3 and before Dose 4		5 (0.4)	
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit		0	
Withdrawn after 1-month post–Dose 4 visit		1 (0.1)	
Reason for withdrawal from the study			
Withdrawal by subject		3 (0.3)	
Lost to follow-up		2 (0.2)	
Protocol deviation		1 (0.1)	

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 visit.
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]) visit.
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10.2. Protocol Deviations – Participants 12 Through 15 Years of Age

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

Appendix 16.2.2 lists important PDs in all Phase 3 participants 12 through 15 years of age that may have significantly impacted the completeness, accuracy, and/or reliability of the study data or that may have significantly affected a participant's rights, safety, or well-being.

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

10.3. Vaccine Administration and Timing – Participants 12 Through 15 Years of Age

All adolescent participants who received Doses 1 and 2 were administered study intervention as randomized. Three (0.3%) participants in the BNT162b2 group and 1 (0.1%) participant in the placebo group were not vaccinated with any study intervention (Table 5).

After unblinding, 89.4% of original adolescent placebo participants received Dose 3 (first dose of BNT162b2 30 µg) and 87.7% received Dose 4 (second dose of BNT162b2 30 µg) at the time of the data cutoff date.

The majority of participants received Dose 2 between 21 to 27 days after Dose 1 in the BNT162b2 (65.0%) and placebo (64.5%) groups (Table 6). After unblinding, most original placebo participants received Dose 4 (second dose of BNT162b2 30 µg) between 14 to 20 (23.4%) days and 21 to 27 (61.2%) days after Dose 3.

Table 5. Vaccine as Administered – Phase 2/3 Subjects 12 Through 15 Years of Age – All Randomized Subjects

Vaccine (as Administered)	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=1134) n[b] (%)	Placebo (N[a]=1130) n[b] (%)
Vaccinated	1131 (99.7)	1129 (99.9)
Not vaccinated	3 (0.3)	1 (0.1)
Dose 1		
BNT162b2 (30 µg)	1131 (99.7)	0
Placebo	0	1129 (99.9)
Dose 2		

Table 5. Vaccine as Administered – Phase 2/3 Subjects 12 Through 15 Years of Age – All Randomized Subjects

Vaccine (as Administered)	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=1134) n[b] (%)	Placebo (N[a]=1130) n[b] (%)
BNT162b2 (30 µg)	1128 (99.5)	0
Placebo	0	1119 (99.0)
Dose 3		
First dose BNT162b2 (30 µg)		1010 (89.4)
Dose 4		
Second dose BNT162b2 (30 µg)		992 (87.8)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/advx s002 adm1 ped6

Table 6. Vaccine Administration Timing – Phase 2/3 Subjects 12 Through 15 Years of Age – All Randomized Subjects

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=1134) n[b] (%)	Placebo (N[a]=1130) n[b] (%)
Randomized	1134 (100.0)	1130 (100.0)
Not vaccinated	3 (0.3)	1 (0.1)
Dose 1	1131 (99.7)	1129 (99.9)
Dose 2[c]	1128 (99.5)	1119 (99.0)
Protocol defined window		
<19 Days	2 (0.2)	1 (0.1)
19-23 Days[d]	1073 (94.6)	1065 (94.2)
>23 Days	53 (4.7)	53 (4.7)
Weekly Intervals		
<14 Days	0	0
14-20 Days	358 (31.6)	364 (32.2)
21-27 Days	737 (65.0)	729 (64.5)
28-34 Days	23 (2.0)	15 (1.3)

Table 6. Vaccine Administration Timing – Phase 2/3 Subjects 12 Through 15 Years of Age – All Randomized Subjects

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=1134) n[b] (%)	Placebo (N[a]=1130) n[b] (%)
35-41 Days	4 (0.4)	4 (0.4)
42-48 Days	1 (0.1)	1 (0.1)
49-55 Days	1 (0.1)	3 (0.3)
>55 Days	4 (0.4)	3 (0.3)
Dose 3 (first dose of BNT162b2 [30 µg])		1010 (89.4)
Dose 4 (second dose of BNT162b2 [30 µg])[e]		992 (87.8)
Protocol defined window		
<19 Days		6 (0.5)
19-23 Days[d]		905 (80.1)
>23 Days		81 (7.2)
Weekly Intervals		
<14 Days		0
14-20 Days		264 (23.4)
21-27 Days		691 (61.2)
28-34 Days		26 (2.3)
35-41 Days		5 (0.4)
42-48 Days		3 (0.3)
49-55 Days		2 (0.2)
>55 Days		1 (0.1)

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. Protocol-specified time frame.
e. Days calculated since Dose 3.
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(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/advx s002 time1 ped6

10.4. Data Sets Analyzed – Participants 12 Through 15 Years of Age

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

The safety population of adolescent participants included 1131 participants in the BNT162b2 group and 1129 participants in the placebo group (Table 7). Four participants were excluded from the safety population because they did not receive any study intervention.

Table 7. Safety Population – Phase 2/3 Subjects 12 Through 15 Years of Age

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
Randomized[b]			2264
Vaccinated	1131	1129	2260 (99.8)
Safety population	1131	1129	2260 (99.8)
Excluded from safety population			4 (0.2)
Reason for exclusion			
Subject did not receive study vaccine			4 (0.2)

a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
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(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/adsl s003 saf1 ped6

During the blinded placebo-controlled follow-up period, median follow-up time for adolescent participants was 4.4 months. There were 634 (56.1%) and 629 (55.7%) of participants in the BNT162b2 and placebo groups, respectively, who had follow-up time between ≥4 months to <6 months after Dose 2 (Table 8). From Dose 2 to the cutoff date, 740 (65.4%) of participants in the BNT162b2 group had a total follow-up time between ≥8 to <10 months, which was composed of blinded and unblinded exposure. There were few participants (18 total) with follow-up time of <6 months, as most adolescent participants 12-15 years of age should have had ≥6 months of follow-up by the data cutoff date (02 September 2021), and also corresponding with the number of participants who withdrew from the study (Table 4).

For original adolescent placebo recipients who received at least the first dose of BNT162b2, median follow-up time was 3.8 months, and 65.0% of these participants had follow-up time between ≥2 months to <4 months after Dose 1 of BNT162b2 (Table 9).

Table 8. Follow-up Time After Dose 2 – Phase 2/3 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] (%)

Table 8. Follow-up Time After Dose 2 – Phase 2/3 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] (%)
Original blinded placebo-controlled follow-up period			
<2 Months	45 (4.0)	62 (5.5)	107 (4.7)
≥2-<4 Months	300 (26.5)	294 (26.0)	594 (26.3)
≥4-<6 Months	634 (56.1)	629 (55.7)	1263 (55.9)
≥6 Months	152 (13.4)	144 (12.8)	296 (13.1)
Mean (SD)	4.5 (1.24)	4.4 (1.27)	4.4 (1.26)
Median	4.4	4.4	4.4
Min, max	(0.0, 10.8)	(0.0, 9.1)	(0.0, 10.8)
Total follow-up period from Dose 2 to cutoff date			
<2 Months	8 (0.7)		
≥2-<4 Months	0		
≥4-<6 Months	10 (0.9)		
≥6-<8 Months	326 (28.8)		
≥8-<10 Months	740 (65.4)		
≥10 Months	47 (4.2)		
Mean (SD)	8.3 (1.03)		
Median	8.4		
Min, max	(0.0, 10.9)		

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adsl_fu_d21_ped6

Table 9. Follow-up Time After Dose 1 of BNT162b2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received Placebo) – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=1010) n[b] (%)
Open-label follow-up period	
<2 Months	66 (6.5)
≥2-<4 Months	656 (65.0)
≥4-<6 Months	228 (22.6)
≥6 Months	60 (5.9)
Mean (SD)	3.8 (1.09)
Median	3.8
Min, max	(0.1, 8.6)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adsl_fu_d11_ped6

10.4.2. Efficacy Populations – Updated Analysis – Participants 12 Through 15 Years of Age

The proportions of participants included in the updated efficacy populations were similar in the BNT162b2 and placebo groups (Table 10). Most participants excluded from the evaluable efficacy population were because they did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

Table 10. Efficacy Populations – Subjects 12 Through 15 Years of Age – Blinded Placebo-Controlled Follow-up Period

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	1134 (100.0)	1130 (100.0)	2264 (100.0)
Dose 1 all-available efficacy population	1131 (99.7)	1129 (99.9)	2260 (99.8)

Table 10. Efficacy Populations – Subjects 12 Through 15 Years of Age – Blinded Placebo-Controlled Follow-up Period

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Subjects without evidence of infection before Dose 1	1083 (95.5)	1078 (95.4)	2161 (95.5)
Subjects excluded from Dose 1 all-available efficacy population	3 (0.3)	1 (0.1)	4 (0.2)
Reason for exclusion[c]			
Did not receive at least 1 vaccination	3 (0.3)	1 (0.1)	4 (0.2)
Dose 2 all-available efficacy population	1123 (99.0)	1117 (98.8)	2240 (98.9)
Subjects without evidence of infection prior to 7 days after Dose 2	1061 (93.6)	1037 (91.8)	2098 (92.7)
Subjects excluded from Dose 2 all-available efficacy population	11 (1.0)	13 (1.2)	24 (1.1)
Reason for exclusion[c]			
Did not receive 2 vaccinations	10 (0.9)	13 (1.2)	23 (1.0)
Unblinded prior to 7 days after Dose 2	1 (0.1)	0	1 (0.0)
Evaluable efficacy (7 days) population	1119 (98.7)	1109 (98.1)	2228 (98.4)
Subjects without evidence of infection prior to 7 days after Dose 2	1057 (93.2)	1030 (91.2)	2087 (92.2)
Subjects excluded from evaluable efficacy (7 days) population	15 (1.3)	21 (1.9)	36 (1.6)
Reason for exclusion[c]			
Randomized but did not meet all eligibility criteria	1 (0.1)	1 (0.1)	2 (0.1)
Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	14 (1.2)	19 (1.7)	33 (1.5)
Unblinded prior to 7 days after Dose 2	1 (0.1)	0	1 (0.0)
Had other important protocol deviations on or prior to 7 days after Dose 2	0	3 (0.3)	3 (0.1)

a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.
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(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adsl_eff_pop_peds

10.5. Demographic and Other Baseline Characteristics – Participants 12 Through 15 Years of Age

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

10.5.1.1. Overall

Demographic characteristics for adolescents (12-15 years of age) were similar in the BNT162b2 and placebo groups in the safety population, and all adolescents were enrolled at

sites in the United States (Table 11). Most adolescent participants in the BNT162b2 group were White (85.8%), with 4.6% Black or African American participants and 6.4% Asian participants, and other racial groups were ≤2.1%. 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 of this age group (based on age- and sex-specific BMI) made up 11.3% (placebo group) to 12.6% (BNT162b2 group).

Table 11. Demographic Characteristics – Phase 2/3 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] (%)
Sex			
Male	567 (50.1)	585 (51.8)	1152 (51.0)
Female	564 (49.9)	544 (48.2)	1108 (49.0)
Race			
White	970 (85.8)	962 (85.2)	1932 (85.5)
Black or African American	52 (4.6)	57 (5.0)	109 (4.8)
All others	109 (9.6)	110 (9.7)	219 (9.7)
American Indian or Alaska Native	4 (0.4)	3 (0.3)	7 (0.3)
Asian	72 (6.4)	71 (6.3)	143 (6.3)
Native Hawaiian or other Pacific Islander	3 (0.3)	0	3 (0.1)
Multiracial	24 (2.1)	29 (2.6)	53 (2.3)
Not reported	6 (0.5)	7 (0.6)	13 (0.6)
Racial designation			
Japanese	5 (0.4)	2 (0.2)	7 (0.3)
Ethnicity			
Hispanic/Latino	132 (11.7)	130 (11.5)	262 (11.6)
Non-Hispanic/non-Latino	997 (88.2)	996 (88.2)	1993 (88.2)
Not reported	2 (0.2)	3 (0.3)	5 (0.2)
Country			
USA	1131 (100.0)	1129 (100.0)	2260 (100.0)
Baseline SARS-CoV-2 status			
Positive[c]	46 (4.1)	50 (4.4)	96 (4.2)
Negative[d]	1083 (95.8)	1078 (95.5)	2161 (95.6)
Missing	2 (0.2)	1 (0.1)	3 (0.1)
Comorbidities[e]			
Yes	249 (22.0)	242 (21.4)	491 (21.7)

Table 11. Demographic Characteristics – Phase 2/3 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] (%)
No	882 (78.0)	887 (78.6)	1769 (78.3)
Obese[f]			
Yes	143 (12.6)	128 (11.3)	271 (12.0)
No	988 (87.4)	1001 (88.7)	1989 (88.0)
Age at vaccination (years)			
Mean (SD)	13.6 (1.11)	13.6 (1.11)	13.6 (1.11)
Median	14.0	14.0	14.0
Min, max	(12, 15)	(12, 15)	(12, 15)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
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. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥95th percentile.
f. Obese is defined as BMI ≥95th percentile from the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html charts/bmiagerev htm.
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(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adsl_s005_all1_ped6_saf

Overall, there were 96 (4.2%) and 2161 (95.6%) participants who were baseline SARs-CoV-2 positive and negative, respectively (Table 11, and Supplemental Tables 14.1 and 14.2). Considering the baseline positive subgroup had fewer participants than the negative subgroup overall, there were no clinically meaningful differences in demographics in the 2 vaccine groups by SARS-CoV-2 status.

Adolescent participants had a diverse medical history profile consistent with that of individuals in the general population in the same age group (Supplemental Table 14.3). For adolescents in the BNT162b2 group, conditions in the immune system disorders (399 [35.3%]; of which 241 [21.3%] were seasonal allergy); psychiatric disorders (293 [25.9%], with frequently reported PTs of attention deficit hyperactivity disorder (182 [16.1%]), anxiety (107 [9.5%]), and depression (51 [4.5%]); respiratory, thoracic, and mediastinal disorders (179 [15.8%]); and skin and subcutaneous tissue disorders (170 [15.0%]) SOCs were most frequently reported.

There were 123 (10.9%) and 136 (12.0%) participants in the BNT162b2 and placebo groups, respectively, who had any comorbidity (per the Charlson comorbidity index) (Supplemental Table 14.4), which was mostly chronic pulmonary disease (119 [10.5%] and 127 [11.2%] participants, respectively).

10.5.1.2. Participants With At Least 6 Months Follow-Up Time – Original BNT162b2 Recipients 12 Through 15 Years of Age

Demographic characteristics for all original BNT162b2 adolescent recipients who had at least 6 months of follow-up time after Dose 2 are presented in Supplemental Table 14.5 and were similar to demographic characteristics in the BNT162b2 group overall (Table 11).

10.5.1.3. Original Placebo Recipients 12 Through 15 Years of Age Who Then Received BNT162b2

Demographic characteristics for all original placebo adolescent recipients who then received BNT162b2 later during the open-label follow-up period are presented in Supplemental Table 14.6 and were similar to demographic characteristics in the placebo group overall (Table 11).

10.5.2. Evaluable Efficacy (7 Days) Population – Blinded Placebo-Controlled Follow-up Period – Participants 12 Through 15 Years of Age

Demographics of participants in the evaluable efficacy (7 days) population for adolescent participants without evidence of infection prior to 7 days after Dose 2 were similar in the BNT162b2 and placebo groups (Supplemental Table 14.7). This analysis population had generally similar demographics compared with the safety population (refer to Section 10.5.1.1).

Demographic characteristics for the Dose 1 all-available efficacy population and for participants with or without evidence of infection prior to 7 days after Dose 2 (evaluable efficacy [7 days] population) were similar to those in the evaluable efficacy (7 days) population (Supplemental Tables 14.8 and 14.9, respectively).

10.6. Participant Compliance – Participants 12 Through 15 Years of Age

10.6.1. Immunogenicity Blood Samples

Refer to the adolescent interim C4591001 CSR dated 14 April 2021, Section 10.6.1 for details about immunogenicity blood samples taken in adolescent participants.

10.6.2. E-Diary

Refer to the adolescent interim C4591001 CSR dated 14 April 2021, Section 10.6.2 for details of transmission about e-diary data in adolescent participants.

10.7. Prior and Concomitant Vaccines, Medications, and Procedures – Participants 12 Through 15 Years of Age

A small percentage of adolescent participants in either group (≤2.8%) received a concomitant vaccine after Dose 1, and the most concomitant vaccine received was the influenza vaccine (Supplemental Table 14.10).

11. EFFICACY EVALUATION

11.1. Updated Efficacy Results – Participants 12 Through 15 Years of Age

In this CSR, updated descriptive efficacy analyses in adolescent participants 12 through 15 years of age were performed with all cases accrued during blinded placebo-controlled follow-up (through the cut-off date of 02 September 2021), including subgroup analyses, and for protocol-defined severe cases and CDC-defined severe cases.

11.1.1. Updated Analysis of Efficacy – Blinded Placebo-Controlled Follow-Up Period

11.1.1.1. Vaccine Efficacy From 7 Days After Dose 2 – Updated Analysis

Among adolescent participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 100.0% (2-sided 95% CI: 86.8%, 100.0%), with 0 and 28 cases in the BNT162b2 and placebo groups, respectively (Table 12).

The VE of BNT162b2 for the same efficacy endpoint based on the Dose 2 all-available efficacy population was 100.0% (2-sided 95% CI: 87.2%, 100.0%), with 0 and 29 cases in the BNT162b2 and placebo group, respectively (Supplemental Table 14.11).

Table 12. 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]=1057)		Placebo (N[a]=1030)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2	0	0.343 (1043)	28	0.322 (1019)	100.0	(86.8, 100.0)
≥7 days after Dose 2 to <2 Months after Dose 2	0	0.138 (1043)	15	0.133 (1019)	100.0	(73.2, 100.0)
≥2 Months after Dose 2 to <4 Months after Dose 2	0	0.148 (1008)	10	0.139 (957)	100.0	(58.0, 100.0)
≥4 Months after Dose 2	0	0.057 (723)	3	0.050 (682)	100.0	(-112.1, 100.0)

Table 12. 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]=1057)		Placebo (N[a]=1030)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
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 for the overall row and from start to the end of the range stated for each time interval.
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: 05OCT2021 (18:29) Source Data: adc19ef Table Generation: 05NOV2021 (10:58)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adc19ef_ve_cov_7pd2_peds_wo_eval

Among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 100.0% (2-sided 95% CI: 87.5%, 100.0%), with 0 and 30 cases in the BNT162b2 and placebo groups, respectively (Table 13). For the 2 additional cases in adolescent participants with evidence of SARS-CoV-2 infection (as compared with those without evidence of infection from Table 12), both participants were SARS-CoV-2 negative at baseline.

Table 13. 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]=1109)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2	0	0.362 (1098)	30	0.345 (1088)	100.0	(87.5, 100.0)
≥7 days after Dose 2 to <2 Months after Dose 2	0	0.146 (1098)	17	0.142 (1088)	100.0	(76.4, 100.0)
≥2 Months after Dose 2 to <4 Months after Dose 2	0	0.155 (1061)	10	0.148 (1022)	100.0	(57.4, 100.0)
≥4 Months after Dose 2	0	0.061 (767)	3	0.055 (726)	100.0	(-117.8, 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 for the overall row and from start to the end of the range stated for each time interval.
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: 05OCT2021 (18:29) Source Data: adc19ef Table Generation: 05NOV2021 (10:58)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adc19ef ve cov 7pd2 peds eval

11.1.1.1.1. Subgroup Analyses

In the evaluable efficacy (7 days) population, among participants without and with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE was 100.0% for all subgroups (Table 14 and Supplemental Table 14.12, respectively).

Table 14. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – 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]=1057)		Placebo (N[a]=1030)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	0	0.343 (1043)	28	0.322 (1019)	100.0	(86.8, 100.0)
Sex						
Male	0	0.175 (524)	16	0.165 (526)	100.0	(75.5, 100.0)
Female	0	0.169 (519)	12	0.157 (493)	100.0	(66.5, 100.0)
Race						
White	0	0.293 (898)	26	0.272 (867)	100.0	(85.8, 100.0)
Black or African American	0	0.017 (41)	2	0.018 (49)	100.0	(-470.9, 100.0)
Ethnicity						
Hispanic/Latino	0	0.042 (119)	7	0.036 (113)	100.0	(41.2, 100.0)
Non-Hispanic/non-Latino	0	0.300 (922)	21	0.285 (903)	100.0	(81.7, 100.0)
Country						
USA	0	0.343 (1043)	28	0.322 (1019)	100.0	(86.8, 100.0)
Comorbidities[f]						
Yes	0	0.078 (230)	9	0.068 (213)	100.0	(55.5, 100.0)
No	0	0.266 (813)	19	0.254 (806)	100.0	(79.5, 100.0)
Obese[g]						
Yes	0	0.046 (134)	6	0.036 (110)	100.0	(33.9, 100.0)
No	0	0.298 (909)	22	0.287 (909)	100.0	(82.4, 100.0)

Table 14. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – 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]=1057)		Placebo (N[a]=1030)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2, and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2) were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Comorbidities are defined as having at least one of the Charlson comorbidity index category or obesity (BMI ≥95th percentile).
g. Obese is defined as BMI ≥95th percentile from the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html charts/bmiagerev htm.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (17:31) Source Data: adc19ef Table Generation: 08DEC2021 (16:11)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adc19ef ve cov 7pd2 p wo sg eval

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

All reports of COVID-19 with onset at any time after Dose 1 are accounted for in Table 15, which provides a summary of VE for all adolescent participants in the Dose 1 all-available efficacy (modified intention-to-treat) population adjusted for exposure, regardless of evidence of infection before or during the vaccination regimen. Among these participants, the estimated VE against confirmed COVID-19 occurring after Dose 1 was 94.0% (2-sided 95% CI: 81.3%, 98.8%), with 3 and 48 cases of COVID-19 in the BNT162b2 and placebo groups, respectively. All 3 cases in the BNT162b2 group occurred <11 days after Dose 1 and in participants who had baseline SARS-CoV-2 negative status, and represented all cases reported in this group at any time.

The observed VE for BNT162b2 in adolescents in the Dose 1 all-available efficacy 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 ≥4 months after Dose 2.

Table 15. 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	0.450 (1109)	48	0.434 (1114)	94.0	(81.3, 98.8)
After Dose 1 to before Dose 2	3	0.065 (1109)	12	0.065 (1114)	75.1	(7.6, 95.5)
After Dose 1 to <11 days after Dose 1	3	0.033 (1109)	4	0.033 (1114)	24.7	(-345.0, 89.0)
≥11 Days after Dose 1 to before Dose 2	0	0.032 (1106)	8	0.031 (1110)	100.0	(42.0, 100.0)
Dose 2 to 7 days after Dose 2	0	0.021 (1103)	5	0.021 (1100)	100.0	(-8.7, 100.0)
≥7 Days after Dose 2	0	0.364 (1102)	31	0.348 (1095)	100.0	(87.9, 100.0)
≥7 days after Dose 2 to <2 Months after Dose 2	0	0.146 (1102)	17	0.143 (1095)	100.0	(76.3, 100.0)
≥2 Months after Dose 2 to <4 Months after Dose 2	0	0.156 (1065)	10	0.149 (1029)	100.0	(57.3, 100.0)
≥4 Months after Dose 2	0	0.062 (770)	4	0.056 (732)	100.0	(-37.7, 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 for the overall row and from start to the end of the range stated for each time interval.
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.
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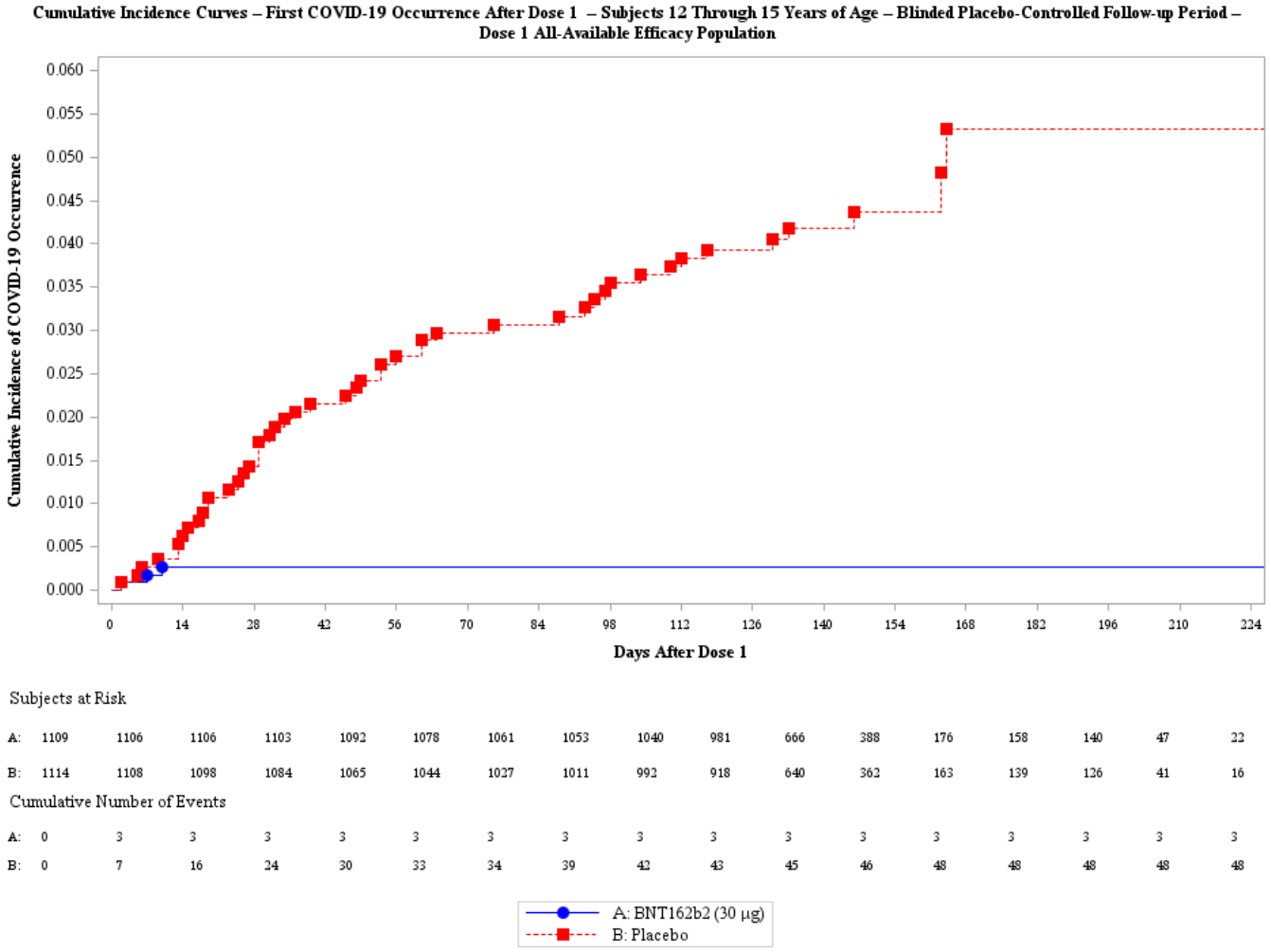
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adc19ef_ve_cov_pd1_st_peds_aai

The early onset of protection is readily apparent in Figure 1, which displays cumulative incidence for the first COVID-19 occurrence after Dose 1 among all vaccinated participants based on Dose 1 all-available efficacy (modified intention-to-treat) population. Disease onset appears to track together for BNT162b2 and placebo until approximately 11 days after Dose 1 (consistent with the data shown in Table 15), at which point the curves diverge, with cases steadily accumulating in the placebo group, while remaining flat with no more cases in the BNT162b2 group.

Figure 1. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1 – Subjects 12 Through 15 Years of Age – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population



PFIZER CONFIDENTIAL SDTM Creation: 30SEP2021 (10:35) Source Data: adc19ef Table Generation: 08NOV2021 (15:26)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adc19ef_f001_km_d1_peds_aai

11.1.1.2.1. Subgroup Analyses

Additionally, in subgroup analyses for VE based on the Dose 1 all-available efficacy (modified intention-to-treat) population (Supplemental Table 14.13), the observed subgroup VEs based on the Dose 1 all-available population were generally similar to those based on the evaluable efficacy population except for a few subgroups that the number of participants and cases were too small to provide robust estimates. The observed VEs for all subgroups were ≥88.7% except for one subgroup (race, all others) with 1 case in each group: American Indian or Alaska native in placebo and Asian in BNT162b2. Due to the small number of participants, the data must be interpreted with caution.

11.1.2. Updated Analysis of Severe COVID-19 Cases

No severe COVID-19 cases (per protocol definition or CDC criteria) were reported in participants 12-15 years of age as of the data cutoff date (02 September 2021) (Appendix 16.2.8.1.1).

11.1.2.1. COVID-19 Narratives – Updated Analysis

One participant in the placebo group had multiple positive COVID-19 NAAT results (Appendix 16.2.8.4.1). The narrative for this participant is provided in Section 14 COVID-19 Case (Severe and/or Multiple).

11.1.3. Variants of Concern

Among the 30 placebo participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen and had COVID-19 cases, most variants sequenced were neither VOI nor VOC except for the B.1.1.7 (Alpha) (Table 17), which was found in 23.3% of placebo participants (Table 16). There were no cases belonging to the Beta, Gamma, Delta, Lambda, or Mu variants (Table 17). Importantly, all of the cases in the efficacy analyses occurred between 02 November 2020 to 19 May 2021, which is before the Delta surge in the US. (Appendix 16.2.8.1.2).

Table 16. Summary of SARS-CoV-2 Variants for the 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]=0)	Placebo (N[a]=30)	Total (N[a]=30)
SARS-CoV-2 Lineage[b] (WHO Classification)	n[c](%)	n[c](%)	n[c](%)
B.1	0	1 (3.3)	1 (3.3)

Table 16. Summary of SARS-CoV-2 Variants for the 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]=0)	Placebo (N[a]=30)	Total (N[a]=30)
SARS-CoV-2 Lineage[b] (WHO Classification)	n[c](%)	n[c](%)	n[c](%)
B.1.1.222	0	1 (3.3)	1 (3.3)
B.1.1.29	0	1 (3.3)	1 (3.3)
B.1.1.519	0	1 (3.3)	1 (3.3)
B.1.1.7 (Alpha)	0	7 (23.3)	7 (23.3)
B.1.142	0	1 (3.3)	1 (3.3)
B.1.2	0	10 (33.3)	10 (33.3)
B.1.243	0	1 (3.3)	1 (3.3)
B.1.361	0	1 (3.3)	1 (3.3)
B.1.369	0	1 (3.3)	1 (3.3)
B.1.400	0	1 (3.3)	1 (3.3)
B.1.427	0	2 (6.7)	2 (6.7)
B.1.526	0	1 (3.3)	1 (3.3)
Unknown[d]	0	1 (3.3)	1 (3.3)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of subjects with first COVID-19 occurrence. This value is the denominator for the percentage calculations.
b. Based on PANGO lineages (cov-lineages.org).
c. n = Number of subjects with the specified characteristic.
d. Include indeterminate result and not quantifiable (QNS) samples.
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(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adxb_seq_var_cov_7pd2_peds_eval

Table 17. Summary of SARS-CoV-2 Variants of Concern or Variants of Interest for the 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)		
SARS-CoV-2 Lineage[b] (WHO Classification)	BNT162b2 (30 µg) (N[a]=0) n[c](%)	Placebo (N[a]=30) n[c](%)	Total (N[a]=30) n[c](%)
B.1.1.7 (Alpha)	0	7 (23.3)	7 (23.3)
B.1.351 (Beta)	0	0	0
P.1 (Gamma)	0	0	0
B.1.617.2 (Delta)	0	0	0
C.37 (Lambda)	0	0	0
B.1.621 (Mu)	0	0	0
Other	0	22 (73.3)	22 (73.3)
Unknown[d]	0	1 (3.3)	1 (3.3)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of subjects with first COVID-19 occurrence. This value is the denominator for the percentage calculations.
b. Based on PANGO lineages (cov-lineages.org).
c. n = Number of subjects with the specified characteristic.
d. Include indeterminate result and not quantifiable (QNS) samples.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2021 (15:56) Source Data: adxb Table Generation: 04NOV2021 (14:59)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adxb_seq_cov_7pd2_peds_eval

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

- In the updated descriptive efficacy analysis (data cutoff date 02 September 2021), among participants in the evaluable efficacy population without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 100% (2-sided 95% CI: 86.8%, 100%), with 0 cases in the BNT162b2 group and 28 cases in the placebo group. Among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 100% (2-sided 95% CI: 87.5%, 100%), with 0 and 30 cases in the BNT162b2 and placebo groups, respectively. For the 2 additional cases in adolescent participants with evidence of SARS-CoV-2 infection as compared with those without evidence of infection, both participants were SARS-CoV-2 negative at baseline.

- Among participants without and with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen (evaluable efficacy population), VE against COVID-19 occurring at least 7 days after Dose 2 was evaluated for demographic and risk subgroups, and the estimated VE was 100.0% for all subgroups.

- From the analysis of all cases of confirmed COVID-19 based on the all-available (modified intention-to-treat) population (regardless of evidence of infection before or during the vaccination regimen), the estimated VE against all cases occurring at any time after Dose 1 was 94.0% (2-sided 95% CI: 81.3%, 98.8%), with 3 cases in the BNT162b2 group (all occurring within <11 days after Dose 1 and in participants who had baseline SARS-CoV-2 negative status) and 48 cases in the placebo group.

- No severe COVID-19 cases (per protocol definition or CDC criteria) were reported in participants 12-15 years of age as of the data cutoff date (02 September 2021).

- Most variants sequenced were neither VOI nor VOC except for the B.1.1.7 (Alpha) found in 23.3% of placebo participants. All of the cases in the efficacy analyses occurred between 02 November 2020 to 19 May 2021, which is before the Delta surge in the US.

12. SAFETY EVALUATION

Refer to the C4591001 6-Month Update Interim CSR, dated 29 April 2021, Sections 12.1 and 12.2, for details of safety evaluations previously conducted in Phase 1and Phase 2/3 of the study (as previously submitted).

12.1. Local Reactions and Systemic Events – Participants 12 Through 15 Years of Age

There are no new reactogenicity data presented in this report since the adolescent interim CSR, dated 14 April 2021.

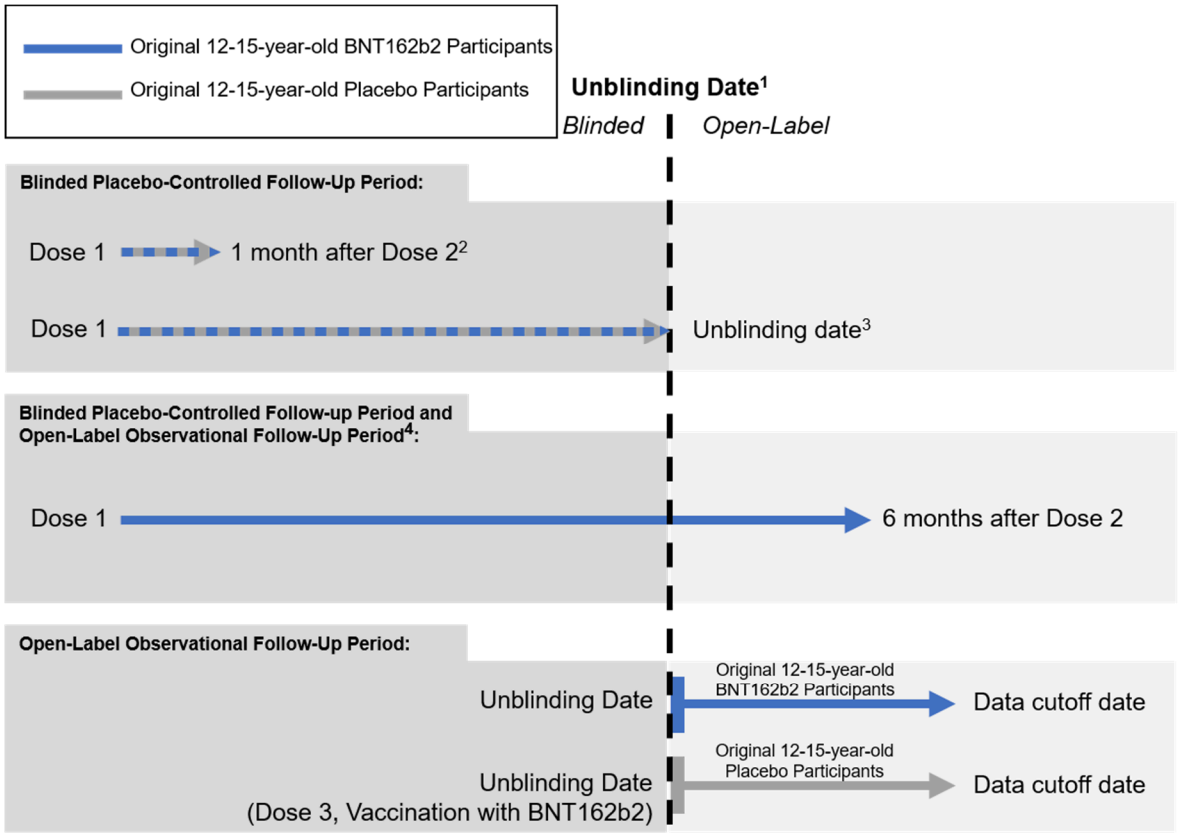
The majority of reactogenicity events previously reported in adolescent participants were mild or moderate in severity and short-lived after dosing (ie, median onset mostly between 1-3 days after dosing and resolution within 1-3 days after onset) (full details in Sections 12.1.1 and 12.1.2 of the adolescent interim C4591001 CSR dated 14 April 2021).

12.2. Adverse Events – Participants 12 Through 15 Years of Age

AE safety data are from either the blinded placebo-controlled follow-up period, the open-label observational follow-up period, or both. The time periods and safety analysis groups are presented below and in Figure 2. AEs reported from Dose 1 to 1 month after Dose 2 during the blinded placebo-controlled follow-up period were previously reported in the adolescent interim CSR, dated 14 April 2021. For each time period, overall safety will be presented in addition to new AEs that were reported since the EUA snapshot occurred (based on a data cutoff date of 13 March 2021), in the following order:

- Blinded placebo-controlled follow-up period from Dose 1 to the unblinding date, including separate summaries for new AEs that were reported after the EUA snapshot date (Section 12.2.1)
- Open-label follow-up period – original BNT162b2 recipients (Section 12.2.2)
- Blinded placebo-controlled and open-label follow-up periods from Dose 1 to 6 months after Dose 2 – original BNT162b2 participants, including separate summaries for new AEs that were reported after the EUA snapshot date (Section 12.2.3)
- Open-label follow-up period – original placebo recipients who then received at least 1 dose of BNT162b2 after unblinding (Section 12.2.4)

Figure 2 Phase 2/3 Safety Analyses of Adolescent Participants: Time Periods and Analysis Groups



[1] Will vary by participant. Adverse event data analyzed from Dose 1 to unblinding date or from unblinding date to data cutoff date are reported as incidence rates adjusted for exposure time.
[2] Data previously reported in the adolescent interim CSR dated 14 April 2021.
[3] Up to ~6 months after Dose 2.
[4] Cumulative BNT162b2 follow-up to at least 6 months after Dose 2.

12.2.1. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date – Participants 12 Through 15 Years of Age

12.2.1.1. Summary of Adverse Events – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date – Participants 12 Through 15 Years of Age

An overview of AE IRs adjusted for exposure time from Dose 1 to the unblinding date for adolescent participants during the blinded placebo-controlled follow-up period is presented in Table 18, and total exposure time in 100 PY was similar in the BNT162b2 and placebo groups (4.6 vs 4.5 per 100 PY, respectively). Hence, frequencies are summarized in the safety results.

The percentage of adolescent participants with any AE was similar in the BNT162b2 and placebo groups (8.4% and 10.0%, respectively). Severe AEs, SAEs, and AEs leading to withdrawal were reported by ≤1.1%, ≤0.9%, and ≤0.1%, respectively, in both groups. All reported SAEs were assessed by the investigator as not related to study intervention. Withdrawals due to related AEs were reported in 1 adolescent participant in the BNT162b2 group (pyrexia occurring 1 day after Dose 1; previously reported in adolescent interim CSR dated 14 April 2021, Section 12.3.2.4.1), and none in the placebo group. There were no deaths.

Table 18. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1131, TE[b]=4.6)			Placebo (N[a]=1129, TE[b]=4.5)		
Adverse Event	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	95 (8.4)	20.8	(16.8, 25.4)	113 (10.0)	25.1	(20.7, 30.1)
Related[f]	36 (3.2)	7.9	(5.5, 10.9)	24 (2.1)	5.3	(3.4, 7.9)
Severe	13 (1.1)	2.8	(1.5, 4.9)	5 (0.4)	1.1	(0.4, 2.6)
Life-threatening	2 (0.2)	0.4	(0.1, 1.6)	1 (0.1)	0.2	(0.0, 1.2)
Any serious adverse event	10 (0.9)	2.2	(1.0, 4.0)	2 (0.2)	0.4	(0.1, 1.6)
Related[f]	0	0.0	(0.0, 0.8)	0	0.0	(0.0, 0.8)
Severe	7 (0.6)	1.5	(0.6, 3.2)	1 (0.1)	0.2	(0.0, 1.2)
Life-threatening	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)
Any nonserious adverse event	89 (7.9)	19.5	(15.6, 24.0)	111 (9.8)	24.6	(20.3, 29.6)
Related[f]	36 (3.2)	7.9	(5.5, 10.9)	24 (2.1)	5.3	(3.4, 7.9)
Severe	6 (0.5)	1.3	(0.5, 2.9)	4 (0.4)	0.9	(0.2, 2.3)
Life-threatening	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Any adverse event leading to withdrawal	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)

Table 18. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1131, TE[b]=4.6)			Placebo (N[a]=1129, TE[b]=4.5)		
Adverse Event	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Related[f]	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Severe	0	0.0	(0.0, 0.8)	0	0.0	(0.0, 0.8)
Life-threatening	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Death	0	0.0	(0.0, 0.8)	0	0.0	(0.0, 0.8)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:22)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s092 all unb1 ped6

12.2.1.1.1. Subgroup Analyses

Total exposure time in 100 PY was similar in the BNT162b2 and placebo groups for each subgroup analysis. An overview of AEs from Dose 1 to the unblinding date by subgroup are presented in the following tables:

Baseline SARS-CoV-2 Status: Positive	Supplemental Table 14.14
Baseline SARS-CoV-2 Status: Negative	Supplemental Table 14.15
Ethnicity: Hispanic/Latino	Supplemental Table 14.16
Ethnicity: Non-Hispanic/Non-Latino	Supplemental Table 14.17
Race: White	Supplemental Table 14.18
Race: Black or African American	Supplemental Table 14.19
Race: All Others	Supplemental Table 14.20
Sex: Male	Supplemental Table 14.21
Sex: Female	Supplemental Table 14.22

There were 4 (8.7%) and 91 (8.4%) participants who were baseline SARS-CoV-2 positive and negative in the BNT162b2 group who reported at least 1 AE, respectively, and 4 (8.0%) and 109 (10.1%) participants who were baseline SARS-CoV-2 positive and negative in the placebo group who reported at least 1 AE, respectively (Supplemental Tables 14.14 and 14.15, respectively). The frequency of severe AEs, SAEs (all assessed as not related), or AEs leading to withdrawal in participants who were SARS-CoV-2 negative was 1.2%, 0.9%, and 0.1%, respectively (Supplemental Table 14.15), while there were no severe AEs, SAEs, or AEs leading to withdrawal in participants who were SARS-CoV-2 positive (Supplemental Table 14.14), supporting previous observations in this study that participants who are SARS-CoV-2 positive at baseline do not report AEs at a higher rate than those who are are negative at baseline (previously reported in 6-month update interim CSR, dated 29 April 2021).

The frequency of at least 1 AE reported in the BNT162b2 group was 6.8% in Hispanic/Latino and 8.6% in non-Hispanic/non-Latino participants (Supplemental Tables 14.16 and 14.17, respectively). The frequency of related AEs, severe AEs, SAEs (all not related), and AEs leading to withdrawal was similar in the Hispanic/Latino and Non-Hispanic/Non-Latino subgroups. Considering that the Hispanic/Latino subgroup (N=132) had fewer participants than the non-Hispanic/non-Latino subgroup (N=997) in the BNT162b2 group, the small numerical differences in these subgroups were not considered clinically meaningful.

The frequency of at least 1 AE reported in the BNT162b2 group was 5.8% to 8.6% across race subgroups (Supplemental Tables 14.18 to 14.20). Related AEs were reported in the BNT162b2 group across race subgroups at frequencies of 1.9% to 5.5%. Low incidences of severe and serious AEs were reported in the BNT162b2 groups across race subgroups (≤1.9%). Considering that some race subgroups had fewer participants than others (within the BNT162b2 groups: White N=970, Black or African American N = 52, and 'All Others' N=109), the small numerical differences in these subgroups were not considered clinically meaningful.

The frequency of at least 1 AE reported in the BNT162b2 group for males and females was 7.4% and 9.4%, respectively, and the corresponding frequency in the placebo group was 9.7% and 10.3%, respectively (Supplemental Tables 14.21 and 14.22, respectively). In the BNT162b2 group, frequencies of at least 1 SAE in male and female participants were 0.5% and 1.2% in the BNT162b2 group and 0.3% and none in the placebo group, respectively.

12.2.1.2. Adverse Events by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date – Participants 12 Through 15 Years of Age

AEs from Dose 1 to the unblinding date during the blinded placebo-controlled follow-up period are presented in Table 19. AEs reported in adolescents were similar in the BNT162b2 and placebo groups (8.4% and 10.0%, respectively). The most frequently reported AEs in the BNT162b2 group included lymphadenopathy (9 [0.8%]), injection site pain (8 [0.7%]), fatigue (8 [0.7%]), pyrexia (6 [0.5%]), depression (6 [0.5%]), nausea (5 [0.4%]), and

headache (5 [0.4%]). Most of these AEs were previously reported in the adolescent interim CSR, dated 14 April 2021.

The number of participants with psychiatric disorder AEs were comparable in the 2 groups, (17 [1.5%] in BNT162b2 group vs. 13 [1.2%] in placebo group) (Table 19). There were 4 participants who were hospitalized with the event of suicidal ideation (3 of these were new after the EUA snapshot (Table 21) and are discussed in Section 12.3.2.1.2; the remaining case that was previously reported in the adolescent interim CSR, dated 14 April 2021 is discussed in Section 12.3.2.1). All participants were in the BNT162b2 group and had an ongoing past medical history of depression and/or anxiety (3 diagnosed within 2020 and 1 since 2018) (Appendix 16.2.5.4). Of these 4 participants, 3 had been taking selective serotonin reuptake inhibitors (fluoxetine or sertraline) for their ongoing condition. The fourth participant had their concomitant medication for attention deficit hyperactivity disorder changed from methylphenidate hydrochloride to demethylphenidate hydrochloride approximately 22 days before the event of suicidal ideation occurred.

A total of 9 participants reported depression: 6 [0.5%] in the BNT162b2 group and 3 [0.3%] in the placebo group (Table 19), (6 of these were new after the EUA snapshot; 4 in the BNT162b2 group and 2 in the placebo group [Table 21]). Of the 6 participants in the BNT162b2 group, 3 participants had a known past medical history of ongoing depression, and of the 4 newly diagnosed cases in the BNT162b2 group, 3 participants had an ongoing past medical history of attention deficit hyperactivity disorder and the depression for the remaining participant in this group was reported to be due to social events. Within the placebo group, 2 of the 3 participants were newly diagnosed with depression (Table 21 and Table 19, respectively).

The event of conversion disorder (BNT162b2 group) has been previously reported in the adolescent interim CSR dated 14 April 2021 Section 12.4.2.1.1 as an SAE of neuralgia and had been extensively investigated. Further follow-up since the adolescent interim CSR; the participant was continuing with physical therapy and had undergone further neurological examination and investigations including an MRI brain scan with and without contrast that was normal. There has been little change in her symptoms, and she continues to require treatment.

The 1 participant in the BNT162b2 group who reported a tic had an exacerbation of their known tic disorder (diagnosed since 2019) and was considered to be due to life stressors (as determined by the principal investigator). This event was previously reported in the adolescent interim CSR dated 14 April 2021.

Table 19. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1131, TE[b]=4.6)			Placebo (N[a]=1129, TE[b]=4.5)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	95 (8.4)	20.8	(16.8, 25.4)	113 (10.0)	25.1	(20.7, 30.1)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	9 (0.8)	2.0	(0.9, 3.7)	2 (0.2)	0.4	(0.1, 1.6)
Lymphadenopathy	9 (0.8)	2.0	(0.9, 3.7)	2 (0.2)	0.4	(0.1, 1.6)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Spine malformation	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
EAR AND LABYRINTH DISORDERS	1 (0.1)	0.2	(0.0, 1.2)	3 (0.3)	0.7	(0.1, 1.9)
Cerumen impaction	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Conductive deafness	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Ear pain	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)
EYE DISORDERS	2 (0.2)	0.4	(0.1, 1.6)	1 (0.1)	0.2	(0.0, 1.2)
Eye pain	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Eyelid rash	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Retinal haemorrhage	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
GASTROINTESTINAL DISORDERS	14 (1.2)	3.1	(1.7, 5.1)	8 (0.7)	1.8	(0.8, 3.5)
Abdominal pain	2 (0.2)	0.4	(0.1, 1.6)	1 (0.1)	0.2	(0.0, 1.2)
Aphthous ulcer	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Constipation	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Diarrhoea	3 (0.3)	0.7	(0.1, 1.9)	1 (0.1)	0.2	(0.0, 1.2)
Gastritis	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Lip swelling	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Mouth swelling	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Mouth ulceration	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Nausea	5 (0.4)	1.1	(0.4, 2.6)	3 (0.3)	0.7	(0.1, 1.9)
Oral mucosal blistering	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Rectal prolapse	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Tooth impacted	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Toothache	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Vomiting	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	17 (1.5)	3.7	(2.2, 6.0)	12 (1.1)	2.7	(1.4, 4.6)
Chills	2 (0.2)	0.4	(0.1, 1.6)	1 (0.1)	0.2	(0.0, 1.2)

Table 19. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1131, TE[b]=4.6)			Placebo (N[a]=1129, TE[b]=4.5)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Fatigue	8 (0.7)	1.7	(0.8, 3.4)	4 (0.4)	0.9	(0.2, 2.3)
Injection site pain	8 (0.7)	1.7	(0.8, 3.4)	8 (0.7)	1.8	(0.8, 3.5)
Injection site swelling	2 (0.2)	0.4	(0.1, 1.6)	0	0.0	(0.0, 0.8)
Nodule	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Oedema peripheral	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Peripheral swelling	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Pyrexia	6 (0.5)	1.3	(0.5, 2.9)	0	0.0	(0.0, 0.8)
Vessel puncture site pain	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
IMMUNE SYSTEM DISORDERS	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)
Food allergy	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Seasonal allergy	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
INFECTIONS AND INFESTATIONS	10 (0.9)	2.2	(1.0, 4.0)	9 (0.8)	2.0	(0.9, 3.8)
Anal abscess	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Appendicitis	0	0.0	(0.0, 0.8)	2 (0.2)	0.4	(0.1, 1.6)
Body tinea	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Candida infection	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Cellulitis	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Conjunctivitis	0	0.0	(0.0, 0.8)	2 (0.2)	0.4	(0.1, 1.6)
Ear infection	3 (0.3)	0.7	(0.1, 1.9)	0	0.0	(0.0, 0.8)
Focal peritonitis	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Infectious mononucleosis	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Otitis externa	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Otitis media	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Paronychia	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Pilonidal cyst	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)
Subcutaneous abscess	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Tinea capitis	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Vulval abscess	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Vulvovaginal mycotic infection	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	15 (1.3)	3.3	(1.8, 5.4)	25 (2.2)	5.5	(3.6, 8.2)
Accident	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)
Ankle fracture	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)

Table 19. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1131, TE[b]=4.6)			Placebo (N[a]=1129, TE[b]=4.5)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Bone contusion	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Clavicle fracture	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)
Concussion	3 (0.3)	0.7	(0.1, 1.9)	4 (0.4)	0.9	(0.2, 2.3)
Contusion	2 (0.2)	0.4	(0.1, 1.6)	2 (0.2)	0.4	(0.1, 1.6)
Fall	2 (0.2)	0.4	(0.1, 1.6)	5 (0.4)	1.1	(0.4, 2.6)
Femur fracture	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Foot fracture	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Hand fracture	1 (0.1)	0.2	(0.0, 1.2)	4 (0.4)	0.9	(0.2, 2.3)
Humerus fracture	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Ligament sprain	1 (0.1)	0.2	(0.0, 1.2)	4 (0.4)	0.9	(0.2, 2.3)
Lip injury	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Meniscus injury	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Muscle strain	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)
Patella fracture	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Procedural pain	2 (0.2)	0.4	(0.1, 1.6)	3 (0.3)	0.7	(0.1, 1.9)
Radius fracture	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Skin laceration	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Tibia fracture	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Tooth fracture	0	0.0	(0.0, 0.8)	2 (0.2)	0.4	(0.1, 1.6)
Upper limb fracture	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)
INVESTIGATIONS	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
SARS-CoV-2 antibody test positive	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	8 (0.7)	1.7	(0.8, 3.4)	14 (1.2)	3.1	(1.7, 5.2)
Arthralgia	2 (0.2)	0.4	(0.1, 1.6)	4 (0.4)	0.9	(0.2, 2.3)
Back pain	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Joint swelling	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Musculoskeletal chest pain	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)
Myalgia	3 (0.3)	0.7	(0.1, 1.9)	2 (0.2)	0.4	(0.1, 1.6)
Neck pain	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Osteochondrosis	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Pain in extremity	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Tendonitis	0	0.0	(0.0, 0.8)	4 (0.4)	0.9	(0.2, 2.3)

Table 19. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1131, TE[b]=4.6)			Placebo (N[a]=1129, TE[b]=4.5)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.1)	0.2	(0.0, 1.2)	3 (0.3)	0.7	(0.1, 1.9)
Fibroadenoma of breast	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Hair follicle tumour benign	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Melanocytic naevus	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Skin papilloma	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
NERVOUS SYSTEM DISORDERS	13 (1.1)	2.8	(1.5, 4.9)	13 (1.2)	2.9	(1.5, 4.9)
Dizziness	2 (0.2)	0.4	(0.1, 1.6)	1 (0.1)	0.2	(0.0, 1.2)
Headache	5 (0.4)	1.1	(0.4, 2.6)	7 (0.6)	1.6	(0.6, 3.2)
Migraine	3 (0.3)	0.7	(0.1, 1.9)	0	0.0	(0.0, 0.8)
Paraesthesia	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Presyncope	1 (0.1)	0.2	(0.0, 1.2)	4 (0.4)	0.9	(0.2, 2.3)
Syncope	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)
PSYCHIATRIC DISORDERS	17 (1.5)	3.7	(2.2, 6.0)	13 (1.2)	2.9	(1.5, 4.9)
Anxiety	4 (0.4)	0.9	(0.2, 2.2)	6 (0.5)	1.3	(0.5, 2.9)
Attention deficit hyperactivity disorder	2 (0.2)	0.4	(0.1, 1.6)	4 (0.4)	0.9	(0.2, 2.3)
Conversion disorder	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Depression	6 (0.5)	1.3	(0.5, 2.9)	3 (0.3)	0.7	(0.1, 1.9)
Disorientation	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Generalised anxiety disorder	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Obsessive-compulsive disorder	0	0.0	(0.0, 0.8)	2 (0.2)	0.4	(0.1, 1.6)
Panic attack	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Sleep terror	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Suicidal ideation	4 (0.4)	0.9	(0.2, 2.2)	0	0.0	(0.0, 0.8)
Tic	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
RENAL AND URINARY DISORDERS	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Dysuria	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Amenorrhoea	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (0.3)	0.7	(0.1, 1.9)	8 (0.7)	1.8	(0.8, 3.5)
Epistaxis	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)

Table 19. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1131, TE[b]=4.6)			Placebo (N[a]=1129, TE[b]=4.5)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Nasal congestion	2 (0.2)	0.4	(0.1, 1.6)	3 (0.3)	0.7	(0.1, 1.9)
Rhinorrhoea	2 (0.2)	0.4	(0.1, 1.6)	4 (0.4)	0.9	(0.2, 2.3)
Sneezing	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	9 (0.8)	2.0	(0.9, 3.7)	16 (1.4)	3.5	(2.0, 5.8)
Acne	2 (0.2)	0.4	(0.1, 1.6)	3 (0.3)	0.7	(0.1, 1.9)
Dermatitis contact	2 (0.2)	0.4	(0.1, 1.6)	1 (0.1)	0.2	(0.0, 1.2)
Eczema	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Pityriasis rosea	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Rash	3 (0.3)	0.7	(0.1, 1.9)	5 (0.4)	1.1	(0.4, 2.6)
Rash maculo-papular	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Seborrhoeic dermatitis	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Urticaria	2 (0.2)	0.4	(0.1, 1.6)	5 (0.4)	1.1	(0.4, 2.6)
SURGICAL AND MEDICAL PROCEDURES	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)
Wisdom teeth removal	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:21)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s131_all_unb1_ped6

12.2.1.2.1. Subgroup Analyses

AEs from Dose 1 to the unblinding date by SOC and PT and by subgroup are presented in the following tables:

Baseline SARS-CoV-2 Status: Positive — Supplemental Table 14.23

Baseline SARS-CoV-2 Status: Negative	Supplemental Table 14.24
Ethnicity: Hispanic/Latino	Supplemental Table 14.25
Ethnicity: Non-Hispanic/Non-Latino	Supplemental Table 14.26
Race: White	Supplemental Table 14.27
Race: Black or African American	Supplemental Table 14.28
Race: All Others	Supplemental Table 14.29
Sex: Male	Supplemental Table 14.30
Sex: Female	Supplemental Table 14.31

For the baseline SARS-CoV-2 positive and negative subgroups, AEs by SOC and PT were similar to those in the overall safety population (Supplemental Table 14.23 and 14.24, respectively). Considering that the positive subgroup (N=46) had fewer participants than the negative subgroup (N=1083) in the BNT162b2 group, differences in SOCs were considered not clinically meaningful, and there is no evidence that individuals who are positive at baseline report AEs at a higher frequency than those who are negative at baseline.

For the ethnicity subgroups, AEs by SOC and PT were similar to those in the overall safety population for Hispanic/Latino and non-Hispanic/non-Latino participants (Supplemental Tables 14.25 and 14.26, respectively). Considering that the Hispanic/Latino subgroup (N=132) had fewer participants than non-Hispanic/non-Latino subgroup (N=997) in the BNT162b2 group, differences in AEs by SOC and PT in these subgroups were not clinically meaningful.

For race subgroups, AEs by SOC and PT were similar to those in the overall safety population (Supplemental Tables 14.27 through 14.29). Considering that some race subgroups had fewer participants than others (within the BNT162b2 groups: White N=970, Black or African American N=52, and 'All Others' N=109), differences in AEs by SOC and PT in these subgroups were not clinically meaningful.

For sex subgroups, AEs by SOC and PT were similar to those in the overall safety population (Supplemental Tables 14.30 and 14.31, respectively). There was a slightly higher frequency of any event reported in the BNT162b2 group in female participants compared to males (53 [9.4%], 42 [7.4%] respectively), and of any SAEs 7 (1.2%) females, 3 (0.5%) males (Supplemental Tables 14.51 and 14.50, respectively). Within the placebo group there were 2 (0.3%) SAEs reported in male participants and none in the females. In the BNT162b2 group, lymphadenopathy was reported in 8 (1.4%) male participants and in 1 (0.2%) female participant. AEs in the psychiatric disorders SOC were reported in 12 (2.1%) female participants compared to 5 (0.9%) male participants. Depression was the most frequently reported event in both sexes (4 [0.7%] females and 2 [0.4%] males). Anxiety was reported in 4 (0.7%) females and no males. Suicidal ideation was the next most frequently reported event: in females, 3 [0.5%], 1 (0.2%) in male.

12.2.1.3. Related Adverse Events by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date – Participants 12 Through 15 Years of Age

From Dose 1 to the unblinding date, adolescent participants with AEs assessed as related by the investigator were similar in the BNT162b2 and placebo groups (36 [3.2%] and 24 [2.1%], respectively) (Supplemental Table 14.32). Most related AEs were reactogenicity events and in the SOC of general disorders and administration site conditions, reported by 16 (1.4%) and 10 (0.9%) participants in the BNT162b2 and placebo groups, respectively.

Related events of lymphadenopathy were reported in 7 (0.6%) adolescents in the BNT162b2 group and 1 (0.1%) adolescent in the placebo group (refer to other significant AEs in Section 12.3.4).

12.2.1.4. Immediate Adverse Events – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date – Participants 12 Through 15 Years of Age

These results were previously reported in the adolescent interim CSR dated 14 April 2021.

Adolescents with immediate AEs were low in frequency (≤0.4%) after either dose of study intervention. 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, most immediate AEs 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.

12.2.1.5. Severe or Life-Threatening Adverse Events – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date – Participants 12 Through 15 Years of Age

From Dose 1 to the unblinding date, severe AEs were reported in 13 (1.1%) adolescent participants in the BNT162b2 group and 5 (0.4%) participants in the placebo group (Supplemental Table 14.33).

The following severe events in the psychiatric orders SOC were previously reported in the adolescent interim CSR, dated 14 April 2021:

- One participant in the BNT162b2 group reported an SAE each of anxiety and depression (discussed in Section 12.3.2.1)

- One participant in the BNT162b2 group reported 2 SAEs of depression (first SAE discussed in Section 12.3.2.1). The second SAE was a new case not previously reported and occurred after the EUA snapshot (discussed in Section 12.3.2.1.2).

- One participant in the BNT162b2 group reported an SAE of suicidal ideation (discussed in Section 12.3.2.1).

Certain severe events discussed below are new cases which have not been previously reported:

- One participant in the placebo group reported a severe AE of urticaria (discussed in Section 12.2.1.6.4)

- One participant in the BNT162b2 group reported a severe SAE of anal abscess (discussed in Section 12.3.2.1.2).

- One participant in the BNT162b2 group reported an SAE of suicidal ideation (discussed in Section 12.3.2.1.2).

There were 3 participants (2 in the BNT162b2 and 1 in the placebo group) who reported at least 1 life-threatening (or Grade 4) AE from Dose 1 to the unblinding date (Supplemental Table 14.34).

The following life-threatening events were previously reported in the adolescent interim CSR, dated 14 April 2021:

- One participant in the placebo group reported an SAE each of focal peritonitis and appendicitis (discussed in Section 12.3.2.1).

- One participant in the BNT162b2 group reported a Grade 4 AE of pyrexia (40.4°C) on Day 2 after Dose 1, with temperature returning to normal on Day 4. The AE was assessed by the investigator as related to study intervention, resolved, and the participant withdrew from the study (Appendix 16.2.7.2.1).

The life-threatening event below is a new case and has not been previously reported:

- One participant in the BNT162b2 group reported a life-threatening (Grade 4) SAE of suicidal ideation, which was a new event after the EUA snapshot (discussed in Section 12.3.2.1.2)

12.2.1.6. New Adverse Events After the EUA Snapshot – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date – Participants 12 Through 15 Years of Age

12.2.1.6.1. Summary of New Adverse Events After the EUA Snapshot – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date – Participants 12 Through 15 Years of Age

The frequency of adolescent participants in the BNT162b2 group with any new AE after the EUA snapshot from Dose 1 to the unblinding date was 2.6%, which was less than the frequency in the placebo group (4.2%) (Table 20). There were 6 (0.5%) participants in the BNT162b2 group with SAEs, and all events were assessed by the investigator as not related to study intervention. No SAEs were reported in the placebo group. There were no withdrawals because of any AEs or deaths.

Table 20. Number (%) of Subjects Reporting at Least 1 New Adverse Event After the EUA Snapshot, From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1130)		Placebo (N[a]=1126)	
Adverse Event	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	29 (2.6)	(1.7, 3.7)	47 (4.2)	(3.1, 5.5)
Related[d]	3 (0.3)	(0.1, 0.8)	3 (0.3)	(0.1, 0.8)
Severe	5 (0.4)	(0.1, 1.0)	2 (0.2)	(0.0, 0.6)
Life-threatening	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Any serious adverse event	6 (0.5)	(0.2, 1.2)	0	(0.0, 0.3)
Related[d]	0	(0.0, 0.3)	0	(0.0, 0.3)
Severe	4 (0.4)	(0.1, 0.9)	0	(0.0, 0.3)
Life-threatening	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Any nonserious adverse event	24 (2.1)	(1.4, 3.1)	47 (4.2)	(3.1, 5.5)
Related[d]	3 (0.3)	(0.1, 0.8)	3 (0.3)	(0.1, 0.8)
Severe	1 (0.1)	(0.0, 0.5)	2 (0.2)	(0.0, 0.6)
Life-threatening	0	(0.0, 0.3)	0	(0.0, 0.3)
Any adverse event leading to withdrawal	0	(0.0, 0.3)	0	(0.0, 0.3)
Related[d]	0	(0.0, 0.3)	0	(0.0, 0.3)
Severe	0	(0.0, 0.3)	0	(0.0, 0.3)
Life-threatening	0	(0.0, 0.3)	0	(0.0, 0.3)
Death	0	(0.0, 0.3)	0	(0.0, 0.3)

Table 20. Number (%) of Subjects Reporting at Least 1 New Adverse Event After the EUA Snapshot, From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1130)		Placebo (N[a]=1126)	
Adverse Event	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Abbreviation: EUA = emergency use authorization.
a. N = number of subjects in the specified group, subjects who withdrew from the study before EUA snapshot 25Mar2021 with the cutoff date 13Mar2021 are not included. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (09:44)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s091_all_unb2_ped6

12.2.1.6.2. New Adverse Events After the EUA Snapshot by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date – Participants 12 Through 15 Years of Age

New AEs after the EUA snapshot from Dose 1 to the unblinding date during the blinded placebo-controlled follow-up period are presented in Table 21.

The most frequently reported AEs in adolescents were in the psychiatric disorders SOC (11 [1.0%] and 9 [0.8%] adolescent participants in the BNT162b2 and placebo groups, respectively). These cases are discussed alongside cumulative cases during this period in Section 12.2.1.2.

One participant in the BNT162b2 group reported a panic attack. This participant had a past medical history of attention deficit hyperactivity disorder since 2016 (Appendix 16.2.5.4). They had ongoing panic attacks starting 60 days post Dose 2 which was considered not related and attributed to social/environmental events. The event was nonserious, and the participant has continued in the study (Appendix 16.2.7.2.1).

Table 21. Number (%) of Subjects Reporting at Least 1 New Adverse Event After the EUA Snapshot, From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1130)		Placebo (N[a]=1126)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	29 (2.6)	(1.7, 3.7)	47 (4.2)	(3.1, 5.5)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Spine malformation	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Conductive deafness	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
EYE DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Eye pain	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
GASTROINTESTINAL DISORDERS	1 (0.1)	(0.0, 0.5)	5 (0.4)	(0.1, 1.0)
Nausea	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.6)
Abdominal pain	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Constipation	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Mouth ulceration	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Tooth impacted	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Vomiting	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Injection site pain	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Chills	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Fatigue	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Injection site swelling	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Pyrexia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
IMMUNE SYSTEM DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Seasonal allergy	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
INFECTIONS AND INFESTATIONS	3 (0.3)	(0.1, 0.8)	1 (0.1)	(0.0, 0.5)
Anal abscess	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Cellulitis	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Paronychia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Pilonidal cyst	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	6 (0.5)	(0.2, 1.2)	13 (1.2)	(0.6, 2.0)
Fall	1 (0.1)	(0.0, 0.5)	4 (0.4)	(0.1, 0.9)
Hand fracture	0	(0.0, 0.3)	4 (0.4)	(0.1, 0.9)

Table 21. Number (%) of Subjects Reporting at Least 1 New Adverse Event After the EUA Snapshot, From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1130)		Placebo (N[a]=1126)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Procedural pain	2 (0.2)	(0.0, 0.6)	1 (0.1)	(0.0, 0.5)
Concussion	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.6)
Ligament sprain	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.6)
Upper limb fracture	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Ankle fracture	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Bone contusion	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Contusion	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Femur fracture	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Meniscus injury	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Skin laceration	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Tibia fracture	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
INVESTIGATIONS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
SARS-CoV-2 antibody test positive	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.1)	(0.0, 0.5)	6 (0.5)	(0.2, 1.2)
Tendonitis	0	(0.0, 0.3)	4 (0.4)	(0.1, 0.9)
Arthralgia	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Back pain	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Musculoskeletal chest pain	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Melanocytic naevus	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
NERVOUS SYSTEM DISORDERS	1 (0.1)	(0.0, 0.5)	6 (0.5)	(0.2, 1.2)
Headache	0	(0.0, 0.3)	3 (0.3)	(0.1, 0.8)
Presyncope	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.6)
Migraine	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Syncope	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
PSYCHIATRIC DISORDERS	11 (1.0)	(0.5, 1.7)	9 (0.8)	(0.4, 1.5)
Anxiety	3 (0.3)	(0.1, 0.8)	4 (0.4)	(0.1, 0.9)
Depression	4 (0.4)	(0.1, 0.9)	2 (0.2)	(0.0, 0.6)
Attention deficit hyperactivity disorder	2 (0.2)	(0.0, 0.6)	3 (0.3)	(0.1, 0.8)
Suicidal ideation	3 (0.3)	(0.1, 0.8)	0	(0.0, 0.3)
Obsessive-compulsive disorder	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.6)

Table 21. Number (%) of Subjects Reporting at Least 1 New Adverse Event After the EUA Snapshot, From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1130)		Placebo (N[a]=1126)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Panic attack	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
RENAL AND URINARY DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Dysuria	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Amenorrhoea	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.1)	(0.0, 0.5)	4 (0.4)	(0.1, 0.9)
Nasal congestion	1 (0.1)	(0.0, 0.5)	3 (0.3)	(0.1, 0.8)
Epistaxis	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Rhinorrhoea	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Sneezing	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.2)	(0.0, 0.6)	3 (0.3)	(0.1, 0.8)
Acne	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Dermatitis contact	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Eczema	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Rash	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Seborrhoeic dermatitis	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Urticaria	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
SURGICAL AND MEDICAL PROCEDURES	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Wisdom teeth removal	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)

Abbreviation: EUA = emergency use authorization.
Note: MedDRA (v24.0) 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, subjects who withdrew from the study before EUA snapshot 25Mar2021 with the cutoff date 13Mar2021 are not included. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (09:47)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s130_all_unb2_ped6

12.2.1.6.3. New Related Adverse Events After the EUA Snapshot by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date – Participants 12 Through 15 Years of Age

There were few adolescent participants with new related AEs that occurred after the EUA snapshot in either group (3 [0.3%] participants each) (Table 22), and each PT was reported by 1 participant each in either group.

One participant in the BNT162b2 group reported an AE of musculoskeletal chest pain (verbatim term reported was bilateral rib pain), on Day 3 after Dose 2 (Appendix 16.2.7.2.3). The AE was moderate in severity and resolved the same day. There is no evidence that the investigator had evaluated the participant for cardiac disease.

Table 22. Number (%) of Subjects Reporting at Least 1 New Related Adverse Event After the EUA Snapshot, From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1130)		Placebo (N[a]=1126)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	3 (0.3)	(0.1, 0.8)	3 (0.3)	(0.1, 0.8)
EAR AND LABYRINTH DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Conductive deafness	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Nausea	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Vomiting	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Injection site pain	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Chills	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Fatigue	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Injection site swelling	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Pyrexia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
INVESTIGATIONS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
SARS-CoV-2 antibody test positive	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Musculoskeletal chest pain	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)

Table 22. Number (%) of Subjects Reporting at Least 1 New Related Adverse Event After the EUA Snapshot, From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1130)		Placebo (N[a]=1126)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Abbreviation: EUA = emergency use authorization.
Note: MedDRA (v24.0) 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, subjects who withdrew from the study before EUA snapshot 25Mar2021 with the cutoff date 13Mar2021 are not included. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (09:48)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/adae s130 rel unb2 ped6

12.2.1.6.4. New Severe or Life-Threatening Adverse Events After the EUA Snapshot – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date – Participants 12 Through 15 Years of Age

New severe AEs after the EUA snapshot were reported in 5 (0.4%) adolescent participants in the BNT162b2 group and 2 (0.2%) participants in the placebo group (Table 23).

Certain severe events are discussed below:

- One participant in the placebo group reported a severe AE of urticaria on Day 55 after Dose 2 with a duration of 8 days, and the AE was assessed by the investigator as not related to study intervention (Appendix 16.2.7.2.3). The participant had a past medical history of penicillin allergy since 2008. The event was nonserious, resolved, and the participant continued in the study, receiving a first dose of BNT162b2 (Appendix 16.1.7) with no further urticaria reported.

- One participant in the BNT162b2 group reported a second severe SAE of depression (previously had a severe SAE and reported in the adolesecent interim CSR, dated 14 April 2021 and discussed in Section 12.3.2.1; second SAE discussed in Section 12.3.2.1.2).

- One participant in the BNT162b2 group reported a severe SAE of suicidal ideation (discussed in Section 12.3.2.1.2).

- One participant in the BNT162b2 group reported a severe SAE of anal abscess (discussed in Section 12.3.2.1.2).

From Dose 1 to the unblinding date, there was 1 participant in the BNT162b2group who reported a life-threatening (or Grade 4) SAE of suicidal ideation (Table 24; discussed in Section 12.3.2.1.2).

All new severe and life-threatening events reported after the EUA snapshot from Dose 1 to the unblinding date were assessed by the investigator as not related to study intervention. Most were resolved as of the data cutoff date (02 September 2021). For additional safety data after the EUA snapshot during blinded placebo-controlled and open-label follow-up periods for original BNT162b2 recipients 12 through 15 years of age, refer to Section 12.2.3.4.

Table 23. Number (%) of Subjects Reporting at Least 1 New Severe Adverse Event After the EUA Snapshot, From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1130)		Placebo (N[a]=1126)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	5 (0.4)	(0.1, 1.0)	2 (0.2)	(0.0, 0.6)
INFECTIONS AND INFESTATIONS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Anal abscess	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.2)	(0.0, 0.6)	1 (0.1)	(0.0, 0.5)
Femur fracture	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Procedural pain	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Upper limb fracture	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
PSYCHIATRIC DISORDERS	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.3)
Depression	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Suicidal ideation	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Urticaria	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)

Table 23. Number (%) of Subjects Reporting at Least 1 New Severe Adverse Event After the EUA Snapshot, From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1130)		Placebo (N[a]=1126)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Abbreviation: EUA = emergency use authorization.
Note: MedDRA (v24.0) 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, subjects who withdrew from the study before EUA snapshot 25Mar2021 with the cutoff date 13Mar2021 are not included. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (09:48)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s130 sev unb2 ped6

Table 24. Number (%) of Subjects Reporting at Least 1 New Life-Threatening Adverse Event After the EUA Snapshot, From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1130)		Placebo (N[a]=1126)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
PSYCHIATRIC DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Suicidal ideation	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)

Table 24. Number (%) of Subjects Reporting at Least 1 New Life-Threatening Adverse Event After the EUA Snapshot, From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1130)		Placebo (N[a]=1126)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Abbreviation: EUA = emergency use authorization.
Note: MedDRA (v24.0) 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, subjects who withdrew from the study before EUA snapshot 25Mar2021 with the cutoff date 13Mar2021 are not included. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (09:49)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/adae s130 lif unb2 ped6

12.2.2. Open-Label Follow-Up Period From the Unblinding Date to the Data Cutoff Date – Original BNT162b2 Recipients 12 Through 15 Years of Age

12.2.2.1. Summary of Adverse Events – Open-Label Follow-Up Period – Original BNT162b2 Recipients 12 Through 15 Years of Age

An overview of AEs from the unblinding date to the data cutoff date for adolescent participants who originally received BNT162b2 during the open-label follow-up period is presented in Table 25 (Note: Per protocol, AEs are reported through approximately 1 month after Dose 2 and within 48 hours after a blood draw. SAEs are reported to approximately 6 months after the last dose of study intervention.)

There were 18 (1.6%) participants who experienced any AE, including 0.4%, 0.3%, and 0% who experienced related, severe, and life-threatening events, respectively (Table 25). This is markedly reduced relative to AEs from Dose 1 to the unblinding date (8.4% of BNT162b2 participants experienced any AE, including 3.2%, 1.1%, and 0.2% who experienced related, severe, and life-threatening events, respectively [Table 18]). The frequencies of SAEs and AEs leading to withdrawal during the open-label follow-up period (0.4% and 0%, respectively [Table 25]) were similar to those from Dose 1 to the unblinding date (0.9% and 0.1%, respectively [Table 18]). There were no adolescent deaths in the study.

Table 25. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (02SEP2021) – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1107, TE[b]=3.3)		
Adverse Event	n[c] (%)	IR[d]	(95% CI[e])
Any event	18 (1.6)	5.4	(3.2, 8.5)
Related[f]	4 (0.4)	1.2	(0.3, 3.1)
Severe	3 (0.3)	0.9	(0.2, 2.6)
Life-threatening	0	0.0	(0.0, 1.1)
Any serious adverse event	4 (0.4)	1.2	(0.3, 3.1)
Related[f]	0	0.0	(0.0, 1.1)
Severe	1 (0.1)	0.3	(0.0, 1.7)
Life-threatening	0	0.0	(0.0, 1.1)
Any nonserious adverse event	14 (1.3)	4.2	(2.3, 7.0)
Related[f]	4 (0.4)	1.2	(0.3, 3.1)
Severe	2 (0.2)	0.6	(0.1, 2.2)
Life-threatening	0	0.0	(0.0, 1.1)
Any adverse event leading to withdrawal	0	0.0	(0.0, 1.1)
Related[f]	0	0.0	(0.0, 1.1)
Severe	0	0.0	(0.0, 1.1)
Life-threatening	0	0.0	(0.0, 1.1)
Death	0	0.0	(0.0, 1.1)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from the unblinding date to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:31)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s092 ubct1 ped6

12.2.2.2. Adverse Events by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Original BNT162b2 Recipients 12 Through 15 Years of Age

From the unblinding date to the data cutoff date (open-label follow-up period), for adolescent participants who originally received BNT162b2, the number of participants who reported at

least 1 AE was 18 (1.6%) (Supplemental Table 14.35) compared to 95 (8.4%) from Dose 1 to the unblinding date (Table 18).

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

The frequency for the SOC of nervous system disorders was 6 (0.5%), including the PTs dizziness (2), headache (2), presyncope (2), and syncope (1). (Supplemental Table 14.35). The frequency for the SOC of general disorders and administration site conditions was 4 (0.4%), with injection site pain (3) as the most frequently reported PT.

12.2.2.3. Related Adverse Events by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Original BNT162b2 Recipients 12 Through 15 Years of Age

From the unblinding date to the data cutoff date (open-label follow-up period), for adolescent participants who originally received BNT162b2, the number of participants with AEs assessed as related by the investigator was 4 (0.4%) (Supplemental Table 14.36). The frequencies of related AEs were highest for reactogenicity events and in the SOCs of general disorders and administration site conditions (injection site pain, fatigue, pyrexia, and pain) and nervous system disorders (headache and dizziness) (Supplemental Table 14.36).

12.2.2.4. Severe or Life-Threatening Adverse Events – Open-Label Follow-Up Period – Original BNT162b2 Recipients 12 Through 15 Years of Age

From the unblinding date to the data cutoff date (open-label follow-up period), 3 (0.3%) BNT162b2 participants experienced severe AEs (Supplemental Table 14.37). Two (2) participants experienced pyrexia (general disorders and administration site conditions), a term consistent with reactogenicity.

There were no life-threatening AEs reported from the unblinding date to the data cutoff date (Table 25).

12.2.3. Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Recipients 12 Through 15 Years of Age

12.2.3.1. Summary of Adverse Events – Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Recipients 12 Through 15 Years of Age

There were 1113 adolescent participants who originally received BNT162b2 and had at least 6 months of follow-up time after Dose 2 for the blinded placebo-controlled and open-label follow-up periods (Table 26). There were 98 (8.8%) participants who reported at least 1 AE, and 34 (3.1%) participants reported at least 1 related AE. Severe AEs and SAEs were reported by 13 (1.2%) and 10 (0.9%) participants, respectively. There were no AEs leading to withdrawal, and there were no deaths.

The frequencies of any AEs and related AEs are 70 (6.3%) and 34 (3.1%) through 1 month after Dose 2 compared with 35 (3.1%) and no related AEs from 1 month after Dose 2 to

6 months after Dose 2, respectively (Table 27). From Dose 1 to 1 month after Dose 2, 3 (0.3%) adolescent participants reported SAEs. From 1 month to 6 months after Dose 2, 9 (0.8%) participants reported SAEs. All SAEs were assessed by the investigator as not related to study intervention. There were no AEs leading to withdrawal, and there were no deaths.

Table 26. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2 – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
Adverse Event	**n[b] (%)**	**(95% CI[c])**
Any event	98 (8.8)	(7.2, 10.6)
Related[d]	34 (3.1)	(2.1, 4.2)
Severe	13 (1.2)	(0.6, 2.0)
Life-threatening	0	(0.0, 0.3)
Any serious adverse event	10 (0.9)	(0.4, 1.6)
Related[d]	0	(0.0, 0.3)
Severe	7 (0.6)	(0.3, 1.3)
Life-threatening	0	(0.0, 0.3)
Any nonserious adverse event	91 (8.2)	(6.6, 9.9)
Related[d]	34 (3.1)	(2.1, 4.2)
Severe	6 (0.5)	(0.2, 1.2)
Life-threatening	0	(0.0, 0.3)
Any adverse event leading to withdrawal	0	(0.0, 0.3)
Related[d]	0	(0.0, 0.3)
Severe	0	(0.0, 0.3)
Life-threatening	0	(0.0, 0.3)
Death	0	(0.0, 0.3)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Assessed by the investigator as related to investigational product.
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(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/adae s091 6m1 ped6

Table 27. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
Adverse Event	Dose 1 to 1 Month After Dose 2 n[b] (%)	1 Month After Dose 2 to 6 Months After Dose 2 n[b] (%)
Any event	70 (6.3)	35 (3.1)
Related[c]	34 (3.1)	0
Severe	6 (0.5)	8 (0.7)
Life-threatening	0	0
Any serious adverse event	3 (0.3)	9 (0.8)
Related[c]	0	0
Severe	1 (0.1)	7 (0.6)
Life-threatening	0	0
Any nonserious adverse event	68 (6.1)	28 (2.5)
Related[c]	34 (3.1)	0
Severe	5 (0.4)	1 (0.1)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:21)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/adae s093 6m1 ped6

12.2.3.2. Adverse Events by System Organ Class and Preferred Term – Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Recipients 12 Through 15 Years of Age

There were 98 (8.8%) adolescent participants who originally received BNT162b2, had at least 6 months of follow-up time after Dose 2, and reported AEs from Dose 1 to 6 months

after Dose 2 (Table 28). Frequently reported AEs included reactogenicity events in the following SOCs:

- general disorders and administration site conditions (16 [1.4%])
- musculoskeletal and connective tissue disorders (8 [0.7%])
- nervous system disorders (16 [1.4%])
- gastrointestinal disorders (16 [1.4%])

AEs were reported by 15 (1.3%) participants in the injury, poisoning, and procedural complications SOC; 10 (0.9%) participants in the infections and infestations SOC, and 16 (1.4%) participants in the psychiatric disorders SOC.

When AEs are compared from Dose 1 to 1 month after Dose 2 and from 1 month after Dose 2 to 6 months after Dose 2, the frequencies of AEs by most SOCs were lower or were similar with the additional follow-up time. The overall frequency of any AE for participants from 1 month after Dose 2 to 6 months after Dose 2 (35 [3.1%]) was less compared with the frequency during 1 month follow-up time after Dose 2 (70 [6.3%]) (Table 29). Overall, AEs reported after 1 month post Dose-2 reflect age-appropriate events consistent with the general population.

All lymphadenopathy events were reported from Dose 1 to 1 month after Dose 2, and none were reported from 1 month to 6 months after Dose 2 (Table 29).

AEs in the pyschiatric disorders SOC were reported by 7 (0.6%) participants from Dose 1 to 1 month after Dose 2 and in 11 (1.0%) participants from 1 month to 6 months after Dose 2.

Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	98 (8.8)	(7.2, 10.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	9 (0.8)	(0.4, 1.5)
Lymphadenopathy	9 (0.8)	(0.4, 1.5)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.1)	(0.0, 0.5)
Syringomyelia	1 (0.1)	(0.0, 0.5)

Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
EAR AND LABYRINTH DISORDERS	1 (0.1)	(0.0, 0.5)
Ear pain	1 (0.1)	(0.0, 0.5)
EYE DISORDERS	1 (0.1)	(0.0, 0.5)
Eye pain	1 (0.1)	(0.0, 0.5)
GASTROINTESTINAL DISORDERS	16 (1.4)	(0.8, 2.3)
Nausea	6 (0.5)	(0.2, 1.2)
Diarrhoea	3 (0.3)	(0.1, 0.8)
Abdominal pain	2 (0.2)	(0.0, 0.6)
Aphthous ulcer	2 (0.2)	(0.0, 0.6)
Abdominal pain upper	1 (0.1)	(0.0, 0.5)
Constipation	1 (0.1)	(0.0, 0.5)
Gastritis	1 (0.1)	(0.0, 0.5)
Lip swelling	1 (0.1)	(0.0, 0.5)
Mouth swelling	1 (0.1)	(0.0, 0.5)
Oral mucosal blistering	1 (0.1)	(0.0, 0.5)
Rectal prolapse	1 (0.1)	(0.0, 0.5)
Vomiting	1 (0.1)	(0.0, 0.5)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	16 (1.4)	(0.8, 2.3)
Fatigue	8 (0.7)	(0.3, 1.4)
Injection site pain	8 (0.7)	(0.3, 1.4)
Pyrexia	5 (0.4)	(0.1, 1.0)
Chills	2 (0.2)	(0.0, 0.6)
Injection site swelling	2 (0.2)	(0.0, 0.6)
Nodule	1 (0.1)	(0.0, 0.5)
Peripheral swelling	1 (0.1)	(0.0, 0.5)
IMMUNE SYSTEM DISORDERS	1 (0.1)	(0.0, 0.5)
Seasonal allergy	1 (0.1)	(0.0, 0.5)
INFECTIONS AND INFESTATIONS	10 (0.9)	(0.4, 1.6)
Ear infection	2 (0.2)	(0.0, 0.6)
Anal abscess	1 (0.1)	(0.0, 0.5)

Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Appendicitis	1 (0.1)	(0.0, 0.5)
Body tinea	1 (0.1)	(0.0, 0.5)
Otitis externa	1 (0.1)	(0.0, 0.5)
Otitis media	1 (0.1)	(0.0, 0.5)
Paronychia	1 (0.1)	(0.0, 0.5)
Pilonidal cyst	1 (0.1)	(0.0, 0.5)
Tinea capitis	1 (0.1)	(0.0, 0.5)
Vulval abscess	1 (0.1)	(0.0, 0.5)
Vulvovaginal mycotic infection	1 (0.1)	(0.0, 0.5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	15 (1.3)	(0.8, 2.2)
Concussion	3 (0.3)	(0.1, 0.8)
Hand fracture	2 (0.2)	(0.0, 0.6)
Procedural pain	2 (0.2)	(0.0, 0.6)
Accident	1 (0.1)	(0.0, 0.5)
Bone contusion	1 (0.1)	(0.0, 0.5)
Clavicle fracture	1 (0.1)	(0.0, 0.5)
Contusion	1 (0.1)	(0.0, 0.5)
Fall	1 (0.1)	(0.0, 0.5)
Femur fracture	1 (0.1)	(0.0, 0.5)
Ligament sprain	1 (0.1)	(0.0, 0.5)
Meniscus injury	1 (0.1)	(0.0, 0.5)
Muscle strain	1 (0.1)	(0.0, 0.5)
Radius fracture	1 (0.1)	(0.0, 0.5)
Upper limb fracture	1 (0.1)	(0.0, 0.5)
INVESTIGATIONS	1 (0.1)	(0.0, 0.5)
SARS-CoV-2 antibody test positive	1 (0.1)	(0.0, 0.5)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	8 (0.7)	(0.3, 1.4)
Myalgia	3 (0.3)	(0.1, 0.8)
Arthralgia	2 (0.2)	(0.0, 0.6)
Musculoskeletal chest pain	1 (0.1)	(0.0, 0.5)
Osteochondrosis	1 (0.1)	(0.0, 0.5)

Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Pain in extremity	1 (0.1)	(0.0, 0.5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.1)	(0.0, 0.5)
Hair follicle tumour benign	1 (0.1)	(0.0, 0.5)
NERVOUS SYSTEM DISORDERS	16 (1.4)	(0.8, 2.3)
Headache	5 (0.4)	(0.1, 1.0)
Migraine	3 (0.3)	(0.1, 0.8)
Presyncope	3 (0.3)	(0.1, 0.8)
Dizziness	2 (0.2)	(0.0, 0.6)
Syncope	2 (0.2)	(0.0, 0.6)
Paraesthesia	1 (0.1)	(0.0, 0.5)
PSYCHIATRIC DISORDERS	16 (1.4)	(0.8, 2.3)
Depression	5 (0.4)	(0.1, 1.0)
Anxiety	4 (0.4)	(0.1, 0.9)
Suicidal ideation	3 (0.3)	(0.1, 0.8)
Attention deficit hyperactivity disorder	2 (0.2)	(0.0, 0.6)
Conversion disorder	1 (0.1)	(0.0, 0.5)
Disorientation	1 (0.1)	(0.0, 0.5)
Generalised anxiety disorder	1 (0.1)	(0.0, 0.5)
Panic attack	1 (0.1)	(0.0, 0.5)
Sleep terror	1 (0.1)	(0.0, 0.5)
Tic	1 (0.1)	(0.0, 0.5)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.1)	(0.0, 0.5)
Amenorrhoea	1 (0.1)	(0.0, 0.5)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (0.3)	(0.1, 0.8)
Nasal congestion	2 (0.2)	(0.0, 0.6)
Rhinorrhoea	2 (0.2)	(0.0, 0.6)
Sneezing	1 (0.1)	(0.0, 0.5)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	8 (0.7)	(0.3, 1.4)
Acne	2 (0.2)	(0.0, 0.6)
Dermatitis contact	2 (0.2)	(0.0, 0.6)

Table 28. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Rash	2 (0.2)	(0.0, 0.6)
Urticaria	2 (0.2)	(0.0, 0.6)
SURGICAL AND MEDICAL PROCEDURES	1 (0.1)	(0.0, 0.5)
Wisdom teeth removal	1 (0.1)	(0.0, 0.5)

Note: MedDRA (v24.0) 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:31)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s130_all_6m1_ped6

Table 29. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1113)			
	Dose 1 to 1 Month After Dose 2		1 Month After Dose 2 to 6 Months After Dose 2	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	70 (6.3)	(4.9, 7.9)	35 (3.1)	(2.2, 4.3)

Table 29. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1113)			
	Dose 1 to 1 Month After Dose 2		1 Month After Dose 2 to 6 Months After Dose 2	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
BLOOD AND LYMPHATIC SYSTEM DISORDERS	9 (0.8)	(0.4, 1.5)	0	(0.0, 0.3)
Lymphadenopathy	9 (0.8)	(0.4, 1.5)	0	(0.0, 0.3)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Syringomyelia	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
EAR AND LABYRINTH DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Ear pain	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
EYE DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Eye pain	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
GASTROINTESTINAL DISORDERS	14 (1.3)	(0.7, 2.1)	3 (0.3)	(0.1, 0.8)
Nausea	5 (0.4)	(0.1, 1.0)	1 (0.1)	(0.0, 0.5)
Diarrhoea	3 (0.3)	(0.1, 0.8)	0	(0.0, 0.3)
Abdominal pain	2 (0.2)	(0.0, 0.6)	1 (0.1)	(0.0, 0.5)
Aphthous ulcer	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Abdominal pain upper	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Constipation	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Gastritis	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Lip swelling	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Mouth swelling	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Oral mucosal blistering	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Rectal prolapse	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Vomiting	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	16 (1.4)	(0.8, 2.3)	0	(0.0, 0.3)
Fatigue	8 (0.7)	(0.3, 1.4)	0	(0.0, 0.3)
Injection site pain	8 (0.7)	(0.3, 1.4)	0	(0.0, 0.3)
Pyrexia	5 (0.4)	(0.1, 1.0)	0	(0.0, 0.3)
Chills	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.3)
Injection site swelling	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.3)
Nodule	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)

Table 29. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1113)			
	Dose 1 to 1 Month After Dose 2		1 Month After Dose 2 to 6 Months After Dose 2	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Peripheral swelling	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Seasonal allergy	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
INFECTIONS AND INFESTATIONS	6 (0.5)	(0.2, 1.2)	4 (0.4)	(0.1, 0.9)
Ear infection	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.3)
Anal abscess	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Appendicitis	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Body tinea	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Otitis externa	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Otitis media	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Paronychia	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Pilonidal cyst	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Tinea capitis	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Vulval abscess	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Vulvovaginal mycotic infection	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	9 (0.8)	(0.4, 1.5)	6 (0.5)	(0.2, 1.2)
Concussion	3 (0.3)	(0.1, 0.8)	0	(0.0, 0.3)
Hand fracture	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Procedural pain	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.6)
Accident	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Bone contusion	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Clavicle fracture	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Contusion	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Fall	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Femur fracture	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Ligament sprain	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Meniscus injury	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Muscle strain	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Radius fracture	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)

Table 29. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1113)			
	Dose 1 to 1 Month After Dose 2		1 Month After Dose 2 to 6 Months After Dose 2	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Upper limb fracture	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
INVESTIGATIONS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
SARS-CoV-2 antibody test positive	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	8 (0.7)	(0.3, 1.4)	0	(0.0, 0.3)
Myalgia	3 (0.3)	(0.1, 0.8)	0	(0.0, 0.3)
Arthralgia	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.3)
Musculoskeletal chest pain	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Osteochondrosis	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Pain in extremity	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Hair follicle tumour benign	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
NERVOUS SYSTEM DISORDERS	11 (1.0)	(0.5, 1.8)	5 (0.4)	(0.1, 1.0)
Headache	5 (0.4)	(0.1, 1.0)	0	(0.0, 0.3)
Migraine	2 (0.2)	(0.0, 0.6)	1 (0.1)	(0.0, 0.5)
Presyncope	1 (0.1)	(0.0, 0.5)	2 (0.2)	(0.0, 0.6)
Dizziness	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.3)
Syncope	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.6)
Paraesthesia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
PSYCHIATRIC DISORDERS	7 (0.6)	(0.3, 1.3)	11 (1.0)	(0.5, 1.8)
Depression	2 (0.2)	(0.0, 0.6)	4 (0.4)	(0.1, 0.9)
Anxiety	1 (0.1)	(0.0, 0.5)	3 (0.3)	(0.1, 0.8)
Suicidal ideation	0	(0.0, 0.3)	3 (0.3)	(0.1, 0.8)
Attention deficit hyperactivity disorder	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.6)
Conversion disorder	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Disorientation	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Generalised anxiety disorder	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Panic attack	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Sleep terror	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)

Table 29. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1113)			
	Dose 1 to 1 Month After Dose 2		1 Month After Dose 2 to 6 Months After Dose 2	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Tic	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Amenorrhoea	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2 (0.2)	(0.0, 0.6)	1 (0.1)	(0.0, 0.5)
Nasal congestion	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Rhinorrhoea	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Sneezing	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	6 (0.5)	(0.2, 1.2)	2 (0.2)	(0.0, 0.6)
Acne	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.3)
Dermatitis contact	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Rash	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Urticaria	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.3)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Wisdom teeth removal	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)

Note: MedDRA (v24.0) 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:21)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s132 6m1 ped6

12.2.3.3. Related Adverse Events by System Organ Class and Preferred Term – Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Recipients 12 Through 15 Years of Age

From Dose 1 to 6 months after Dose 2, 34 (3.1%) original BNT162b2 adolescent recipients reported AEs assessed by the investigator as related to study intervention (Supplemental

Table 14.38). Most related AEs were reactogenicity events and in the SOC of general disorders and administration site conditions, reported by 15 (1.3%) participants. Related events of lymphadenopathy were reported by 7 (0.6%) adolescents in the BNT162b2 group (refer to other significant AEs in Section 12.3.4.1).

12.2.3.4. New Adverse Events After the EUA Snapshot – Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Recipients 12 Through 15 Years of Age

12.2.3.4.1. Summary of New Adverse Events After the EUA Snapshot – Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Recipients 12 Through 15 Years of Age

From the time after the EUA snapshot for adolescent participants who had at least 6 months of follow-up time after Dose 2 during the blinded placebo-controlled and open-label follow-up periods, there were 36 (3.2%) participants who reported at least 1 AE, and 3 (0.3%) participants reported at least 1 related AE (Table 30). Severe AEs and SAEs were reported by 6 (0.5%) and 7 (0.6%) participants, respectively. There were no AEs leading to withdrawal, and there were no deaths.

When frequencies of new AEs for participants with at least 6 months of follow-up time are examined by time since the second dose, the frequency of any AEs and related AEs is 6 (0.5%) and 3 (0.3%) through 1 month after Dose 2 compared with 32 (2.9%) and no related AEs from 1 month after Dose 2 to 6 months after Dose 2 (Table 31). At 1 month after Dose 2, no adolescent participants reported severe AEs or SAEs. From 1 month to 6 months after Dose 2, the number of participants with severe AEs and SAEs was 6 (0.5%) and 7 (0.6%), respectively. All new SAEs and all AEs reported from 1 month after Dose 2 to 6 months after Dose 2 were assessed by the investigator as not related to study intervention.

Table 30. Number (%) of Subjects Reporting at Least 1 New Adverse Event After the EUA Snapshot, From Dose 1 to 6 Months After Dose 2 – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
Adverse Event	n[b] (%)	(95% CI[c])
Any event	36 (3.2)	(2.3, 4.4)
Related[d]	3 (0.3)	(0.1, 0.8)
Severe	6 (0.5)	(0.2, 1.2)
Life-threatening	0	(0.0, 0.3)
Any serious adverse event	7 (0.6)	(0.3, 1.3)

Table 30. Number (%) of Subjects Reporting at Least 1 New Adverse Event After the EUA Snapshot, From Dose 1 to 6 Months After Dose 2 – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
Adverse Event	n[b] (%)	(95% CI[c])
Related[d]	0	(0.0, 0.3)
Severe	5 (0.4)	(0.1, 1.0)
Life-threatening	0	(0.0, 0.3)
Any nonserious adverse event	30 (2.7)	(1.8, 3.8)
Related[d]	3 (0.3)	(0.1, 0.8)
Severe	1 (0.1)	(0.0, 0.5)
Life-threatening	0	(0.0, 0.3)
Any adverse event leading to withdrawal	0	(0.0, 0.3)
Related[d]	0	(0.0, 0.3)
Severe	0	(0.0, 0.3)
Life-threatening	0	(0.0, 0.3)
Death	0	(0.0, 0.3)

Abbreviation: EUA = emergency use authorization.
Note: EUA snapshot 25Mar2021 with the cutoff date 13Mar2021.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (09:49)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s091 6m2 ped6

Table 31. Number (%) of Subjects Reporting at Least 1 New Adverse Event After the EUA Snapshot, From Dose 1 to 6 Months After Dose 2, by Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
	Dose 1 to 1 Month After Dose 2	1 Month After Dose 2 to 6 Months After Dose 2
Adverse Event	n[b] (%)	n[b] (%)
Any event	6 (0.5)	32 (2.9)
Related[c]	3 (0.3)	0
Severe	0	6 (0.5)
Life-threatening	0	0
Any serious adverse event	0	7 (0.6)
Related[c]	0	0
Severe	0	5 (0.4)
Life-threatening	0	0
Any nonserious adverse event	6 (0.5)	26 (2.3)
Related[c]	3 (0.3)	0
Severe	0	1 (0.1)
Life-threatening	0	0
Any adverse event leading to withdrawal	0	0
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

Abbreviation: EUA = emergency use authorization.
Note: EUA snapshot 25Mar2021 with the cutoff date 13Mar2021.
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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (09:45)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s093 6m2 ped6

12.2.3.4.2. New Adverse Events After the EUA Snapshot by System Organ Class and Preferred Term – Blinded Placebo-Controlled and Open-Label Follow-Up Periods

From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Recipients 12 Through 15 Years of Age

Most of the new AEs reported after the EUA snapshot in adolescent participants with at least 6 months of follow-up time after Dose 2 were in the psychiatric disorders SOC (11 [1.0%]) (Table 32).

When AEs are compared from Dose 1 to 1 month after Dose 2 and from 1 month after Dose 2 to 6 months after Dose 2, AEs reported in the psychiatric disorders SOC was 1 (0.1%) and 10 (0.9%) participants, respectively (Table 33). All AEs in this SOC were assessed by the investigator as not related to study intervention (Appendix 16.2.7.2.3).

Table 32. Number (%) of Subjects Reporting at Least 1 New Adverse Event After the EUA Snapshot, From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	36 (3.2)	(2.3, 4.4)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.1)	(0.0, 0.5)
Syringomyelia	1 (0.1)	(0.0, 0.5)
EYE DISORDERS	1 (0.1)	(0.0, 0.5)
Eye pain	1 (0.1)	(0.0, 0.5)
GASTROINTESTINAL DISORDERS	3 (0.3)	(0.1, 0.8)
Abdominal pain upper	1 (0.1)	(0.0, 0.5)
Aphthous ulcer	1 (0.1)	(0.0, 0.5)
Constipation	1 (0.1)	(0.0, 0.5)
Nausea	1 (0.1)	(0.0, 0.5)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.1)	(0.0, 0.5)
Chills	1 (0.1)	(0.0, 0.5)
Fatigue	1 (0.1)	(0.0, 0.5)
Injection site pain	1 (0.1)	(0.0, 0.5)
Injection site swelling	1 (0.1)	(0.0, 0.5)
Pyrexia	1 (0.1)	(0.0, 0.5)
IMMUNE SYSTEM DISORDERS	1 (0.1)	(0.0, 0.5)
Seasonal allergy	1 (0.1)	(0.0, 0.5)

Table 32. Number (%) of Subjects Reporting at Least 1 New Adverse Event After the EUA Snapshot, From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
INFECTIONS AND INFESTATIONS	4 (0.4)	(0.1, 0.9)
Anal abscess	1 (0.1)	(0.0, 0.5)
Appendicitis	1 (0.1)	(0.0, 0.5)
Paronychia	1 (0.1)	(0.0, 0.5)
Pilonidal cyst	1 (0.1)	(0.0, 0.5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	6 (0.5)	(0.2, 1.2)
Procedural pain	2 (0.2)	(0.0, 0.6)
Bone contusion	1 (0.1)	(0.0, 0.5)
Femur fracture	1 (0.1)	(0.0, 0.5)
Hand fracture	1 (0.1)	(0.0, 0.5)
Meniscus injury	1 (0.1)	(0.0, 0.5)
Upper limb fracture	1 (0.1)	(0.0, 0.5)
INVESTIGATIONS	1 (0.1)	(0.0, 0.5)
SARS-CoV-2 antibody test positive	1 (0.1)	(0.0, 0.5)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.1)	(0.0, 0.5)
Musculoskeletal chest pain	1 (0.1)	(0.0, 0.5)
NERVOUS SYSTEM DISORDERS	4 (0.4)	(0.1, 0.9)
Presyncope	2 (0.2)	(0.0, 0.6)
Migraine	1 (0.1)	(0.0, 0.5)
Syncope	1 (0.1)	(0.0, 0.5)
PSYCHIATRIC DISORDERS	11 (1.0)	(0.5, 1.8)
Anxiety	4 (0.4)	(0.1, 0.9)
Depression	4 (0.4)	(0.1, 0.9)
Attention deficit hyperactivity disorder	2 (0.2)	(0.0, 0.6)
Suicidal ideation	2 (0.2)	(0.0, 0.6)
Panic attack	1 (0.1)	(0.0, 0.5)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.1)	(0.0, 0.5)
Amenorrhoea	1 (0.1)	(0.0, 0.5)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.1)	(0.0, 0.5)
Nasal congestion	1 (0.1)	(0.0, 0.5)

Table 32. Number (%) of Subjects Reporting at Least 1 New Adverse Event After the EUA Snapshot, From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Rhinorrhoea	1 (0.1)	(0.0, 0.5)
Sneezing	1 (0.1)	(0.0, 0.5)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.2)	(0.0, 0.6)
Acne	1 (0.1)	(0.0, 0.5)
Dermatitis contact	1 (0.1)	(0.0, 0.5)
SURGICAL AND MEDICAL PROCEDURES	1 (0.1)	(0.0, 0.5)
Wisdom teeth removal	1 (0.1)	(0.0, 0.5)

Abbreviation: EUA = emergency use authorization.
Note: EUA snapshot 25Mar2021 with the cutoff date 13Mar2021.
Note: MedDRA (v24.0) 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.
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(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s130 all 6m2 ped6

Table 33. Number (%) of Subjects Reporting at Least 1 New Adverse Event After the EUA Snapshot, From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1113)			
	Dose 1 to 1 Month After Dose 2		1 Month After Dose 2 to 6 Months After Dose 2	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	6 (0.5)	(0.2, 1.2)	32 (2.9)	(2.0, 4.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Syringomyelia	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
EYE DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Eye pain	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.3)	3 (0.3)	(0.1, 0.8)
Abdominal pain upper	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Aphthous ulcer	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Constipation	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Nausea	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Chills	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Fatigue	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Injection site pain	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Injection site swelling	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Pyrexia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Seasonal allergy	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
INFECTIONS AND INFESTATIONS	0	(0.0, 0.3)	4 (0.4)	(0.1, 0.9)
Anal abscess	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Appendicitis	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Paronychia	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Pilonidal cyst	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.3)	6 (0.5)	(0.2, 1.2)
Procedural pain	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.6)
Bone contusion	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)

Table 33. Number (%) of Subjects Reporting at Least 1 New Adverse Event After the EUA Snapshot, From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1113)			
	Dose 1 to 1 Month After Dose 2		1 Month After Dose 2 to 6 Months After Dose 2	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Femur fracture	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Hand fracture	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Meniscus injury	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Upper limb fracture	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
INVESTIGATIONS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
SARS-CoV-2 antibody test positive	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Musculoskeletal chest pain	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.3)	4 (0.4)	(0.1, 0.9)
Presyncope	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.6)
Migraine	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Syncope	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
PSYCHIATRIC DISORDERS	1 (0.1)	(0.0, 0.5)	10 (0.9)	(0.4, 1.6)
Anxiety	1 (0.1)	(0.0, 0.5)	3 (0.3)	(0.1, 0.8)
Depression	0	(0.0, 0.3)	4 (0.4)	(0.1, 0.9)
Attention deficit hyperactivity disorder	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.6)
Suicidal ideation	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.6)
Panic attack	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Amenorrhoea	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Nasal congestion	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Rhinorrhoea	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Sneezing	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Acne	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)

Table 33. Number (%) of Subjects Reporting at Least 1 New Adverse Event After the EUA Snapshot, From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1113)			
	Dose 1 to 1 Month After Dose 2		1 Month After Dose 2 to 6 Months After Dose 2	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dermatitis contact	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Wisdom teeth removal	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)

Abbreviation: EUA = emergency use authorization.
Note: EUA snapshot 25Mar2021 with the cutoff date 13Mar2021.
Note: MedDRA (v24.0) 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (09:45)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s132_6m2_ped6

12.2.3.4.3. New Related Adverse Events After the EUA Snapshot by System Organ Class and Preferred Term – Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Recipients 12 Through 15 Years of Age

There were few new related AEs reported, and most of these events were reactogenicity (Table 34). One (1) participant in the BNT162b2 group reported musculoskeletal chest pain, which is discussed in Section 12.2.1.6.3.

Table 34. Number (%) of Subjects Reporting at Least 1 New Related Adverse Event After the EUA Snapshot, From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	3 (0.3)	(0.1, 0.8)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.1)	(0.0, 0.5)
Chills	1 (0.1)	(0.0, 0.5)
Fatigue	1 (0.1)	(0.0, 0.5)
Injection site pain	1 (0.1)	(0.0, 0.5)
Injection site swelling	1 (0.1)	(0.0, 0.5)
Pyrexia	1 (0.1)	(0.0, 0.5)
INVESTIGATIONS	1 (0.1)	(0.0, 0.5)
SARS-CoV-2 antibody test positive	1 (0.1)	(0.0, 0.5)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.1)	(0.0, 0.5)
Musculoskeletal chest pain	1 (0.1)	(0.0, 0.5)

Abbreviation: EUA = emergency use authorization.
Note: EUA snapshot 25Mar2021 with the cutoff date 13Mar2021.
Note: MedDRA (v24.0) 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (09:51)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s130_rel_6m2_ped6

12.2.4. Open-Label Follow-Up Period From Dose 3 to the Data Cutoff Date – Original Placebo Recipients 12 Through 15 Years of Age Who Then Received BNT162b2 After Unblinding

12.2.4.1. Summary of Adverse Events – Open-Label Follow-Up Period – Original Placebo Recipients 12 Through 15 Years of Age Who Then Received BNT162b2 After Unblinding

An overview of AEs for 1,010 original placebo recipients who then were unblinded and received BNT162b2 to the data cutoff date during the open-label follow-up period is presented in Table 35.

The total exposure time is shorter among the original placebo recipients who received BNT162b2 after unblinding than those who originally received BNT162b2 (2.9 per 100 PY vs 4.6 per 100 PY, respectively [Table 35 and Table 18]).

After participants who originally received placebo were unblinded and then received BNT162b2 after unblinding, events related to reactogenicity were not reported using an e-diary but were instead reported as AEs. Because an e-diary was not used after original placebo recipients received open-label BNT162b2, in comparison to participants randomized to BNT162b2 from Dose 1 to the unblinding date, the frequencies for any AE and at least 1 related AE for participants who originally received placebo and then received BNT162b2 are greater (26.2% and 24.0%) than the frequencies (8.4% and 3.2%) for participants who originally received BNT162b2, respectively (Table 35 and Table 18). However, the frequencies for severe, life-threatening AE, SAE, AEs leading to withdrawal and deaths were similar (1.2%, 0%, 0.6%, 0%, 0% [Table 35] versus 1.1%, 0.2%, 0.9%, 0.1%, 0% [Table 18], respectively). There was 1 related SAE of appendicitis for a placebo recipient who was vaccinated with BNT162b2 (see Section 12.3.2.4).

Table 35. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (02SEP2021) – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1010, TE[b]=2.9)		
Adverse Event	n[c] (%)	IR[d]	(95% CI[e])
Any event	265 (26.2)	90.3	(79.7, 101.8)
Related[f]	242 (24.0)	82.5	(72.4, 93.5)
Severe	12 (1.2)	4.1	(2.1, 7.1)
Life-threatening	0	0.0	(0.0, 1.3)
Any serious adverse event	6 (0.6)	2.0	(0.8, 4.4)

Table 35. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (02SEP2021) – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1010, TE[b]=2.9)		
Adverse Event	n[c] (%)	IR[d]	(95% CI[e])
Related[f]	1 (0.1)	0.3	(0.0, 1.9)
Severe	3 (0.3)	1.0	(0.2, 3.0)
Life-threatening	0	0.0	(0.0, 1.3)
Any nonserious adverse event	262 (25.9)	89.3	(78.8, 100.8)
Related[f]	241 (23.9)	82.1	(72.1, 93.2)
Severe	9 (0.9)	3.1	(1.4, 5.8)
Life-threatening	0	0.0	(0.0, 1.3)
Any adverse event leading to withdrawal	0	0.0	(0.0, 1.3)
Related[f]	0	0.0	(0.0, 1.3)
Severe	0	0.0	(0.0, 1.3)
Life-threatening	0	0.0	(0.0, 1.3)
Death	0	0.0	(0.0, 1.3)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:31)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/adae s092 cut1 ped6

12.2.4.2. Adverse Events by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Original Placebo Recipients Who Then Received BNT162b2 After Unblinding – Participants 12 Through 15 Years of Age

From vaccination with BNT162b2 for placebo participants to the data cutoff date (open-label follow-up period), 265 (26.2%) of BNT162b2 participants reported at least 1 AE (Table 36).

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

- general disorders and administration site conditions (225 [22.3%])
- nervous system disorders (75 [7.4%])
- musculoskeletal and connective tissue disorders (48 [4.8%])
- gastrointestinal disorders (20 [2.0%])

As shown in Table 36, the most frequently reported AEs overall were injection site pain (15.5%), fatigue (10.3%), headache (7.0%), pyrexia (6.3%), chills (4.5%), myalgia (3.8%), pain (3.5%), nausea (1.2%), pain in extremity (0.9%), vomiting (0.7%), malaise (0.7%), and injection site erythema (0.5%).

Table 36. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (02SEP2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1010, TE[b]=2.9)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])
Any event	265 (26.2)	90.3	(79.7, 101.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	2 (0.2)	0.7	(0.1, 2.5)
Lymphadenitis	1 (0.1)	0.3	(0.0, 1.9)
Lymphadenopathy	1 (0.1)	0.3	(0.0, 1.9)
CARDIAC DISORDERS	1 (0.1)	0.3	(0.0, 1.9)
Myocarditis	1 (0.1)	0.3	(0.0, 1.9)
EAR AND LABYRINTH DISORDERS	2 (0.2)	0.7	(0.1, 2.5)
Ear pain	1 (0.1)	0.3	(0.0, 1.9)
Motion sickness	1 (0.1)	0.3	(0.0, 1.9)
ENDOCRINE DISORDERS	1 (0.1)	0.3	(0.0, 1.9)
Autoimmune thyroiditis	1 (0.1)	0.3	(0.0, 1.9)
Thyroid mass	1 (0.1)	0.3	(0.0, 1.9)
GASTROINTESTINAL DISORDERS	20 (2.0)	6.8	(4.2, 10.5)
Abdominal pain upper	2 (0.2)	0.7	(0.1, 2.5)
Diarrhoea	1 (0.1)	0.3	(0.0, 1.9)
Nausea	12 (1.2)	4.1	(2.1, 7.1)
Tooth impacted	1 (0.1)	0.3	(0.0, 1.9)
Vomiting	7 (0.7)	2.4	(1.0, 4.9)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	225 (22.3)	76.7	(67.0, 87.4)
Adverse drug reaction	1 (0.1)	0.3	(0.0, 1.9)

Table 36. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (02SEP2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1010, TE[b]=2.9)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])
Axillary pain	1 (0.1)	0.3	(0.0, 1.9)
Chest discomfort	1 (0.1)	0.3	(0.0, 1.9)
Chest pain	1 (0.1)	0.3	(0.0, 1.9)
Chills	45 (4.5)	15.3	(11.2, 20.5)
Fatigue	104 (10.3)	35.4	(29.0, 42.9)
Injection site bruising	3 (0.3)	1.0	(0.2, 3.0)
Injection site erythema	5 (0.5)	1.7	(0.6, 4.0)
Injection site hypoaesthesia	1 (0.1)	0.3	(0.0, 1.9)
Injection site pain	157 (15.5)	53.5	(45.5, 62.5)
Injection site reaction	1 (0.1)	0.3	(0.0, 1.9)
Injection site swelling	4 (0.4)	1.4	(0.4, 3.5)
Malaise	7 (0.7)	2.4	(1.0, 4.9)
Non-cardiac chest pain	1 (0.1)	0.3	(0.0, 1.9)
Pain	35 (3.5)	11.9	(8.3, 16.6)
Pyrexia	64 (6.3)	21.8	(16.8, 27.8)
Thirst	1 (0.1)	0.3	(0.0, 1.9)
IMMUNE SYSTEM DISORDERS	1 (0.1)	0.3	(0.0, 1.9)
Food allergy	1 (0.1)	0.3	(0.0, 1.9)
INFECTIONS AND INFESTATIONS	12 (1.2)	4.1	(2.1, 7.1)
Appendicitis	1 (0.1)	0.3	(0.0, 1.9)
Cellulitis	1 (0.1)	0.3	(0.0, 1.9)
Ear infection	2 (0.2)	0.7	(0.1, 2.5)
Hand-foot-and-mouth disease	1 (0.1)	0.3	(0.0, 1.9)
Herpes zoster	1 (0.1)	0.3	(0.0, 1.9)
Otitis externa	1 (0.1)	0.3	(0.0, 1.9)
Otitis media	1 (0.1)	0.3	(0.0, 1.9)
Paronychia	1 (0.1)	0.3	(0.0, 1.9)
Pharyngitis streptococcal	1 (0.1)	0.3	(0.0, 1.9)
Sinusitis	1 (0.1)	0.3	(0.0, 1.9)
Skin candida	1 (0.1)	0.3	(0.0, 1.9)
Tinea infection	1 (0.1)	0.3	(0.0, 1.9)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	11 (1.1)	3.7	(1.9, 6.7)

Table 36. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (02SEP2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1010, TE[b]=2.9)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])
Arthropod bite	1 (0.1)	0.3	(0.0, 1.9)
Concussion	1 (0.1)	0.3	(0.0, 1.9)
Facial bones fracture	1 (0.1)	0.3	(0.0, 1.9)
Hand fracture	1 (0.1)	0.3	(0.0, 1.9)
Hyphaema	1 (0.1)	0.3	(0.0, 1.9)
Joint injury	1 (0.1)	0.3	(0.0, 1.9)
Ligament rupture	1 (0.1)	0.3	(0.0, 1.9)
Ligament sprain	1 (0.1)	0.3	(0.0, 1.9)
Meniscus injury	1 (0.1)	0.3	(0.0, 1.9)
Muscle strain	1 (0.1)	0.3	(0.0, 1.9)
Sports injury	1 (0.1)	0.3	(0.0, 1.9)
Sunburn	1 (0.1)	0.3	(0.0, 1.9)
Traumatic renal injury	1 (0.1)	0.3	(0.0, 1.9)
Wound	1 (0.1)	0.3	(0.0, 1.9)
INVESTIGATIONS	3 (0.3)	1.0	(0.2, 3.0)
Body temperature increased	3 (0.3)	1.0	(0.2, 3.0)
METABOLISM AND NUTRITION DISORDERS	3 (0.3)	1.0	(0.2, 3.0)
Decreased appetite	1 (0.1)	0.3	(0.0, 1.9)
Glucose tolerance impaired	1 (0.1)	0.3	(0.0, 1.9)
Vitamin D deficiency	2 (0.2)	0.7	(0.1, 2.5)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	48 (4.8)	16.4	(12.1, 21.7)
Arthralgia	2 (0.2)	0.7	(0.1, 2.5)
Musculoskeletal chest pain	1 (0.1)	0.3	(0.0, 1.9)
Musculoskeletal stiffness	1 (0.1)	0.3	(0.0, 1.9)
Myalgia	38 (3.8)	12.9	(9.2, 17.8)
Neck pain	1 (0.1)	0.3	(0.0, 1.9)
Pain in extremity	9 (0.9)	3.1	(1.4, 5.8)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.1)	0.3	(0.0, 1.9)
Skin papilloma	1 (0.1)	0.3	(0.0, 1.9)
NERVOUS SYSTEM DISORDERS	75 (7.4)	25.6	(20.1, 32.0)
Dizziness	4 (0.4)	1.4	(0.4, 3.5)

Table 36. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (02SEP2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1010, TE[b]=2.9)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])
Epilepsy	1 (0.1)	0.3	(0.0, 1.9)
Headache	71 (7.0)	24.2	(18.9, 30.5)
Somnolence	1 (0.1)	0.3	(0.0, 1.9)
Syncope	1 (0.1)	0.3	(0.0, 1.9)
PSYCHIATRIC DISORDERS	1 (0.1)	0.3	(0.0, 1.9)
Major depression	1 (0.1)	0.3	(0.0, 1.9)
RENAL AND URINARY DISORDERS	1 (0.1)	0.3	(0.0, 1.9)
Dysuria	1 (0.1)	0.3	(0.0, 1.9)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (0.3)	1.0	(0.2, 3.0)
Cough	1 (0.1)	0.3	(0.0, 1.9)
Nasal congestion	1 (0.1)	0.3	(0.0, 1.9)
Rhinorrhoea	1 (0.1)	0.3	(0.0, 1.9)
Upper-airway cough syndrome	1 (0.1)	0.3	(0.0, 1.9)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	5 (0.5)	1.7	(0.6, 4.0)
Hyperhidrosis	1 (0.1)	0.3	(0.0, 1.9)
Ingrowing nail	2 (0.2)	0.7	(0.1, 2.5)
Photosensitivity reaction	1 (0.1)	0.3	(0.0, 1.9)
Urticaria	1 (0.1)	0.3	(0.0, 1.9)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:31)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s131_cut1_ped6

An analysis was conducted to evaluate if the imbalance in AEs (higher frequencies of some PTs relative to others) observed from Dose 3 to the data cutoff date was attributed to reactogenicity events. The analysis examined the AEs reported within 7 days after each dose (Dose 3 and Dose 4 [first and second dose of BNT162b2 30 µg]), which represented the reactogenicity reporting period.

PTs reported from Dose 3 to 7 days after Dose 3 and from Dose 4 to 7 days after Dose 4 in the SOCs of general disorders and administration site conditions (injection site pain, fatigue, chills, pyrexia, and pain), nervous system disorders (headache), musculoskeletal and connective tissue disorders (myalgia), and gastrointestinal disorders (nausea) represented the majority of PTs reported in those SOCs (Supplemental Tables 14.39 and 14.40).

An SAE of myocarditis was reported in 1 participant within 7 days after Dose 4 (Supplemental Table 14.40 and Appendix 16.2.7.2.1) (previously reported to CBER and discussed by the ACIP). Full details are disussed in Section 12.3.4.1.

In addition to analysis of AEs corresponding to e-diary terms, consideration was given to additional AEs that were reported within 7 days after Dose 3 or Dose 4 such as but not limited to pain in extremity, decreased appetite, malaise, and hyperhidrosis. Similar to the analysis that examined these events 7 days within Dose 1 and Dose 2 of BNT162b2 in blinded placebo-controlled follow-up (adolescent interim CSR, dated 14 April 2021, Section 12.3.2.1.1.1), these events reported in open-label follow-up are interpreted as largely attributable to the experience of local reactions and systemic events after vaccination with Dose 3 and Dose 4 (first and second dose of BNT162b2).

12.2.4.3. Related Adverse Events by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Original Placebo Recipients Who Then Received BNT162b2 – Participants 12 Through 15 Years of Age

From vaccination with BNT162b2 to the data cutoff date (open-label follow-up period) for original placebo recipients who then received BNT162b2 after unblinding, 242 (24.0%) experienced AEs that were assessed as related by the investigator (Supplemental Table 14.41). Related AEs were highest for reactogenicity events and in the SOC of general disorders and administration site conditions (223 [22.1%]) for the following PTs:

- injection site pain (157 [15.5%])
- fatigue (104 [10.3%])
- pyrexia (63 [6.2%])
- chills (45 [4.5%])

Frequently reported related AEs also included PTs of headache 70 (6.9%) and myalgia 37 (3.7%).

Related events of lymphadenitis and appendicitis were reported in 1 participant each:

- One participant experienced a nonserious adverse event of lymphadenitis (right axillary adenitis) on Day 6 after Dose 3. It was moderate in severity, lasted for 24 days, and then resolved (Appendix 16.2.7.2.1).

- See Section 12.3.2.4 for details on related SAE of appendicitis.

12.2.4.4. Immediate Adverse Events – Open-Label Follow-Up Period – Original Placebo Recipients Who Then Received BNT162b2 – Participants 12 Through 15 Years of Age

After vaccination with BNT162b2 (Dose 3/4), 7 (0.7%) placebo adolescent recipients who received BNT162b2 after unblinding reported immediate AEs. Most AEs reported were injection site pain for 6 (0.6%) participants, and 1 (0.1%) participant reported injection site erythema (Supplemental Table 14.42).

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

12.2.4.5. Severe or Life-Threatening Adverse Events – Open-Label Follow-Up Period – Original Placebo Recipients Who Then Received BNT162b2 – Participants 12 Through 15 Years of Age

From vaccination with BNT162b2 to the data cutoff date (open-label follow-up period) for original placebo recipients who then received BNT162b2 after unblinding, 12 (1.2%) reported severe AEs (Supplemental Table 14.43). Three (3) participants reported pyrexia, 2 reported fatigue, and 1 reported malaise (all PTs in the general disorders and administration site conditions SOC), and 1 participant reported myalgia (musculoskeletal and connective tissue disorders SOC), all of which are terms that are consistent with reactogenicity.

One participant experienced a severe SAE of myocarditis (see Section 12.3.2.4).

There were no life-threatening AEs reported from vaccination with BNT162b2 to the data cutoff date (Table 35).

12.3. Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events – Participants 12 Through 15 Years of Age

12.3.1. Deaths

There were no deaths reported for adolescent participants as of the data cutoff date (02 September 2021) (Appendix 16.2.7.7).

12.3.2. Serious Adverse Events – Participants 12 Through 15 Years of Age

12.3.2.1. Blinded Placebo-Controlled Follow-Up From Dose 1 to the Unblinding Date - Participants 12 Through 15 Years of Age

From Dose 1 to the unblinding date, there were 10 (0.9%) and 2 (0.2%) adolescent participants who reported at least 1 SAE in the BNT162b2 and placebo groups, respectively

(Table 37). All SAEs were assessed by the investigator as not related to study intervention (Table 18).

Certain SAEs discussed below (Appendix 16.2.7.2.1) were previously reported in the adolescent interim CSR, dated 14 April 2021:

- One participant in the placebo group reported a life-threatening (Grade 4) SAE each of focal peritonitis and appendicitis concurrently on Day 19 after Dose 2 with a duration of 2 days, and the event was assessed by the investigator as not related to study intervention. Both events were resolved, and the participant continued in the study.

- One participant reported an SAE each of anxiety and depression (both severe) reported concurrently on Day 8 after Dose 1 with a duration of 27 days, and both events were assessed by the investigator as not related to study intervention. This was a worsening of pre-existing anxiety and depression in a 13-year-old female. The participant had an extensive psychiatric past medical history of attention deficit hyperactivity disorder and separation anxiety disorder from 2010, disruptive mood dysregulation disorder since 2012, depression, anxiety, and recurring insomnia from 2014, post traumatic stress disorder and recurring nightmares since 2015 and aggressive behaviours in 2017. The participant had been prescribed duloxetine hydrochloride and citalopram hydrobromide for depression since October 2019 and October 2020 respectively, however these were both stopped during this event, and the participant was prescribed aripiprazole and venlafaxine to manage this event. Both events resolved and the participant continued in the study. No further exacerbations were reported after receiving Dose 2.

- One participant reported an SAE of suicidal ideation on Day 40 after Dose 2 with a duration of 28 days, and the event was assessed by the investigator as not related to study intervention. This 14-year-old female had a past medical history of attention deficit hyperactivity disorder since 2015, and anxiety and depression since 2020. The participant had been prescribed methylphenidate hydrochloride for attention hyperactivity disorder; this was changed to dexmethylphenidate hydrochloride extended release approximately 22 days before being hospitalized for this event. After discharge the participant has continued an extensive outpatient therapy program, combined with fluoxetine. The event resolved and the participant continued in the study.

- One participant reported a severe SAE of depression on Day 16 after Dose 1 with a duration of 5 days, and the event was assessed by the investigator as not related to study intervention. This was a worsening of pre-existing depression in a 15-year-old male. The participant had a past medical history of attention deficit hyperactivity disorder, depression, and anxiety from 2018. The participant had been prescribed escitalopram oxalate for depression/anxiety from December 2020 which was stopped during this event and the participant was prescribed fluvoxamine and risperidone to manage the event. The event was reported as an SAE, resolved, and the participant continued in the study. This participant reported another severe SAE of depression, which occurred after the EUA snapshot (second SAE discussed in Section 12.3.2.1.2).

Table 37. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1131, TE[b]=4.6)			Placebo (N[a]=1129, TE[b]=4.5)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	10 (0.9)	2.2	(1.0, 4.0)	2 (0.2)	0.4	(0.1, 1.6)
GASTROINTESTINAL DISORDERS	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Abdominal pain	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Constipation	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
INFECTIONS AND INFESTATIONS	1 (0.1)	0.2	(0.0, 1.2)	2 (0.2)	0.4	(0.1, 1.6)
Anal abscess	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Appendicitis	0	0.0	(0.0, 0.8)	2 (0.2)	0.4	(0.1, 1.6)
Focal peritonitis	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Femur fracture	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
PSYCHIATRIC DISORDERS	8 (0.7)	1.7	(0.8, 3.4)	0	0.0	(0.0, 0.8)
Anxiety	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Conversion disorder	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Depression	3 (0.3)	0.7	(0.1, 1.9)	0	0.0	(0.0, 0.8)
Suicidal ideation	4 (0.4)	0.9	(0.2, 2.2)	0	0.0	(0.0, 0.8)

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:21)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s131 sae unb1 ped6

12.3.2.1.1. Subgroup Analyses

There were 10 (0.9%) and 2 (0.2%) adolescent participants who reported at least 1 SAE in the BNT162b2 and placebo groups, respectively (Table 37). Overall, no clinically meaningful differences in frequencies of SAEs were observed by baseline SARS-CoV-2

status, ethnicity, race, or sex subgroups. IRs and frequencies of at least 1 SAE from Dose 1 to the unblinding date by SOC and PT and by subgroup are presented in the following tables:

Baseline SARS-CoV-2 Status: Negative	Supplemental Table 14.44
Ethnicity: Hispanic/Latino	Supplemental Table 14.45
Ethnicity: Non-Hispanic/Non-Latino	Supplemental Table 14.46
Race: White	Supplemental Table 14.47
Race: Black or African American	Supplemental Table 14.48
Race: All Others	Supplemental Table 14.49
Sex: Male	Supplemental Table 14.50
Sex: Female	Supplemental Table 14.51

12.3.2.1.2. New Serious Adverse Events After the EUA Snapshot

There were 6 (0.5%) adolescent participants in the BNT162b2 group who reported an SAE after the EUA snapshot, and none were reported in the placebo group (Table 38).

Certain SAEs are discussed below (Appendix 16.2.7.4):

One participant reported a second severe SAE of depression on Day 57 after Dose 2 with a duration of 5 days, and the event was assessed by the investigator as not related to study intervention. The first SAE is discussed in Section 12.3.2.1, which was also previously reported in the adolescent interim CSR, dated 14 April 2021. This was a second episode of worsening of pre-existing depression in a 15-year-old male. The participant had a past medical history of attention deficit hyperactivity disorder, depression, and anxiety from 2018 (Appendix 16.2.5.4). They had been prescribed fluvoxamine and risperidone to manage the previously reported event (discussed in Section 12.3.2.1). The event was reported as resolved, and the participant continued in the study.

One participant reported a severe SAE of suicidal ideation on Day 76 after Dose 2 with a duration of 2 days, and the event was assessed by the investigator as not related to study intervention. This 15-year-old male had a past medical history of anxiety and depression since March 2020, and had been prescribed fluoxetine for the depression. They were hospitalized with suicidal ideation for 2 days, after discharge they continued an intensive outpatient therapy program, combined with escitalopram oxalate and hydroxyzine. The event was resolved, and the participant continued in the study.

One participant in the BNT162b2 group reported a life-threatening (Grade 4) SAE of suicidal ideation on Day 70 after Dose 2 with a duration of 10 days, and the event was assessed by the investigator as not related to study intervention. This 14 year-old female participant (aged 13 when initially enrolled) had a past medical history of anxiety since 2018, major depression since 2018 for which they were hospitalized in November 2020, and post traumatic stress disorder since 2020. They had been prescribed sertraline hydrochloride for anxiety/depression from 2019. After being discharged from the hospital, the participant has

continued with outpatient treatment including an increase in the dose of sertraline and additional aripiprazole. The event was resolved, and the participant continued in the study.

One participant in the BNT162b2 group reported a moderate SAE of suicidal ideation on Day 44 after Dose 2 with a duration of 5 days. The event was reported as resolved, and the participant continued in the study.

One participant in the BNT162b2 group reported a severe SAE of anal abscess on Day 78 after Dose 2, and the event was recovering/resolving as of the data cutoff date.

Overall, all SAEs occurred long after vaccination.

Table 38. Number (%) of Subjects Reporting at Least 1 New Serious Adverse Event After the EUA Snapshot, From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1130)		Placebo (N[a]=1126)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	6 (0.5)	(0.2, 1.2)	0	(0.0, 0.3)
INFECTIONS AND INFESTATIONS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Anal abscess	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Femur fracture	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
PSYCHIATRIC DISORDERS	4 (0.4)	(0.1, 0.9)	0	(0.0, 0.3)
Suicidal ideation	3 (0.3)	(0.1, 0.8)	0	(0.0, 0.3)
Depression	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)

Abbreviation: EUA = emergency use authorization.
Note: MedDRA (v24.0) 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, subjects who withdrew from the study before EUA snapshot 25Mar2021 with the cutoff date 13Mar2021 are not included. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (09:47)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/adae s130 sae unb2 ped6

12.3.2.2. Open-Label Follow-Up Period – Original BNT162b2 Recipients 12 Through 15 Years of Age

From unblinding date to the data cutoff date, 4 (0.4%) original BNT162b2 adolescent participants experienced at least 1 SAE (Supplemental Table 14.52). Of these, 2 participants experienced appendicitis long after vaccination from Dose 2 (Day 148 and Day 177) (infections and infestations SOC); both events were assessed by the investigator as not related (Appendix 16.2.7.4).

12.3.2.3. Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Recipients 12 Through 15 Years of Age

From Dose 1 to 6 months after Dose 2, during the blinded placebo-controlled and open-label follow-up periods, 10 (0.9%) adolescent participants who originally received BNT162b2 reported at least 1 SAE (Table 39).

Comparison of SAEs reported from Dose 1 to 1 month after Dose 2 to SAEs reported from 1 month after Dose 2 to 6 months after Dose 2 shows that the frequency of SAEs was 0.3% and 0.8%, respectively (Table 40). The frequency of SAEs reported in the psychiatric disorders SOC was similar from Dose 1 to 1 month after Dose 2 versus 1 month after Dose 2 to 6 months after Dose 2.

Table 39. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	10 (0.9)	(0.4, 1.6)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.1)	(0.0, 0.5)
Syringomyelia	1 (0.1)	(0.0, 0.5)
GASTROINTESTINAL DISORDERS	1 (0.1)	(0.0, 0.5)
Abdominal pain	1 (0.1)	(0.0, 0.5)
Constipation	1 (0.1)	(0.0, 0.5)
INFECTIONS AND INFESTATIONS	2 (0.2)	(0.0, 0.6)
Anal abscess	1 (0.1)	(0.0, 0.5)

Table 39. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Appendicitis	1 (0.1)	(0.0, 0.5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.1)	(0.0, 0.5)
Femur fracture	1 (0.1)	(0.0, 0.5)
PSYCHIATRIC DISORDERS	6 (0.5)	(0.2, 1.2)
Suicidal ideation	3 (0.3)	(0.1, 0.8)
Depression	2 (0.2)	(0.0, 0.6)
Conversion disorder	1 (0.1)	(0.0, 0.5)

Note: MedDRA (v24.0) 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:31)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s130 ser 6m1 ped6

Table 40. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (Na=1113)			
	Dose 1 to 1 Month After Dose 2		1 Month After Dose 2 to 6 Months After Dose 2	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	3 (0.3)	(0.1, 0.8)	9 (0.8)	(0.4, 1.5)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Syringomyelia	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
GASTROINTESTINAL DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Abdominal pain	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Constipation	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
INFECTIONS AND INFESTATIONS	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.6)
Anal abscess	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Appendicitis	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Femur fracture	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
PSYCHIATRIC DISORDERS	3 (0.3)	(0.1, 0.8)	4 (0.4)	(0.1, 0.9)
Suicidal ideation	0	(0.0, 0.3)	3 (0.3)	(0.1, 0.8)
Depression	2 (0.2)	(0.0, 0.6)	1 (0.1)	(0.0, 0.5)
Conversion disorder	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)

Note: MedDRA (v24.0) 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:22)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s132_ser_6m1_ped6

12.3.2.3.1. New Serious Adverse Events After the EUA Snapshot

For original BNT162b2 adolescent recipients with at least 6 months of follow-up time after Dose 2, there were 7 (0.6%) new SAEs reported after the EUA snapshot (Table 41), and all

of the SAEs were reported from 1 month after Dose 2 to 6 months after Dose 2 (Table 42; also discussed in Section 12.2.3.4.1).

Table 41. Number (%) of Subjects Reporting at Least 1 New Serious Adverse Event After the EUA Snapshot, From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	7 (0.6)	(0.3, 1.3)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.1)	(0.0, 0.5)
Syringomyelia	1 (0.1)	(0.0, 0.5)
INFECTIONS AND INFESTATIONS	2 (0.2)	(0.0, 0.6)
Anal abscess	1 (0.1)	(0.0, 0.5)
Appendicitis	1 (0.1)	(0.0, 0.5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.1)	(0.0, 0.5)
Femur fracture	1 (0.1)	(0.0, 0.5)
PSYCHIATRIC DISORDERS	3 (0.3)	(0.1, 0.8)
Suicidal ideation	2 (0.2)	(0.0, 0.6)
Depression	1 (0.1)	(0.0, 0.5)

Abbreviation: EUA = emergency use authorization.
Note: EUA snapshot 25Mar2021 with the cutoff date 13Mar2021.
Note: MedDRA (v24.0) 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (09:50)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s130 ser 6m2 ped6

Table 42. Number (%) of Subjects Reporting at Least 1 New Serious Adverse Event After the EUA Snapshot, From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term and Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (Na=1113)			
	Dose 1 to 1 Month After Dose 2		1 Month After Dose 2 to 6 Months After Dose 2	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	0	(0.0, 0.3)	7 (0.6)	(0.3, 1.3)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Syringomyelia	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
INFECTIONS AND INFESTATIONS	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.6)
Anal abscess	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Appendicitis	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Femur fracture	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
PSYCHIATRIC DISORDERS	0	(0.0, 0.3)	3 (0.3)	(0.1, 0.8)
Suicidal ideation	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.6)
Depression	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)

Abbreviation: EUA = emergency use authorization.
Note: EUA snapshot 25Mar2021 with the cutoff date 13Mar2021.
Note: MedDRA (v24.0) 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (09:46)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s132 ser 6m2 ped6

12.3.2.4. Open-Label Follow-Up Period – Original Placebo Recipients Who Then Received BNT162b2 After Unblinding

From Dose 3 (first dose of BNT162b2) to the data cutoff date, 6 (0.6%) adolescent participants who originally received placebo then received BNT162b2 after unblinding

reported at least 1 SAE (Table 43). Narratives for participants with reported SAEs are located in Section 14 Narratives.

1 SAE, appendicitis, was assessed by the investigator as related to study intervention (Appendix 16.2.7.4). The event of appendicitis occurred in a 13-year-old female (aged 12 years when initially enrolled) on Day 4 after Dose 4 (second dose of BNT162b2), an ultrasound performed in the hospital confirmed the diagnosis, as did macroscopic inspection of the appendix during surgery and the pathology report received post appendectomy. The event lasted for 1 day, as the participant underwent surgery and was considered resolved post surgery.

1 SAE, epilepsy, was assessed by the investigator as not related to study intervention (Appendix 16.2.7.4). This event occurred in a 12-year-old male on Day 8 after Dose 4, there was no past medical history of febrile seizures in early childhood, however, there was a positive family history of epilepsy (b) (6)). The diagnosis of epilepsy was confirmed by electroencephalogram, the participant was not prescribed any medication and remains on neurology follow-up. There have been no further seizures upon continued follow-up with the participant.

An SAE of myocarditis was reported in a 16-year-old male participant who experienced chest pain on Day 3 after Dose 2 of BNT162b2 (previously reported to CBER and discussed by ACIP). Full details are discussed in Section 12.3.4.1.

Table 43. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (02SEP2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1010, TE[b]=2.9)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])
Any event	6 (0.6)	2.0	(0.8, 4.4)
CARDIAC DISORDERS	1 (0.1)	0.3	(0.0, 1.9)
Myocarditis	1 (0.1)	0.3	(0.0, 1.9)
INFECTIONS AND INFESTATIONS	1 (0.1)	0.3	(0.0, 1.9)
Appendicitis	1 (0.1)	0.3	(0.0, 1.9)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.1)	0.3	(0.0, 1.9)
Traumatic renal injury	1 (0.1)	0.3	(0.0, 1.9)
NERVOUS SYSTEM DISORDERS	2 (0.2)	0.7	(0.1, 2.5)

Table 43. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (02SEP2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1010, TE[b]=2.9)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])
Epilepsy	1 (0.1)	0.3	(0.0, 1.9)
Somnolence	1 (0.1)	0.3	(0.0, 1.9)
PSYCHIATRIC DISORDERS	1 (0.1)	0.3	(0.0, 1.9)
Major depression	1 (0.1)	0.3	(0.0, 1.9)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:31)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s131 ser cut1 ped6

12.3.3. Safety-Related Participant Withdrawals

12.3.3.1. Blinded Placebo-Controlled Follow-Up From Dose 1 to the Unblinding Date - Participants 12 Through 15 Years of Age

From Dose 1 to the unblinding date, 1 (0.1%) participant in the BNT162b2 group had an AE of pyrexia leading to withdrawal that was assessed by the investigator as related to study intervention (previously reported in Section 12.3.2.4.1 of the adolescent interim CSR dated 14 April 2021; Supplemental Table 14.53).

12.3.3.2. Open-Label Follow-Up Period – Original BNT162b2 Recipients 12 Through 15 Years of Age

From the unblinding date to the data cutoff date, there were no original BNT162b2 adolescent participants who were withdrawn because of AEs (Table 25).

12.3.3.3. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Recipients 12 Through 15 Years of Age

From Dose 1 to 6 months after Dose 2 during the blinded placebo-controlled and open-label follow-up periods, there were no adolescent participants with at least 6 months of follow-up time after Dose 2 who were withdrawn because of AEs (Table 26).

12.3.3.4. Open-Label Follow-Up Period – Original Placebo Recipients 12 Through 15 Years of Age Who Then Received BNT162b2 After Unblinding

From Dose 3 (first dose of BNT162b2 30 µg) administration to the data cutoff date, there were no original placebo adolescent participants who were withdrawn because of AEs (Table 35).

12.3.4. Other Significant Adverse Events

AEs 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). AEs of clinical interest occurring in the adolescent group were reviewed for the blinded placebo-controlled period.

12.3.4.1. FDA-Requested Adverse Events of Clinical Interest

No cases of anaphylaxis, hypersensitivity, Bell's palsy, or vaccine-related appendicitis were reported as of the data cutoff date (02 September 2021) during the blinded placebo-controlled period. Other events that were reported in the safety database are summarized below.

Lymphadenopathy

Lymphadenopathy is identified as an adverse reaction for BNT162b2 vaccine.

During the blinded placebo-controlled follow-up period, 9 and 2 participants in the BNT162b2 and placebo groups reported AEs of lymphadenopathy, respectively (Table 44). All events were mild or moderate in severity (only 1 moderate AE in the BNT162b2 group). The majority of these events occurred in the arm and neck region. Median onset was 8.0 days (after Dose 1 but before Dose 2) and 3.0 days (after Dose 2) in the BNT162b2 group and none (after Dose 1 but before Dose 2) and 12.5 days (after Dose 2) in the placebo group. The events resolved with median duration of 6.0 days in the BNT162b2 group and 25.5 days in the placebo group.

Table 44. Subjects Reporting an Adverse Event of Lymphadenopathy – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=9) n[b] (%)	Placebo (N[a]=2) n[b] (%)
Severity		
Mild	8 (88.9)	2 (100.0)
Moderate	1 (11.1)	0
Severe	0	0
Life-threatening	0	0
Onset day after Dose 1 and before Dose 2		
n	5	0
Mean (SD)	8.2 (2.28)	NE (NE)
Median	8.0	NE
Min, max	6 - 12	NE - NE
Onset day after Dose 2		
n	4	2
Mean (SD)	9.0 (12.70)	12.5 (3.54)
Median	3.0	12.5
Min, max	2 - 28	10 - 15
Duration (days)		
n	8	2
Mean (SD)	10.8 (11.03)	25.5 (24.75)
Median	6.0	25.5
Min, max	1 - 29	8 - 43
Unknown[c]	1	0

Abbreviation: NE = not estimable.
Note: For each event, the worst severity, earliest onset, and longest duration will be counted.
a. N = number of subjects reporting lymphadenopathy. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the event.
c. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (21:24)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_lym_unb_1

Appendicitis

During the blinded placebo-controlled follow-up period, 2 participants in the placebo group each had an SAE of appendicitis, and both events were assessed by the investigator as not related to study intervention (Appendix 16.2.7.4).

During the open-label follow-up period:

- Two original BNT162b2 recipients each had an SAE of appendicitis long after vaccination from Dose 2 (Day 148 and Day 177), and both events were assessed by the investigator as not related to study intervention (discussed in Section 12.3.2.2).

- One original placebo recipient had an SAE of appendicitis that was assessed by the investigator as related to study intervention (discussed in Section 12.3.2.4).

Myocarditis/pericarditis

One original placebo participant 16 years of age had an SAE of myocarditis on Day 3 after Dose 2 of BNT162b2 (previously reported to CBER and discussed by ACIP). The participant had been participating in a dance class prior to reporting the symptom and attended the ER the same evening where he was hospitalized for further investigation and treatment. EKG performed and reviewed by a cardiologist showed diffuse ST elevations, and troponin levels were elevated on serial measurements throughout the admission, (maximum measurement was 0.71 ng/mL [normal range 0 to <0.01 ng/mL]). The chest pain was considered by the investigator to be most likely due to an ongoing viral infection, which could have caused myopericarditis. This conclusion was based on the participant's recent history (one week previously) of a temperature of 100.5°F associated with cough and rhinorrhea, and clinical symptoms at the time of the event (temperature 100.1°F; rhinovirus PCR was positive on a respiratory virus panel, but negative for enterovirus and parvovirus B19, SARS-CoV-2 RNA PCR was negative). The chest pain resolved within 24 hours upon receiving ketorolac, and the participant was discharged home after 2 days hospitalization and treatment. Further continuing cardiology follow-up of this participant confirmed that the condition has resolved, and the participant has resumed gym exercises. The investigator considered the event was not related to study intervention. However, Pfizer considers that there is a reasonable possibility that this event is related to the administration of BNT162b2, considering the prior reports of myocarditis/pericarditis in recipients of mRNA vaccines in younger individuals.

12.3.4.2. Other Adverse Events of Special Interest

Additional AEs of clinical interest, including those on the CDC AESI list, were evaluated based on sponsor agent safety data review. These AEs were identified from the C4591001 study database as of the data cutoff date (02 September 2021). From this analysis, notable pertinent negatives (ie, no cases reported in this population as of the data cutoff for this submission) with regard to the CDC list of AESIs included (but were not limited to): thromboembolic or intravascular coagulation events, autoimmune or demyelination events, meningitis, encephalitis, optic neuritis, Kawasaki disease, MIS-C, or acute respiratory distress syndrome.

An analysis of AEs of clinical interest for potential numerical imbalance (based on risk difference >0) between BNT162b2 and placebo SOC and PT as shown in Table 45, with most PTs showing no numerical difference between the BNT162b2 and placebo groups. SOCs which did include PTs more frequently reported after BNT162b2 compared to placebo, or otherwise considered of particular clinical interest, are summarized below.

Table 45. Incidence Rates of at Least 1 Adverse Event of Special Interest From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=1131, TE[b]=4.6)			Placebo (N[a]=1129, TE[b]=4.5)			Difference	
System Organ Class Preferred Term	n[c]	IR[d]	(95% CI[e])	n[c]	IR[d]	(95% CI[e])	IRD[f]	(95% CI[g])
EYE DISORDERS								
Retinal haemorrhage	0	0.0	(0.0, 0.8)	1	0.2	(0.0, 1.2)	-0.22	(-0.66, 0.21)
GASTROINTESTINAL DISORDERS								
Lip swelling	1	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)	0.22	(-0.21, 0.65)
Mouth swelling	1	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)	0.22	(-0.21, 0.65)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS								
Pyrexia	6	1.3	(0.5, 2.9)	0	0.0	(0.0, 0.8)	1.31	(0.26, 2.36)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS								
Bone contusion	1	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)	0.22	(-0.21, 0.65)
Contusion	2	0.4	(0.1, 1.6)	2	0.4	(0.1, 1.6)	-0.01	(-0.87, 0.86)
INVESTIGATIONS								
SARS-CoV-2 antibody test positive	1	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)	0.22	(-0.21, 0.65)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS								
Arthralgia	2	0.4	(0.1, 1.6)	4	0.9	(0.2, 2.3)	-0.45	(-1.51, 0.61)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS								
Epistaxis	0	0.0	(0.0, 0.8)	1	0.2	(0.0, 1.2)	-0.22	(-0.66, 0.21)
Sneezing	1	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)	0.22	(-0.21, 0.65)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS								
Rash	3	0.7	(0.1, 1.9)	5	1.1	(0.4, 2.6)	-0.45	(-1.68, 0.77)
Urticaria	2	0.4	(0.1, 1.6)	5	1.1	(0.4, 2.6)	-0.67	(-1.82, 0.47)

Table 45. Incidence Rates of at Least 1 Adverse Event of Special Interest From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=1131, TE[b]=4.6)			Placebo (N[a]=1129, TE[b]=4.5)			Difference	
System Organ Class Preferred Term	n[c]	IR[d]	(95% CI[e])	n[c]	IR[d]	(95% CI[e])	IRD[f]	(95% CI[g])

Note: MedDRA (v24.0) coding dictionary applied.
Note: The 95% confidence interval quantifies the precision of the incidence rate difference estimate. Confidence intervals are not adjusted for multiplicity. They should only be used to identify potentially important adverse events.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of the blinded follow-up period. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Difference in incidence rate (BNT162b2 [30 µg] - placebo).
g. 2-sided Wald CI for the incidence rate difference.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:41)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s131_sp_unb1_ped6

General Disorders and Administration Site Conditions

There was a numerical difference for events of pyrexia, which was reported by 6 participants in the BNT162b2 group and none in the placebo group (Table 45). These are recognized as reactogenicity events known to be associated with BNT162b2 vaccination.

Arthralgia

There was no imbalance of arthralgia being reported more frequently in the BNT162b2 group. During the blinded placebo-controlled follow-up period, 2 participants (1 moderate and 1 severe) and 4 participants (2 mild and 2 moderate) in the BNT162b2 and placebo groups reported AEs of arthralgia, respectively (Table 46).

Table 46. Subjects Reporting an Adverse Event of Arthralgia – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=2) n[b] (%)	Placebo (N[a]=4) n[b] (%)
Severity		
Mild	0	2 (50.0)
Moderate	1 (50.0)	2 (50.0)
Severe	1 (50.0)	0
Life-threatening	0	0
Onset day after Dose 1 and before Dose 2		
n	2	3
Mean (SD)	3.0 (2.83)	9.0 (6.24)
Median	3.0	7.0
Min, max	1 - 5	4 - 16
Onset day after Dose 2		
n	0	1
Mean (SD)	NE (NE)	131.0 (NE)
Median	NE	131.0
Min, max	NE - NE	131 - 131
Duration (days)		
n	2	4
Mean (SD)	13.0 (16.97)	14.5 (15.59)
Median	13.0	9.5
Min, max	1 - 25	3 - 36

Abbreviation: NE = not estimable.
Note: For each event, the worst severity, earliest onset, and longest duration will be counted.
a. N = number of subjects reporting arthralgia. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the event.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (17:29) Source Data: adae Table Generation: 10NOV2021 (15:42)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/adae arth unb 1

12.3.4.2.1. New Adverse Events of Special Interest After the EUA Snapshot

New AEs of special interest after the EUA snapshot from Dose 1 to the unblinding date during the blinded placebo-controlled follow-up period are presented in Table 47. New AEs reported in adolescents were similar in the BNT162b2 and placebo groups (0.4% each), and PTs were reported in 1 participant each.

Table 47. Number (%) of Subjects Reporting at Least 1 New Adverse Event of Special Interest After the EUA Snapshot, From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=1130)		Placebo (N[a]=1126)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	4 (0.4)	(0.1, 0.9)	5 (0.4)	(0.1, 1.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Pyrexia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Bone contusion	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
Contusion	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
INVESTIGATIONS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
SARS-CoV-2 antibody test positive	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Arthralgia	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.1)	(0.0, 0.5)	1 (0.1)	(0.0, 0.5)
Epistaxis	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Sneezing	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	(0.0, 0.3)	2 (0.2)	(0.0, 0.6)
Rash	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)
Urticaria	0	(0.0, 0.3)	1 (0.1)	(0.0, 0.5)

Abbreviation: EUA = emergency use authorization.
Note: MedDRA (v24.0) 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, subjects who withdrew from the study before EUA snapshot 25Mar2021 with the cutoff date 13Mar2021 are not included. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (09:52)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/adae s130 sp unb2 ped6

12.3.5. Other Safety Assessments

12.3.5.1. Severe COVID-19 Illness

No AEs were reported that suggested any potential cases of severe COVID-19 among adolescent participants as of the data cutoff date (02 September 2021) (Appendix 16.2.7.4).

12.3.5.2. Pregnancy

No pregnancies were reported in adolescent participants as of the data cutoff date (02 September 2021) (Appendix 16.2.7.7).

12.3.6. Analysis and Discussion of Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events – Phase 2/3

Overall, there were no deaths (Appendix 16.2.7.6). There was 1 original placebo recipient who received BNT162b2 after unblinding with an SAE of appendicitis that was assessed by the investigator as related to study intervention (Appendix 16.2.7.4; discussed in Section 12.3.2.4). All other SAEs to date were assessed by the investigator as not related to study intervention. During the blinded placebo-controlled follow-up period, only 1 participant in the BNT162b2 group had an AE of pyrexia leading to withdrawal that was assessed by the investigator as related to study intervention (Appendix 16.2.7.5). There were no other AEs leading to withdrawal during the study.

12.4. Safety Conclusions – Participants 12 Through 15 Years of Age

12.4.1. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date – Participants 12 Through 15 Years of Age

- Most AEs from Dose 1 to the unblinding date were mild or moderate in severity. The frequency of adolescent participants with AEs was similar in the BNT162b2 and placebo groups (8.4% and 10.0%, respectively).

- SAEs were low in frequency in the BNT162b2 and placebo groups (0.9% and 0.2%, respectively). All SAEs were assessed by the investigator as not related to study intervention. One participant in the BNT162b2 group was withdrawn because of an AE, and there were no deaths.

- AEs assessed as related to BNT162b2 were reactogenicity events and lymphadenopathy.

12.4.2. New Adverse Events After the EUA Snapshot – Original BNT162b2 Recipients 12 Through 15 Years of Age

- No new safety signals or concerns were for new AEs reported after the EUA snapshot. Most new AEs were mild or moderate in severity. All SAEs were assessed by the investigator as not related to study intervention. There were no new AEs leading to withdrawal, and there were no deaths.

12.4.3. Open-Label Follow-Up Period – Original BNT162b2 Participants 12 Through 15 Years of Age

- Most AEs were mild or moderate in severity. The frequency of adolescent participants with AEs in the BNT162b2 group was 1.6%, which was markedly reduced relative to any AEs reported from Dose 1 to the unblinding date (8.4%).
- There were no related SAEs, no withdrawals because of AEs, and no deaths.
- No new safety signals or concerns were identified with additional follow-up.

12.4.4. Blinded Placebo-Controlled and Open-Label Follow-Up Periods to 6 Months After Dose 2 – Original BNT162b2 Recipients 12 Through 15 Years of Age

For the 1113 adolescent participants with at least 6 months of follow-up time:

- Most AEs were mild or moderate in severity. There were 8.8% of participants with any AEs. AE frequencies overall decreased over time from 1 month after the Dose 2 to 6 months after Dose 2.
- SAEs were reported in 0.9% of adolescent participants; all were assessed by the investigator as not related to study intervention. There were no withdrawals because of AEs, and there were no deaths.
- Overall, BNT162b2 at 30 µg was well tolerated with at least 6 months of follow-up after Dose 2.
- No new safety signals or concerns were identified with additional follow-up.

12.4.5. Open-Label Follow-Up Period – Original Placebo Recipients 12 Through 15 Years of Age Who Then Received BNT162b2

For the 1,010 original placebo recipients who then received BNT162b2 after unblinding:

- Most AEs were mild or moderate in severity. There were 26.2% of participants with any AEs, which was greater than the frequency in original BNT162b2 participants (8.4%), due to reactogenicity events being reported as AE rather than e-diary after original placebo recipients received BNT162b2.
- AEs after receipt of BNT162b2 in placebo participants were mostly reactogenicity events.
- There were no withdrawals because of AEs, and there were no deaths.

13. DISCUSSION AND OVERALL CONCLUSIONS

13.1. Discussion – Participants 12 Through 15 Years of Age

In this report, safety data are evaluated from approximately 2200 participants 12-15 years of age, including those with at least 6 months of follow-up after Dose 2 for participants

originally randomized to BNT162b2, comprising the combined blinded and open-label periods.

The long-term AE profile among adolescents reflects age-appropriate events consistent with the general population, 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 adolescents. The incidence of SAEs in adolescents was low and similar between the vaccine and placebo groups. Most SAEs, including all SAEs in the psychiatric disorders SOCs, were assessed by the investigator as not related to study intervention. One (1) participant reported an SAE of myocarditis (previously reported to CBER), which was assessed by the investigator as not related to study intervention (Pfizer assessed event as related to study intervention). Refer to Section 12.2.3.4 for additional case details, and refer to Section 2.5.6 of the CO (Module 2.5 Clinical Overview) for the benefit-risk assessment of myocarditis. Only 1 participant was withdrawn from the study because of an AE. No deaths occurred in the adolescent group. Review of AEs, SAEs, and events of clinical interest suggested no clear patterns or additional safety signals or concerns among adolescents.

Similarly, the AE profile of new events after the EUA snapshot were consistent with those observed cumulatively and did not reveal additional safety signals or concerns among adolescents.

As of the safety data cutoff date (02 September 2021), no severe COVID-19 cases were reported in adolescents.

The adolescent interim CSR, dated 14 April 2021, demonstrated that after 2 doses of BNT162b2 30 µg, immune responses in adolescent participants were noninferior to the immune responses in young adults (16-25 years of age), and in fact were statistically greater than that observed in young adults. These data provide reassurance that the vaccine will provide a robust immune response to SARS-CoV-2 in the adolescent population.

Previous descriptive efficacy analyses showed observed VE for the evaluable efficacy population was 100% for adolescent participants (reported in the adolescent interim CSR, dated 14 April 2021). Updated descriptive efficacy analyses for adolescents were consistent with prior analyses. During the blinded placebo-controlled follow-up period, median follow-up time for adolescent participants was 4.4 months. Based on confirmed COVID-19 cases reported from at least 7 days after Dose 2 through the data cutoff date (02 September 2021), observed VE was 100.0% (2-sided 95% CI: 86.8%, 100.0%) for individuals without evidence of prior SARS-CoV-2 infection before and during vaccination regimen, and 100.0% (2-sided 95% CI: 87.5%, 100.0%) for individuals with or without evidence of prior SARS-CoV-2 infection before and during vaccination regimen. Sequencing data shows that most variants were neither VOI or VOC except for B.1.1.7 (Alpha), which was found in 23.3% of placebo participants.

In the Dose 1 all-available (modified intention-to-treat) population, 3 participants in the BNT162b2 group and 48 participants in the placebo group had COVID-19 cases occurring after Dose 1, for an observed VE of 94.0% (2-sided 95% CI: 81.3%, 98.8%). All 3 cases in

the BNT162b2 group were SARS-CoV-2 negative at baseline, 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. 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, immunogenicity, descriptive efficacy, and available long-term safety data in adolescent participants continue to support the safety, tolerability, and effectiveness of BNT162b2 at 30 µg administered as a 2-dose regimen (21 days apart) to individuals 12 through 15 years of age for the prevention of COVID-19.

13.2. Overall Conclusions – Participants 12 Through 15 Years of Age

- In Phase 2/3, updated descriptive efficacy analysis continues to show that BNT162b2 at 30 µg provided a high level of protection against COVID-19 in participants 12 through 15 years of age with or without evidence of infection with SARS-CoV-2 (100% VE), with no severe cases overall observed in this age group.

- The tolerability and safety profile of BNT162b2 30 µg in participants 12 through 15 years of age at up to 6 months after Dose 2 was acceptable throughout the follow-up period (to the data cutoff date) and consistent with results previously reported.

14. TABLES AND FIGURES

SUPPLEMENTAL TABLES

Conduct of Study

14.1. Demographic Characteristics, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=46) n[b] (%)	Placebo (N[a]=50) n[b] (%)	Total (N[a]=96) n[b] (%)
Sex			
Male	21 (45.7)	25 (50.0)	46 (47.9)
Female	25 (54.3)	25 (50.0)	50 (52.1)
Race			
White	39 (84.8)	40 (80.0)	79 (82.3)
Black or African American	6 (13.0)	7 (14.0)	13 (13.5)
All others	1 (2.2)	3 (6.0)	4 (4.2)
American Indian or Alaska Native	0	1 (2.0)	1 (1.0)
Asian	0	1 (2.0)	1 (1.0)
Multiracial	1 (2.2)	0	1 (1.0)
Not reported	0	1 (2.0)	1 (1.0)
Ethnicity			
Hispanic/Latino	7 (15.2)	10 (20.0)	17 (17.7)
Non-Hispanic/non-Latino	39 (84.8)	40 (80.0)	79 (82.3)
Country			
USA	46 (100.0)	50 (100.0)	96 (100.0)
Comorbidities[c]			
Yes	11 (23.9)	12 (24.0)	23 (24.0)
No	35 (76.1)	38 (76.0)	73 (76.0)
Obese[d]			
Yes	6 (13.0)	10 (20.0)	16 (16.7)
No	40 (87.0)	40 (80.0)	80 (83.3)
Age at vaccination (years)			
Mean (SD)	13.5 (1.19)	13.7 (1.07)	13.6 (1.13)
Median	14.0	14.0	14.0
Min, max	(12, 15)	(12, 15)	(12, 15)

14.1. Demographic Characteristics, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=46) n[b] (%)	Placebo (N[a]=50) n[b] (%)	Total (N[a]=96) n[b] (%)

Abbreviations: NE = not estimable; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥95th percentile.
d. Obese is defined as BMI ≥95th percentile from the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html charts/bmiagerev htm.
PFIZER CONFIDENTIAL SDTM Creation: 30SEP2021 (10:35) Source Data: adsl Table Generation: 12NOV2021 (15:30)
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14.2. Demographic Characteristics, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1083) n[b] (%)	Placebo (N[a]=1078) n[b] (%)	Total (N[a]=2161) n[b] (%)
Sex			
Male	545 (50.3)	560 (51.9)	1105 (51.1)
Female	538 (49.7)	518 (48.1)	1056 (48.9)
Race			
White	929 (85.8)	921 (85.4)	1850 (85.6)
Black or African American	46 (4.2)	50 (4.6)	96 (4.4)
All others	108 (10.0)	107 (9.9)	215 (9.9)
American Indian or Alaska Native	4 (0.4)	2 (0.2)	6 (0.3)
Asian	72 (6.6)	70 (6.5)	142 (6.6)
Native Hawaiian or other Pacific Islander	3 (0.3)	0	3 (0.1)
Multiracial	23 (2.1)	29 (2.7)	52 (2.4)
Not reported	6 (0.6)	6 (0.6)	12 (0.6)
Racial designation			
Japanese	5 (0.5)	2 (0.2)	7 (0.3)
Ethnicity			
Hispanic/Latino	125 (11.5)	120 (11.1)	245 (11.3)
Non-Hispanic/non-Latino	956 (88.3)	955 (88.6)	1911 (88.4)
Not reported	2 (0.2)	3 (0.3)	5 (0.2)
Country			
USA	1083 (100.0)	1078 (100.0)	2161 (100.0)
Comorbidities[c]			
Yes	238 (22.0)	230 (21.3)	468 (21.7)
No	845 (78.0)	848 (78.7)	1693 (78.3)
Obese[d]			
Yes	137 (12.7)	118 (10.9)	255 (11.8)
No	946 (87.3)	960 (89.1)	1906 (88.2)
Age at vaccination (years)			
Mean (SD)	13.6 (1.10)	13.6 (1.11)	13.6 (1.11)
Median	14.0	14.0	14.0
Min, max	(12, 15)	(12, 15)	(12, 15)

14.2. Demographic Characteristics, by Baseline SARS-CoV-2 Status – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=1083) n^b (%)	Placebo (N^a=1078) n^b (%)	Total (N^a=2161) n^b (%)

Abbreviations: NE = not estimable; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥95th percentile.
d. Obese is defined as BMI ≥95th percentile from the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html charts/bmiagerev htm.
PFIZER CONFIDENTIAL SDTM Creation: 30SEP2021 (10:35) Source Data: adsl Table Generation: 12NOV2021 (15:30)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adsl_s005_base1_ped6_saf

14.3. Medical History – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=1129) n[b] (%)
Any medical history	850 (75.2)	832 (73.7)
Blood and lymphatic system disorders	3 (0.3)	8 (0.7)
Anaemia	0	1 (0.1)
Immune thrombocytopenia	3 (0.3)	1 (0.1)
Iron deficiency anaemia	0	3 (0.3)
Lymphadenopathy	0	2 (0.2)
Thrombocytopenia	0	1 (0.1)
Cardiac disorders	5 (0.4)	3 (0.3)
Aortic valve disease	2 (0.2)	0
Arrhythmia	1 (0.1)	0
Postural orthostatic tachycardia syndrome	1 (0.1)	1 (0.1)
Pulmonary valve stenosis	1 (0.1)	0
Supraventricular tachycardia	0	1 (0.1)
Ventricular extrasystoles	0	1 (0.1)
Congenital, familial and genetic disorders	29 (2.6)	45 (4.0)
Adenomatous polyposis coli	0	1 (0.1)
Ankyloglossia congenital	0	1 (0.1)
Anorectal malformation	0	1 (0.1)
Atrial septal defect	1 (0.1)	2 (0.2)
Bicuspid aortic valve	2 (0.2)	2 (0.2)
Birth mark	0	2 (0.2)
Cerebral cavernous malformation	0	1 (0.1)
Cerebral palsy	0	1 (0.1)
Chondrodystrophy	1 (0.1)	0
Cleft lip and palate	1 (0.1)	0
Cleft palate	1 (0.1)	1 (0.1)
Colour blindness	1 (0.1)	0
Congenital anomaly	1 (0.1)	0
Congenital diaphragmatic hernia	1 (0.1)	0
Congenital flat feet	1 (0.1)	0
Congenital megacolon	0	1 (0.1)
Congenital nystagmus	2 (0.2)	0
Congenital skin dimples	0	1 (0.1)
Cryptorchism	1 (0.1)	0
Cystic fibrosis	0	2 (0.2)

14.3. Medical History – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=1129) n[b] (%)
Developmental hip dysplasia	0	1 (0.1)
Ehlers-Danlos syndrome	0	1 (0.1)
Factor V Leiden carrier	1 (0.1)	1 (0.1)
Factor V Leiden mutation	0	1 (0.1)
Gilbert's syndrome	0	1 (0.1)
Hemivertebra	0	1 (0.1)
Hereditary motor and sensory neuropathy	0	1 (0.1)
Hereditary spherocytosis	0	1 (0.1)
Hypoplastic left heart syndrome	0	1 (0.1)
Hypospadias	0	1 (0.1)
Imperforate hymen	0	1 (0.1)
Malformation venous	1 (0.1)	0
Metabolic myopathy	1 (0.1)	0
Microgenia	0	1 (0.1)
Multiple epiphyseal dysplasia	0	1 (0.1)
Naevus flammeus	0	1 (0.1)
Neurofibromatosis	0	2 (0.2)
Oculoauriculovertebral dysplasia	0	1 (0.1)
Otospondylomegaepiphyseal dysplasia	1 (0.1)	0
Pectus carinatum	0	1 (0.1)
Pectus excavatum	2 (0.2)	1 (0.1)
Phimosis	1 (0.1)	1 (0.1)
Polydactyly	1 (0.1)	0
Renal dysplasia	0	1 (0.1)
Sickle cell anaemia	1 (0.1)	0
Sickle cell trait	0	3 (0.3)
Spina bifida occulta	1 (0.1)	0
Strabismus congenital	1 (0.1)	0
Talipes	1 (0.1)	0
Thalassaemia beta	2 (0.2)	0
Thalassaemia minor	0	1 (0.1)
Thyroglossal cyst	1 (0.1)	0
Tourette's disorder	2 (0.2)	2 (0.2)
Transposition of the great vessels	0	1 (0.1)
Ventricular septal defect	0	1 (0.1)
Von Willebrand's disease	1 (0.1)	2 (0.2)
Ear and labyrinth disorders	11 (1.0)	10 (0.9)
Auditory disorder	1 (0.1)	0
Deafness	2 (0.2)	0

14.3. Medical History – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=1129) n[b] (%)
Deafness bilateral	1 (0.1)	0
Deafness unilateral	1 (0.1)	1 (0.1)
Ear pain	0	1 (0.1)
Eustachian tube disorder	1 (0.1)	0
Eustachian tube dysfunction	2 (0.2)	0
Hypoacusis	1 (0.1)	2 (0.2)
Middle ear adhesions	0	1 (0.1)
Motion sickness	0	1 (0.1)
Tinnitus	1 (0.1)	2 (0.2)
Tympanic membrane perforation	1 (0.1)	1 (0.1)
Vestibular disorder	0	1 (0.1)
Endocrine disorders	7 (0.6)	7 (0.6)
Autoimmune thyroiditis	0	1 (0.1)
Growth hormone deficiency	1 (0.1)	3 (0.3)
Hypopituitarism	1 (0.1)	0
Hypothyroidism	3 (0.3)	1 (0.1)
Precocious puberty	2 (0.2)	2 (0.2)
Eye disorders	46 (4.1)	59 (5.2)
Amblyopia	1 (0.1)	2 (0.2)
Amblyopia strabismic	1 (0.1)	0
Anisometropia	1 (0.1)	0
Astigmatism	1 (0.1)	6 (0.5)
Blepharitis	2 (0.2)	0
Blindness unilateral	0	1 (0.1)
Cataract	1 (0.1)	0
Chalazion	0	1 (0.1)
Conjunctivitis allergic	1 (0.1)	0
Dacryostenosis acquired	0	1 (0.1)
Eyelid ptosis	1 (0.1)	0
Hypermetropia	5 (0.4)	7 (0.6)
Myopia	20 (1.8)	27 (2.4)
Optic atrophy	0	1 (0.1)
Optic nerve cupping	0	1 (0.1)
Presbyopia	1 (0.1)	0
Punctate keratitis	1 (0.1)	0
Pupils unequal	0	1 (0.1)
Recession of chamber angle of eye	0	1 (0.1)
Refractive amblyopia	0	1 (0.1)

14.3. Medical History – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=1129) n[b] (%)
Strabismus	4 (0.4)	4 (0.4)
Visual acuity reduced	8 (0.7)	12 (1.1)
Gastrointestinal disorders	43 (3.8)	44 (3.9)
Abdominal hernia	1 (0.1)	0
Abdominal migraine	2 (0.2)	1 (0.1)
Abdominal pain	1 (0.1)	3 (0.3)
Abdominal pain upper	1 (0.1)	1 (0.1)
Coeliac disease	4 (0.4)	4 (0.4)
Constipation	10 (0.9)	11 (1.0)
Cyclic vomiting syndrome	1 (0.1)	0
Diarrhoea	1 (0.1)	2 (0.2)
Dyspepsia	3 (0.3)	0
Dysphagia	0	1 (0.1)
Enterocolitis	1 (0.1)	0
Eosinophilic oesophagitis	1 (0.1)	3 (0.3)
Gastrooesophageal reflux disease	12 (1.1)	14 (1.2)
Hiatus hernia	0	1 (0.1)
Inguinal hernia	1 (0.1)	1 (0.1)
Intussusception	2 (0.2)	0
Irritable bowel syndrome	2 (0.2)	2 (0.2)
Malabsorption	1 (0.1)	0
Oesophagitis	1 (0.1)	0
Oral pain	0	1 (0.1)
Tooth impacted	0	1 (0.1)
Toothache	0	1 (0.1)
Umbilical hernia	2 (0.2)	3 (0.3)
General disorders and administration site conditions	10 (0.9)	10 (0.9)
Adverse food reaction	1 (0.1)	0
Cyst	1 (0.1)	1 (0.1)
Developmental delay	0	2 (0.2)
Drug intolerance	1 (0.1)	2 (0.2)
Medical device pain	1 (0.1)	1 (0.1)
Pain	5 (0.4)	3 (0.3)
Peripheral swelling	1 (0.1)	0
Pyrexia	0	1 (0.1)
Hepatobiliary disorders	4 (0.4)	0
Cholelithiasis	2 (0.2)	0

14.3. Medical History – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=1129) n[b] (%)
Hepatic steatosis	1 (0.1)	0
Non-alcoholic steatohepatitis	1 (0.1)	0
Immune system disorders	399 (35.3)	391 (34.6)
Allergy to animal	24 (2.1)	19 (1.7)
Allergy to arthropod bite	1 (0.1)	2 (0.2)
Allergy to arthropod sting	2 (0.2)	4 (0.4)
Allergy to chemicals	1 (0.1)	0
Allergy to metals	0	2 (0.2)
Allergy to plants	4 (0.4)	2 (0.2)
Anaphylactic reaction	1 (0.1)	0
Cockroach allergy	1 (0.1)	1 (0.1)
Drug hypersensitivity	130 (11.5)	97 (8.6)
Food allergy	32 (2.8)	40 (3.5)
Hypersensitivity	22 (1.9)	16 (1.4)
Milk allergy	3 (0.3)	5 (0.4)
Mite allergy	1 (0.1)	4 (0.4)
Multiple allergies	0	1 (0.1)
Mycotic allergy	0	1 (0.1)
Oral allergy syndrome	0	4 (0.4)
Perennial allergy	2 (0.2)	3 (0.3)
Perfume sensitivity	1 (0.1)	0
Reaction to colouring	1 (0.1)	0
Reaction to food additive	0	1 (0.1)
Rubber sensitivity	6 (0.5)	5 (0.4)
Seasonal allergy	241 (21.3)	247 (21.9)
Selective IgA immunodeficiency	0	1 (0.1)
Serum sickness	1 (0.1)	0
Infections and infestations	72 (6.4)	52 (4.6)
Abscess limb	0	1 (0.1)
Adenoiditis	11 (1.0)	6 (0.5)
Appendicitis	6 (0.5)	9 (0.8)
Body tinea	1 (0.1)	0
Cellulitis	1 (0.1)	0
Chronic sinusitis	2 (0.2)	1 (0.1)
Chronic tonsillitis	2 (0.2)	3 (0.3)
Conjunctivitis	1 (0.1)	1 (0.1)
Croup infectious	1 (0.1)	1 (0.1)
Dermatophytosis of nail	1 (0.1)	0

14.3. Medical History – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=1129) n[b] (%)
Ear infection	12 (1.1)	8 (0.7)
Gastrointestinal viral infection	1 (0.1)	0
Herpes simplex	1 (0.1)	0
Histoplasmosis	1 (0.1)	0
Impetigo	1 (0.1)	0
Infectious mononucleosis	0	1 (0.1)
Kidney infection	1 (0.1)	0
Lyme disease	2 (0.2)	0
Meningitis	1 (0.1)	0
Meningitis viral	1 (0.1)	0
Molluscum contagiosum	0	1 (0.1)
Nail infection	1 (0.1)	0
Oral herpes	1 (0.1)	0
Osteomyelitis	2 (0.2)	0
Otitis media	3 (0.3)	1 (0.1)
Otitis media acute	1 (0.1)	0
Otitis media chronic	1 (0.1)	2 (0.2)
Paronychia	1 (0.1)	0
Pharyngeal abscess	0	1 (0.1)
Pharyngitis	2 (0.2)	0
Pharyngitis streptococcal	1 (0.1)	3 (0.3)
Pneumonia	6 (0.5)	4 (0.4)
Respiratory syncytial virus bronchiolitis	0	1 (0.1)
Respiratory syncytial virus infection	1 (0.1)	0
Rhinitis	1 (0.1)	1 (0.1)
Rotavirus infection	0	1 (0.1)
Scarlet fever	1 (0.1)	1 (0.1)
Sinusitis	4 (0.4)	1 (0.1)
Staphylococcal scalded skin syndrome	1 (0.1)	0
Tinea infection	0	1 (0.1)
Tonsillitis	11 (1.0)	8 (0.7)
Urinary tract infection	0	2 (0.2)
Viral infection	1 (0.1)	0
Vulvovaginal mycotic infection	1 (0.1)	0
Injury, poisoning and procedural complications	58 (5.1)	48 (4.3)
Ankle fracture	5 (0.4)	1 (0.1)
Chest injury	1 (0.1)	0
Chillblains	1 (0.1)	1 (0.1)
Clavicle fracture	2 (0.2)	3 (0.3)

14.3. Medical History – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=1129) n[b] (%)
Concussion	5 (0.4)	3 (0.3)
Contusion	1 (0.1)	0
Epiphyseal fracture	1 (0.1)	0
Facial bones fracture	1 (0.1)	2 (0.2)
Fall	1 (0.1)	0
Femur fracture	0	1 (0.1)
Fibula fracture	1 (0.1)	0
Foot fracture	8 (0.7)	3 (0.3)
Foreign body in ear	0	1 (0.1)
Hand fracture	8 (0.7)	5 (0.4)
Humerus fracture	0	1 (0.1)
Jaw fracture	0	1 (0.1)
Joint dislocation	0	1 (0.1)
Joint injury	0	2 (0.2)
Ligament injury	1 (0.1)	0
Ligament rupture	1 (0.1)	0
Ligament sprain	0	2 (0.2)
Limb fracture	2 (0.2)	0
Limb injury	1 (0.1)	0
Lower limb fracture	1 (0.1)	1 (0.1)
Meniscus injury	2 (0.2)	0
Muscle strain	4 (0.4)	1 (0.1)
Nasal injury	0	1 (0.1)
Post concussion syndrome	0	1 (0.1)
Radius fracture	5 (0.4)	1 (0.1)
Skin laceration	0	1 (0.1)
Stress fracture	1 (0.1)	2 (0.2)
Tibia fracture	3 (0.3)	5 (0.4)
Torus fracture	0	2 (0.2)
Upper limb fracture	12 (1.1)	11 (1.0)
VIIth nerve injury	1 (0.1)	0
Wrist fracture	10 (0.9)	6 (0.5)
Investigations	14 (1.2)	8 (0.7)
Blood pressure increased	1 (0.1)	2 (0.2)
Body height decreased	1 (0.1)	0
Cardiac murmur	9 (0.8)	4 (0.4)
Endoscopy	1 (0.1)	0
Endoscopy upper gastrointestinal tract	0	1 (0.1)
Menstruation normal	1 (0.1)	1 (0.1)

14.3. Medical History – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=1129) n[b] (%)
Serum ferritin decreased	1 (0.1)	0
Weight decreased	1 (0.1)	0
Metabolism and nutrition disorders	39 (3.4)	51 (4.5)
Calcium deficiency	0	1 (0.1)
Dairy intolerance	1 (0.1)	1 (0.1)
Decreased appetite	2 (0.2)	1 (0.1)
Dehydration	1 (0.1)	0
Dyslipidaemia	1 (0.1)	2 (0.2)
Food intolerance	2 (0.2)	2 (0.2)
Fructose intolerance	1 (0.1)	1 (0.1)
Glucose tolerance impaired	1 (0.1)	0
Gluten sensitivity	0	2 (0.2)
Hyperglycaemia	1 (0.1)	0
Hyperlipidaemia	4 (0.4)	0
Hypertriglyceridaemia	1 (0.1)	1 (0.1)
Iron deficiency	0	2 (0.2)
Lactose intolerance	5 (0.4)	7 (0.6)
Obesity	15 (1.3)	20 (1.8)
Overweight	1 (0.1)	4 (0.4)
Type 1 diabetes mellitus	2 (0.2)	5 (0.4)
Underweight	1 (0.1)	0
Vitamin D deficiency	4 (0.4)	6 (0.5)
Musculoskeletal and connective tissue disorders	58 (5.1)	49 (4.3)
Arthralgia	12 (1.1)	8 (0.7)
Back pain	1 (0.1)	1 (0.1)
Discoid meniscus	0	1 (0.1)
Exostosis	1 (0.1)	0
Foot deformity	2 (0.2)	2 (0.2)
Growing pains	1 (0.1)	0
Growth retardation	1 (0.1)	0
Hypermobility syndrome	0	1 (0.1)
Joint instability	1 (0.1)	0
Juvenile idiopathic arthritis	0	2 (0.2)
Knee deformity	2 (0.2)	0
Kyphosis	2 (0.2)	1 (0.1)
Lordosis	1 (0.1)	0
Myalgia	1 (0.1)	5 (0.4)
Neck pain	1 (0.1)	0

14.3. Medical History – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=1129) n[b] (%)
Osteitis	1 (0.1)	1 (0.1)
Osteochondrosis	3 (0.3)	4 (0.4)
Pain in extremity	2 (0.2)	3 (0.3)
Pain in jaw	1 (0.1)	0
Patellofemoral pain syndrome	0	2 (0.2)
Plantar fascial fibromatosis	0	1 (0.1)
Rotator cuff syndrome	1 (0.1)	0
Scoliosis	21 (1.9)	12 (1.1)
Short stature	6 (0.5)	2 (0.2)
Shoulder deformity	0	1 (0.1)
Synovial cyst	0	1 (0.1)
Temporomandibular joint syndrome	2 (0.2)	1 (0.1)
Tendon disorder	0	1 (0.1)
Tendonitis	1 (0.1)	3 (0.3)
Toe walking	1 (0.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10 (0.9)	14 (1.2)
Benign ear neoplasm	1 (0.1)	0
Cholesteatoma	0	1 (0.1)
Eyelid haemangioma	1 (0.1)	0
Fibroadenoma of breast	0	1 (0.1)
Fibroma	0	1 (0.1)
Haemangioma	1 (0.1)	0
Lipoma	0	1 (0.1)
Melanocytic naevus	1 (0.1)	3 (0.3)
Nephroblastoma	0	1 (0.1)
Skin papilloma	6 (0.5)	6 (0.5)
Nervous system disorders	94 (8.3)	68 (6.0)
Apraxia	1 (0.1)	0
Arachnoid cyst	1 (0.1)	0
Benign rolandic epilepsy	1 (0.1)	0
Convulsion in childhood	1 (0.1)	0
Disturbance in attention	4 (0.4)	0
Dizziness	2 (0.2)	0
Dysgraphia	0	2 (0.2)
Dyslexia	1 (0.1)	6 (0.5)
Epilepsy	4 (0.4)	1 (0.1)
Febrile convulsion	3 (0.3)	0
Headache	38 (3.4)	30 (2.7)

14.3. Medical History – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=1129) n[b] (%)
Hydrocephalus	0	1 (0.1)
Idiopathic intracranial hypertension	0	1 (0.1)
Mental impairment	2 (0.2)	0
Migraine	30 (2.7)	25 (2.2)
Migraine with aura	2 (0.2)	1 (0.1)
Migraine without aura	0	2 (0.2)
Nystagmus	1 (0.1)	0
Ophthalmic migraine	0	1 (0.1)
Retinal migraine	1 (0.1)	0
Seizure	1 (0.1)	1 (0.1)
Sensory disturbance	0	1 (0.1)
Sensory processing disorder	1 (0.1)	1 (0.1)
Speech disorder	2 (0.2)	0
Syncope	1 (0.1)	1 (0.1)
Tension headache	1 (0.1)	0
Tethered cord syndrome	1 (0.1)	0
Pregnancy, puerperium and perinatal conditions	2 (0.2)	1 (0.1)
Premature baby	2 (0.2)	1 (0.1)
Product issues	0	1 (0.1)
Device breakage	0	1 (0.1)
Psychiatric disorders	293 (25.9)	285 (25.2)
Adjustment disorder with depressed mood	1 (0.1)	1 (0.1)
Adjustment disorder with mixed anxiety and depressed mood	0	1 (0.1)
Aggression	1 (0.1)	1 (0.1)
Anger	0	1 (0.1)
Anxiety	107 (9.5)	96 (8.5)
Anxiety disorder	4 (0.4)	3 (0.3)
Attention deficit hyperactivity disorder	182 (16.1)	166 (14.7)
Autism spectrum disorder	10 (0.9)	10 (0.9)
Behaviour disorder	2 (0.2)	1 (0.1)
Bipolar disorder	2 (0.2)	0
Childhood depression	1 (0.1)	0
Chronic tic disorder	0	2 (0.2)
Depression	51 (4.5)	46 (4.1)
Depressive symptom	0	1 (0.1)
Disruptive mood dysregulation disorder	3 (0.3)	2 (0.2)
Eating disorder	1 (0.1)	2 (0.2)

14.3. Medical History – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=1129) n[b] (%)
Enuresis	3 (0.3)	2 (0.2)
Gender dysphoria	2 (0.2)	0
Generalised anxiety disorder	8 (0.7)	14 (1.2)
Hallucination, auditory	1 (0.1)	0
Impulse-control disorder	2 (0.2)	0
Impulsive behaviour	0	1 (0.1)
Insomnia	27 (2.4)	29 (2.6)
Learning disorder	0	1 (0.1)
Major depression	5 (0.4)	6 (0.5)
Neurodevelopmental disorder	1 (0.1)	0
Nightmare	1 (0.1)	0
Obsessive-compulsive disorder	5 (0.4)	9 (0.8)
Oppositional defiant disorder	2 (0.2)	3 (0.3)
Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection	0	1 (0.1)
Persistent depressive disorder	1 (0.1)	0
Post-traumatic stress disorder	4 (0.4)	5 (0.4)
Reactive attachment disorder of infancy or early childhood	0	1 (0.1)
Reading disorder	0	1 (0.1)
Separation anxiety disorder	1 (0.1)	0
Sleep disorder	0	3 (0.3)
Social anxiety disorder	0	1 (0.1)
Speech sound disorder	1 (0.1)	0
Suicidal ideation	1 (0.1)	1 (0.1)
Tic	3 (0.3)	2 (0.2)
Renal and urinary disorders	5 (0.4)	6 (0.5)
Dysuria	0	1 (0.1)
Haematuria	1 (0.1)	1 (0.1)
Hydronephrosis	1 (0.1)	0
Nephrolithiasis	1 (0.1)	0
Renal cyst	0	1 (0.1)
Renal disorder	1 (0.1)	0
Single functional kidney	0	1 (0.1)
Urinary retention	0	1 (0.1)
Urinary tract disorder	1 (0.1)	0
Vesicoureteric reflux	1 (0.1)	1 (0.1)
Reproductive system and breast disorders	32 (2.8)	35 (3.1)
Abnormal uterine bleeding	2 (0.2)	1 (0.1)

14.3. Medical History – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=1129) n[b] (%)
Breast cyst	1 (0.1)	0
Dysmenorrhoea	11 (1.0)	15 (1.3)
Epididymal cyst	1 (0.1)	0
Gynaecomastia	0	1 (0.1)
Heavy menstrual bleeding	7 (0.6)	9 (0.8)
Intermenstrual bleeding	0	1 (0.1)
Menstruation irregular	4 (0.4)	6 (0.5)
Ovulation disorder	1 (0.1)	0
Polycystic ovaries	3 (0.3)	1 (0.1)
Premenstrual dysphoric disorder	0	2 (0.2)
Testicular torsion	1 (0.1)	0
Vaginal disorder	1 (0.1)	0
Varicocele	1 (0.1)	1 (0.1)
Respiratory, thoracic and mediastinal disorders	179 (15.8)	179 (15.9)
Adenoidal hypertrophy	1 (0.1)	0
Asthma	108 (9.5)	110 (9.7)
Asthma exercise induced	11 (1.0)	16 (1.4)
Bronchial hyperreactivity	6 (0.5)	4 (0.4)
Bronchitis chronic	0	1 (0.1)
Bronchospasm	0	1 (0.1)
Epistaxis	6 (0.5)	5 (0.4)
Nasal inflammation	1 (0.1)	0
Nasal polyps	0	1 (0.1)
Nasal septum deviation	1 (0.1)	1 (0.1)
Nasal turbinate hypertrophy	3 (0.3)	0
Oropharyngeal pain	1 (0.1)	1 (0.1)
Rhinitis allergic	41 (3.6)	46 (4.1)
Rhinitis perennial	1 (0.1)	0
Sleep apnoea syndrome	5 (0.4)	3 (0.3)
Snoring	2 (0.2)	0
Tonsillar hypertrophy	2 (0.2)	1 (0.1)
Tonsillolith	1 (0.1)	0
Tracheomalacia	0	1 (0.1)
Vasomotor rhinitis	1 (0.1)	0
Vocal cord disorder	1 (0.1)	0
Vocal cord thickening	1 (0.1)	0
Wheezing	2 (0.2)	0
Skin and subcutaneous tissue disorders	170 (15.0)	182 (16.1)

14.3. Medical History – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=1129) n[b] (%)
Acanthosis nigricans	0	1 (0.1)
Acne	96 (8.5)	99 (8.8)
Acne cosmetica	1 (0.1)	0
Acne cystic	0	1 (0.1)
Actinic keratosis	1 (0.1)	1 (0.1)
Alopecia	1 (0.1)	0
Alopecia areata	1 (0.1)	0
Blister	1 (0.1)	0
Dermatitis	4 (0.4)	1 (0.1)
Dermatitis allergic	0	1 (0.1)
Dermatitis atopic	10 (0.9)	12 (1.1)
Dermatitis contact	5 (0.4)	4 (0.4)
Drug eruption	0	3 (0.3)
Dry skin	0	2 (0.2)
Eczema	35 (3.1)	44 (3.9)
Hand dermatitis	8 (0.7)	2 (0.2)
Hirsutism	0	1 (0.1)
Hyperhidrosis	1 (0.1)	3 (0.3)
Hyperkeratosis	1 (0.1)	0
Idiopathic urticaria	2 (0.2)	0
Ingrowing nail	1 (0.1)	1 (0.1)
Keratosis pilaris	1 (0.1)	2 (0.2)
Miliaria	1 (0.1)	0
Nail psoriasis	1 (0.1)	0
Pityriasis alba	0	1 (0.1)
Pityriasis rosea	0	1 (0.1)
Psoriasis	6 (0.5)	7 (0.6)
Rash	0	2 (0.2)
Rosacea	1 (0.1)	1 (0.1)
Seborrhoea	1 (0.1)	0
Spider naevus	0	1 (0.1)
Urticaria	8 (0.7)	2 (0.2)
Vitiligo	0	2 (0.2)
Social circumstances	104 (9.2)	95 (8.4)
Corrective lens user	8 (0.7)	10 (0.9)
Menarche	11 (1.0)	16 (1.4)
Premenarche	88 (7.8)	69 (6.1)
Vegan	1 (0.1)	0
Vegetarian	2 (0.2)	6 (0.5)

14.3. Medical History – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=1129) n[b] (%)
Woman of childbearing potential	0	1 (0.1)
Surgical and medical procedures	111 (9.8)	117 (10.4)
Abdominal hernia repair	1 (0.1)	0
Abscess drainage	0	2 (0.2)
Adenoidectomy	33 (2.9)	22 (1.9)
Adenotonsillectomy	1 (0.1)	2 (0.2)
Ankle operation	0	1 (0.1)
Anorectal operation	0	1 (0.1)
Appendicectomy	9 (0.8)	10 (0.9)
Arterial switch operation	0	1 (0.1)
Atrial septal defect repair	1 (0.1)	1 (0.1)
Bone operation	1 (0.1)	1 (0.1)
Cardiac ablation	0	1 (0.1)
Cardiac operation	0	1 (0.1)
Cataract operation	0	1 (0.1)
Cautery to nose	1 (0.1)	1 (0.1)
Central venous catheterisation	1 (0.1)	0
Cerebral cyst excision	1 (0.1)	0
Cholecystectomy	1 (0.1)	0
Chondroplasty	1 (0.1)	0
Circumcision	2 (0.2)	4 (0.4)
Colon operation	0	1 (0.1)
Dacryocystorhinostomy	0	1 (0.1)
Ear operation	0	1 (0.1)
Ear tube insertion	12 (1.1)	10 (0.9)
Ear tube removal	1 (0.1)	1 (0.1)
Elbow operation	0	1 (0.1)
Epiphyseal surgery	1 (0.1)	0
Epiphysiodesis	1 (0.1)	0
Eye operation	2 (0.2)	4 (0.4)
Facial lesion excision	1 (0.1)	1 (0.1)
Finger amputation	1 (0.1)	1 (0.1)
Foot operation	0	1 (0.1)
Fracture treatment	3 (0.3)	5 (0.4)
Hernia diaphragmatic repair	1 (0.1)	1 (0.1)
Hernia repair	2 (0.2)	0
Hip surgery	0	1 (0.1)
Hydrocele operation	1 (0.1)	0
Hymenectomy	1 (0.1)	0

14.3. Medical History – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=1129) n[b] (%)
Inguinal hernia repair	1 (0.1)	1 (0.1)
Intestinal operation	1 (0.1)	0
Intrauterine contraception	2 (0.2)	0
Jaw operation	1 (0.1)	0
Joint stabilisation	0	1 (0.1)
Knee operation	2 (0.2)	0
Lacrimal duct procedure	0	1 (0.1)
Ligament operation	1 (0.1)	0
Limb operation	3 (0.3)	1 (0.1)
Limb reconstructive surgery	0	1 (0.1)
Lipoma excision	0	1 (0.1)
Liposuction	0	1 (0.1)
Lymphadenectomy	0	1 (0.1)
Mass excision	1 (0.1)	0
Mastoidectomy	1 (0.1)	0
Medical device change	0	1 (0.1)
Medical diet	1 (0.1)	0
Meniscus operation	1 (0.1)	0
Middle ear operation	1 (0.1)	0
Mole excision	0	1 (0.1)
Myringotomy	11 (1.0)	8 (0.7)
Nail operation	1 (0.1)	0
Nephrectomy	0	1 (0.1)
Oesophagogastric fundoplasty	0	1 (0.1)
Open reduction of fracture	2 (0.2)	1 (0.1)
Orchidopexy	1 (0.1)	0
Ostectomy	1 (0.1)	0
Pharyngeal reconstruction	0	1 (0.1)
Pilonidal sinus repair	0	1 (0.1)
Portal shunt procedure	0	1 (0.1)
Removal of foreign body from external ear	0	1 (0.1)
Rhinoplasty	0	1 (0.1)
Scoliosis surgery	1 (0.1)	1 (0.1)
Scrotal cystectomy	0	1 (0.1)
Sinuplasty	0	1 (0.1)
Skin lesion removal	1 (0.1)	0
Spinal fusion surgery	2 (0.2)	1 (0.1)
Strabismus correction	2 (0.2)	2 (0.2)
Suture insertion	1 (0.1)	0
Temporomandibular joint surgery	0	1 (0.1)

14.3. Medical History – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=1129) n[b] (%)
Testes exploration	1 (0.1)	0
Testicular operation	1 (0.1)	0
Thyroglossal cyst excision	1 (0.1)	0
Toe operation	1 (0.1)	0
Tonsillectomy	33 (2.9)	31 (2.7)
Tooth extraction	1 (0.1)	1 (0.1)
Transgender hormonal therapy	0	1 (0.1)
Turbinectomy	1 (0.1)	0
Turbinoplasty	1 (0.1)	0
Tympanoplasty	1 (0.1)	0
Umbilical hernia repair	2 (0.2)	3 (0.3)
Urethral repair	1 (0.1)	1 (0.1)
Urinary tract operation	0	1 (0.1)
Vitrectomy	0	1 (0.1)
Wisdom teeth removal	2 (0.2)	5 (0.4)
Vascular disorders	3 (0.3)	2 (0.2)
Hypertension	0	1 (0.1)
Hypotension	1 (0.1)	1 (0.1)
Peripheral venous disease	1 (0.1)	0
Raynaud's phenomenon	1 (0.1)	0

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic. Subjects with multiple occurrences of the same preferred term are counted only once.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (18:33) Source Data: admh Table Generation: 03NOV2021 (10:03)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/admh_s002_all1_ped6

14.4. Baseline Charlson Comorbidities – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)	
Charlson Comorbidity Index Category	BNT162b2 (30 µg) (N^a=1131) n^b (%)	Placebo (N^a=1129) n^b (%)
Subjects with any Charlson comorbidity	123 (10.9)	136 (12.0)
Any malignancy	0	1 (0.1)
Chronic pulmonary disease	119 (10.5)	127 (11.2)
Diabetes without chronic complication	2 (0.2)	5 (0.4)
Hemiplegia or paraplegia	0	1 (0.1)
Mild liver disease	2 (0.2)	0
Rheumatic disease	0	2 (0.2)

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic. Subjects with multiple occurrences within each category are counted only once. For "Subjects with any Charlson comorbidity," n = number of subjects reporting at least 1 occurrence of any Charlson comorbidity.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (18:33) Source Data: admh Table Generation: 03NOV2021 (10:03)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/admh_s002_risk1_ped6

14.5. Demographic Characteristics – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=1113) n[b] (%)
Sex	
Male	553 (49.7)
Female	560 (50.3)
Race	
White	955 (85.8)
Black or African American	51 (4.6)
All others	107 (9.6)
American Indian or Alaska Native	4 (0.4)
Asian	70 (6.3)
Native Hawaiian or other Pacific Islander	3 (0.3)
Multiracial	24 (2.2)
Not reported	6 (0.5)
Racial designation	
Japanese	5 (0.4)
Ethnicity	
Hispanic/Latino	130 (11.7)
Non-Hispanic/non-Latino	981 (88.1)
Not reported	2 (0.2)
Country	
USA	1113 (100.0)
Baseline SARS-CoV-2 status	
Positive[c]	45 (4.0)
Negative[d]	1066 (95.8)
Missing	2 (0.2)
Comorbidities[e]	
Yes	243 (21.8)
No	870 (78.2)
Obese[f]	
Yes	140 (12.6)
No	973 (87.4)
Age at vaccination (years)	
Mean (SD)	13.6 (1.11)
Median	14.0
Min, max	(12, 15)

14.5. Demographic Characteristics – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=1113) n[b] (%)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
e. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥95th percentile.
f. Obese is defined as BMI ≥95th percentile from the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev htm.
PFIZER CONFIDENTIAL SDTM Creation: 30SEP2021 (10:35) Source Data: adsl Table Generation: 08NOV2021 (03:38)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/adsl s005 6m1 ped6 saf

14.6. Demographic Characteristics – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=1010) n[b] (%)
Sex	
Male	518 (51.3)
Female	492 (48.7)
Race	
White	866 (85.7)
Black or African American	48 (4.8)
All others	96 (9.5)
American Indian or Alaska Native	2 (0.2)
Asian	62 (6.1)
Multiracial	26 (2.6)
Not reported	6 (0.6)
Racial designation	
Japanese	2 (0.2)
Ethnicity	
Hispanic/Latino	115 (11.4)
Non-Hispanic/non-Latino	892 (88.3)
Not reported	3 (0.3)
Country	
USA	1010 (100.0)
Baseline SARS-CoV-2 status	
Positive[c]	43 (4.3)
Negative[d]	966 (95.6)
Missing	1 (0.1)
Comorbidities[e]	
Yes	215 (21.3)
No	795 (78.7)
Obese[f]	
Yes	116 (11.5)
No	894 (88.5)
Age at vaccination (years)	
Mean (SD)	13.6 (1.11)
Median	14.0
Min, max	(12, 15)

14.6. Demographic Characteristics – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=1010) n[b] (%)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
e. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥95th percentile.
f. Obese is defined as BMI ≥95th percentile from the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev htm.
PFIZER CONFIDENTIAL SDTM Creation: 30SEP2021 (10:35) Source Data: adsl Table Generation: 08NOV2021 (03:38)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/adsl s005 cr1 ped6 saf

14.7. Demographic Characteristics – 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]=1057) n[b] (%)	Placebo (N[a]=1030) n[b] (%)	Total (N[a]=2087) n[b] (%)
Sex			
Male	530 (50.1)	533 (51.7)	1063 (50.9)
Female	527 (49.9)	497 (48.3)	1024 (49.1)
Race			
White	909 (86.0)	874 (84.9)	1783 (85.4)
Black or African American	44 (4.2)	50 (4.9)	94 (4.5)
All others	104 (9.8)	106 (10.3)	210 (10.1)
American Indian or Alaska Native	4 (0.4)	2 (0.2)	6 (0.3)
Asian	68 (6.4)	69 (6.7)	137 (6.6)
Native Hawaiian or other Pacific Islander	3 (0.3)	0	3 (0.1)
Multiracial	23 (2.2)	29 (2.8)	52 (2.5)
Not reported	6 (0.6)	6 (0.6)	12 (0.6)
Ethnicity			
Hispanic/Latino	121 (11.4)	113 (11.0)	234 (11.2)
Non-Hispanic/non-Latino	934 (88.4)	914 (88.7)	1848 (88.5)
Not reported	2 (0.2)	3 (0.3)	5 (0.2)
Country			
USA	1057 (100.0)	1030 (100.0)	2087 (100.0)
Comorbidities[c]			
Yes	233 (22.0)	216 (21.0)	449 (21.5)
No	824 (78.0)	814 (79.0)	1638 (78.5)
Obese[d]			
Yes	135 (12.8)	111 (10.8)	246 (11.8)
No	922 (87.2)	919 (89.2)	1841 (88.2)
Age at vaccination (years)			
Mean (SD)	13.6 (1.10)	13.6 (1.11)	13.6 (1.11)
Median	14.0	14.0	14.0
Min, max	(12, 15)	(12, 15)	(12, 15)

14.7. Demographic Characteristics – 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]=1057) n[b] (%)	Placebo (N[a]=1030) n[b] (%)	Total (N[a]=2087) n[b] (%)

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. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥95th percentile.
d. Obese is defined as BMI ≥95th percentile from the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev htm.
PFIZER CONFIDENTIAL SDTM Creation: 30SEP2021 (11:35) Source Data: adsl Table Generation: 03NOV2021 (11:38)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/adsl demo 7d peds eval eff

14.8. Demographic Characteristics – 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) n[b] (%)	Placebo (N[a]=1129) n[b] (%)	Total (N[a]=2260) n[b] (%)
Sex			
Male	567 (50.1)	585 (51.8)	1152 (51.0)
Female	564 (49.9)	544 (48.2)	1108 (49.0)
Race			
White	970 (85.8)	962 (85.2)	1932 (85.5)
Black or African American	52 (4.6)	57 (5.0)	109 (4.8)
All others	109 (9.6)	110 (9.7)	219 (9.7)
American Indian or Alaska Native	4 (0.4)	3 (0.3)	7 (0.3)
Asian	72 (6.4)	71 (6.3)	143 (6.3)
Native Hawaiian or other Pacific Islander	3 (0.3)	0	3 (0.1)
Multiracial	24 (2.1)	29 (2.6)	53 (2.3)
Not reported	6 (0.5)	7 (0.6)	13 (0.6)
Ethnicity			
Hispanic/Latino	132 (11.7)	130 (11.5)	262 (11.6)
Non-Hispanic/non-Latino	997 (88.2)	996 (88.2)	1993 (88.2)
Not reported	2 (0.2)	3 (0.3)	5 (0.2)
Country			
USA	1131 (100.0)	1129 (100.0)	2260 (100.0)
Comorbidities[c]			
Yes	249 (22.0)	242 (21.4)	491 (21.7)
No	882 (78.0)	887 (78.6)	1769 (78.3)
Obese[d]			
Yes	143 (12.6)	128 (11.3)	271 (12.0)
No	988 (87.4)	1001 (88.7)	1989 (88.0)
Baseline SARS-CoV-2 status			
Positive[e]	46 (4.1)	50 (4.4)	96 (4.2)
Negative[f]	1083 (95.8)	1078 (95.5)	2161 (95.6)
Unknown	2 (0.2)	1 (0.1)	3 (0.1)
Age at vaccination (years)			
Mean (SD)	13.6 (1.11)	13.6 (1.11)	13.6 (1.11)
Median	14.0	14.0	14.0
Min, max	(12, 15)	(12, 15)	(12, 15)

14.8. Demographic Characteristics – 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) n^b (%)	Placebo (N^a=1129) n^b (%)	Total (N^a=2260) n^b (%)

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. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥95th percentile.
d. Obese is defined as BMI ≥95th percentile from the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.
e. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
f. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 30SEP2021 (11:35) Source Data: adsl Table Generation: 03NOV2021 (11:38)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adsl_demo_d1_peds_aai

14.9. Demographic Characteristics – 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) n[b] (%)	Placebo (N[a]=1109) n[b] (%)	Total (N[a]=2228) n[b] (%)
Sex			
Male	559 (50.0)	573 (51.7)	1132 (50.8)
Female	560 (50.0)	536 (48.3)	1096 (49.2)
Race			
White	961 (85.9)	943 (85.0)	1904 (85.5)
Black or African American	50 (4.5)	57 (5.1)	107 (4.8)
All others	108 (9.7)	109 (9.8)	217 (9.7)
American Indian or Alaska Native	4 (0.4)	2 (0.2)	6 (0.3)
Asian	71 (6.3)	71 (6.4)	142 (6.4)
Native Hawaiian or other Pacific Islander	3 (0.3)	0	3 (0.1)
Multiracial	24 (2.1)	29 (2.6)	53 (2.4)
Not reported	6 (0.5)	7 (0.6)	13 (0.6)
Ethnicity			
Hispanic/Latino	131 (11.7)	127 (11.5)	258 (11.6)
Non-Hispanic/non-Latino	986 (88.1)	979 (88.3)	1965 (88.2)
Not reported	2 (0.2)	3 (0.3)	5 (0.2)
Country			
USA	1119 (100.0)	1109 (100.0)	2228 (100.0)
Comorbidities[c]			
Yes	244 (21.8)	236 (21.3)	480 (21.5)
No	875 (78.2)	873 (78.7)	1748 (78.5)
Obese[d]			
Yes	141 (12.6)	125 (11.3)	266 (11.9)
No	978 (87.4)	984 (88.7)	1962 (88.1)
Baseline SARS-CoV-2 status			
Positive[e]	46 (4.1)	49 (4.4)	95 (4.3)
Negative[f]	1071 (95.7)	1059 (95.5)	2130 (95.6)
Unknown	2 (0.2)	1 (0.1)	3 (0.1)
Age at vaccination (years)			
Mean (SD)	13.6 (1.11)	13.6 (1.11)	13.6 (1.11)
Median	14.0	14.0	14.0
Min, max	(12, 15)	(12, 15)	(12, 15)

14.9. Demographic Characteristics – 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) n[b] (%)	Placebo (N[a]=1109) n[b] (%)	Total (N[a]=2228) n[b] (%)

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. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥95th percentile.
d. Obese is defined as BMI ≥95th percentile from the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html charts/bmiagerev.htm.
e. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
f. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 30SEP2021 (11:35) Source Data: adsl Table Generation: 03NOV2021 (11:38)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adsl demo 7d wwo peds eval eff

14.10. Concomitant Vaccines Received After Dose 1 – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

Vaccine[b]	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1131) n[c] (%)	Placebo (N[a]=1129) n[c] (%)
Any concomitant vaccine	32 (2.8)	31 (2.7)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	3 (0.3)	0
HPV VACCINE	3 (0.3)	10 (0.9)
HPV VACCINE VLP RL1 4V (YEAST)	4 (0.4)	2 (0.2)
INFLUENZA VACCINE	12 (1.1)	5 (0.4)
INFLUENZA VACCINE INACT SPLIT 4V	2 (0.2)	1 (0.1)
MENINGOCOCCAL VACCINE	3 (0.3)	7 (0.6)
MENINGOCOCCAL VACCINE A/C/Y/W	1 (0.1)	1 (0.1)
MENINGOCOCCAL VACCINE A/C/Y/W CONJ (DIP TOX)	3 (0.3)	4 (0.4)
MENINGOCOCCAL VACCINE B	1 (0.1)	0
MENINGOCOCCAL VACCINE B RFHBP/NADA/NHBA OMV	1 (0.1)	0
MENINGOCOCCAL VACCINE B RFHBPA/FHBPB	0	2 (0.2)
MENINGOCOCCAL VACCINE CONJ	1 (0.1)	1 (0.1)
POLIO VACCINE	0	1 (0.1)
RABIES VACCINE	1 (0.1)	0
TETANUS VACCINE	0	1 (0.1)

Note: WHODDG B3 v202103 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: 05OCT2021 (18:29) Source Data: adcm Table Generation: 03NOV2021 (10:23)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/adcm s001 1 ped6

Efficacy

14.11. 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 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=1061)		Placebo (N[a]=1037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2	0	0.345 (1047)	29	0.325 (1026)	100.0	(87.2, 100.0)
≥7 days after Dose 2 to <2 Months after Dose 2	0	0.139 (1047)	15	0.134 (1026)	100.0	(73.1, 100.0)
≥2 Months after Dose 2 to <4 Months after Dose 2	0	0.148 (1012)	10	0.140 (964)	100.0	(57.9, 100.0)
≥4 Months after Dose 2	0	0.058 (726)	4	0.051 (688)	100.0	(-34.2, 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 for the overall row and from start to the end of the range stated for each time interval.
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: 05OCT2021 (18:29) Source Data: adc19ef Table Generation: 05NOV2021 (11:01)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adc19ef_ve_cov_7pd2_peds_wo_aai2

14.12. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – 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]=1109)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	0	0.362 (1098)	30	0.345 (1088)	100.0	(87.5, 100.0)
Sex						
Male	0	0.183 (550)	18	0.177 (561)	100.0	(78.0, 100.0)
Female	0	0.179 (548)	12	0.169 (527)	100.0	(66.1, 100.0)
Race						
White	0	0.309 (945)	28	0.291 (926)	100.0	(86.8, 100.0)
Black or African American	0	0.019 (47)	2	0.021 (56)	100.0	(-492.9, 100.0)
Ethnicity						
Hispanic/Latino	0	0.045 (127)	7	0.040 (125)	100.0	(37.8, 100.0)
Non-Hispanic/non-Latino	0	0.317 (969)	23	0.304 (960)	100.0	(83.3, 100.0)
Country						
USA	0	0.362 (1098)	30	0.345 (1088)	100.0	(87.5, 100.0)
Comorbidities[f]						
Yes	0	0.082 (241)	11	0.073 (228)	100.0	(64.6, 100.0)
No	0	0.280 (857)	19	0.273 (860)	100.0	(79.2, 100.0)
Obese[g]						
Yes	0	0.048 (140)	7	0.039 (122)	100.0	(43.1, 100.0)
No	0	0.314 (958)	23	0.306 (966)	100.0	(83.1, 100.0)
Prior SARS-CoV-2 Status						
Negative at baseline but positive prior to 7 days after Dose 2[h]	0	0.001 (3)	2	0.004 (11)	100.0	(-1374.1, 100.0)
Negative prior to 7 days after Dose 2[i]	0	0.343 (1043)	28	0.322 (1019)	100.0	(86.8, 100.0)

14.12. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – 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]=1109)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Comorbidities are defined as having at least one of the Charlson comorbidity index category or obesity (BMI ≥95th percentile).
g. Obese is defined as BMI ≥95th percentile from the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html charts/bmiagerev htm.
h. Negative N-binding antibody result and negative NAAT result at Visit 1, positive NAAT result at Visit 2 or at unscheduled visit, if any, prior to 7 days after Dose 2.
i. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1 and Visit 2, and negative NAAT result at unscheduled visit, if any, prior to 7 days after Dose 2.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (17:31) Source Data: adc19ef Table Generation: 08DEC2021 (16:13)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adc19ef ve cov 7pd2 p sg eval

14.13. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1, by Subgroup – 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						
Overall	3	0.450 (1109)	48	0.434 (1114)	94.0	(81.3, 98.8)
Sex						
Male	3	0.227 (557)	26	0.223 (575)	88.7	(63.0, 97.8)
Female	0	0.223 (552)	22	0.211 (539)	100.0	(82.7, 100.0)
Race						
White	2	0.384 (953)	45	0.367 (951)	95.8	(83.8, 99.5)
Black or African American	0	0.024 (49)	2	0.026 (56)	100.0	(-479.7, 100.0)
All others	1	0.042 (107)	1	0.042 (107)	1.4	(-7638.0, 98.7)
American Indian or Alaska native	0	0.002 (4)	1	0.001 (3)	100.0	(-1965.1, 100.0)
Asian	1	0.027 (70)	0	0.027 (69)	UND	(NA, NA)
Ethnicity						
Hispanic/Latino	1	0.055 (128)	11	0.051 (130)	91.6	(42.3, 99.8)
Non-Hispanic/non-Latino	2	0.394 (979)	37	0.382 (981)	94.8	(79.7, 99.4)
Country						
USA	3	0.450 (1109)	48	0.434 (1114)	94.0	(81.3, 98.8)
Comorbidities[f]						
Yes	1	0.102 (246)	18	0.092 (238)	95.0	(68.3, 99.9)
No	2	0.348 (863)	30	0.342 (876)	93.4	(74.2, 99.2)
Obese[g]						
Yes	0	0.060 (142)	11	0.049 (127)	100.0	(67.0, 100.0)
No	3	0.391 (967)	37	0.385 (987)	92.0	(74.8, 98.4)
Baseline SARS-CoV-2 status						
Positive[h]	0	0.019 (45)	1	0.021 (50)	100.0	(-4202.3, 100.0)
Positive NAAT only	0	0.002 (6)	1	0.004 (10)	100.0	(-5725.9, 100.0)
Negative[i]	3	0.431 (1062)	47	0.413 (1063)	93.9	(81.0, 98.8)

14.13. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1, by Subgroup – 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])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; UND=Undefined; VE = vaccine efficacy.

a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Comorbidities are defined as having at least one of the Charlson comorbidity index category or obesity (BMI ≥95th percentile).
g. Obese is defined as BMI ≥95th percentile from the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.
h. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
i. 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: 05OCT2021 (17:31) Source Data: adc19ef Table Generation: 08DEC2021 (16:16)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adc19ef_ve_cov_pd1_sg_peds_aai

Adverse Events

14.14. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Baseline SARS-CoV-2 Status – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=46, TE[b]=0.2)			Placebo (N[a]=50, TE[b]=0.2)		
Adverse Event	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	4 (8.7)	20.8	(5.7, 53.3)	4 (8.0)	19.2	(5.2, 49.1)
Related[f]	1 (2.2)	5.2	(0.1, 29.0)	2 (4.0)	9.6	(1.2, 34.6)
Severe	0	0.0	(0.0, 19.2)	0	0.0	(0.0, 17.7)
Life-threatening	0	0.0	(0.0, 19.2)	0	0.0	(0.0, 17.7)
Any serious adverse event	0	0.0	(0.0, 19.2)	0	0.0	(0.0, 17.7)
Related[f]	0	0.0	(0.0, 19.2)	0	0.0	(0.0, 17.7)
Severe	0	0.0	(0.0, 19.2)	0	0.0	(0.0, 17.7)
Life-threatening	0	0.0	(0.0, 19.2)	0	0.0	(0.0, 17.7)
Any nonserious adverse event	4 (8.7)	20.8	(5.7, 53.3)	4 (8.0)	19.2	(5.2, 49.1)
Related[f]	1 (2.2)	5.2	(0.1, 29.0)	2 (4.0)	9.6	(1.2, 34.6)
Severe	0	0.0	(0.0, 19.2)	0	0.0	(0.0, 17.7)
Life-threatening	0	0.0	(0.0, 19.2)	0	0.0	(0.0, 17.7)
Any adverse event leading to withdrawal	0	0.0	(0.0, 19.2)	0	0.0	(0.0, 17.7)
Related[f]	0	0.0	(0.0, 19.2)	0	0.0	(0.0, 17.7)
Severe	0	0.0	(0.0, 19.2)	0	0.0	(0.0, 17.7)
Life-threatening	0	0.0	(0.0, 19.2)	0	0.0	(0.0, 17.7)
Death	0	0.0	(0.0, 19.2)	0	0.0	(0.0, 17.7)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 12NOV2021 (15:47)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/adae s092 unb base1 ped6

14.15. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Baseline SARS-CoV-2 Status – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1083, TE[b]=4.4)			Placebo (N[a]=1078, TE[b]=4.3)		
Adverse Event	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	91 (8.4)	20.8	(16.8, 25.6)	109 (10.1)	25.4	(20.8, 30.6)
Related[f]	35 (3.2)	8.0	(5.6, 11.1)	22 (2.0)	5.1	(3.2, 7.8)
Severe	13 (1.2)	3.0	(1.6, 5.1)	5 (0.5)	1.2	(0.4, 2.7)
Life-threatening	2 (0.2)	0.5	(0.1, 1.7)	1 (0.1)	0.2	(0.0, 1.3)
Any serious adverse event	10 (0.9)	2.3	(1.1, 4.2)	2 (0.2)	0.5	(0.1, 1.7)
Related[f]	0	0.0	(0.0, 0.8)	0	0.0	(0.0, 0.9)
Severe	7 (0.6)	1.6	(0.6, 3.3)	1 (0.1)	0.2	(0.0, 1.3)
Life-threatening	1 (0.1)	0.2	(0.0, 1.3)	1 (0.1)	0.2	(0.0, 1.3)
Any nonserious adverse event	85 (7.8)	19.4	(15.5, 24.0)	107 (9.9)	24.9	(20.4, 30.1)
Related[f]	35 (3.2)	8.0	(5.6, 11.1)	22 (2.0)	5.1	(3.2, 7.8)
Severe	6 (0.6)	1.4	(0.5, 3.0)	4 (0.4)	0.9	(0.3, 2.4)
Life-threatening	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Any adverse event leading to withdrawal	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Related[f]	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Severe	0	0.0	(0.0, 0.8)	0	0.0	(0.0, 0.9)
Life-threatening	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Death	0	0.0	(0.0, 0.8)	0	0.0	(0.0, 0.9)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 12NOV2021 (15:47)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/adae s092 unb base1 ped6

14.16. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Ethnicity – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=132, TE[b]=0.6)			Placebo (N[a]=130, TE[b]=0.5)		
Adverse Event	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	9 (6.8)	16.0	(7.3, 30.3)	16 (12.3)	29.8	(17.0, 48.4)
Related[f]	3 (2.3)	5.3	(1.1, 15.6)	4 (3.1)	7.5	(2.0, 19.1)
Severe	2 (1.5)	3.6	(0.4, 12.8)	0	0.0	(0.0, 6.9)
Life-threatening	0	0.0	(0.0, 6.6)	0	0.0	(0.0, 6.9)
Any serious adverse event	2 (1.5)	3.6	(0.4, 12.8)	0	0.0	(0.0, 6.9)
Related[f]	0	0.0	(0.0, 6.6)	0	0.0	(0.0, 6.9)
Severe	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
Life-threatening	0	0.0	(0.0, 6.6)	0	0.0	(0.0, 6.9)
Any nonserious adverse event	8 (6.1)	14.2	(6.1, 28.0)	16 (12.3)	29.8	(17.0, 48.4)
Related[f]	3 (2.3)	5.3	(1.1, 15.6)	4 (3.1)	7.5	(2.0, 19.1)
Severe	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
Life-threatening	0	0.0	(0.0, 6.6)	0	0.0	(0.0, 6.9)
Any adverse event leading to withdrawal	0	0.0	(0.0, 6.6)	0	0.0	(0.0, 6.9)
Related[f]	0	0.0	(0.0, 6.6)	0	0.0	(0.0, 6.9)
Severe	0	0.0	(0.0, 6.6)	0	0.0	(0.0, 6.9)
Life-threatening	0	0.0	(0.0, 6.6)	0	0.0	(0.0, 6.9)
Death	0	0.0	(0.0, 6.6)	0	0.0	(0.0, 6.9)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (16:17)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s092_unb_eth1_ped6

14.17. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Ethnicity – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=997, TE[b]=4.0)			Placebo (N[a]=996, TE[b]=4.0)		
Adverse Event	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	86 (8.6)	21.5	(17.2, 26.5)	96 (9.6)	24.2	(19.6, 29.6)
Related[f]	33 (3.3)	8.2	(5.7, 11.6)	20 (2.0)	5.1	(3.1, 7.8)
Severe	11 (1.1)	2.7	(1.4, 4.9)	5 (0.5)	1.3	(0.4, 2.9)
Life-threatening	2 (0.2)	0.5	(0.1, 1.8)	1 (0.1)	0.3	(0.0, 1.4)
Any serious adverse event	8 (0.8)	2.0	(0.9, 3.9)	2 (0.2)	0.5	(0.1, 1.8)
Related[f]	0	0.0	(0.0, 0.9)	0	0.0	(0.0, 0.9)
Severe	6 (0.6)	1.5	(0.6, 3.3)	1 (0.1)	0.3	(0.0, 1.4)
Life-threatening	1 (0.1)	0.2	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.4)
Any nonserious adverse event	81 (8.1)	20.2	(16.1, 25.2)	94 (9.4)	23.7	(19.2, 29.0)
Related[f]	33 (3.3)	8.2	(5.7, 11.6)	20 (2.0)	5.1	(3.1, 7.8)
Severe	5 (0.5)	1.2	(0.4, 2.9)	4 (0.4)	1.0	(0.3, 2.6)
Life-threatening	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Any adverse event leading to withdrawal	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Related[f]	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Severe	0	0.0	(0.0, 0.9)	0	0.0	(0.0, 0.9)
Life-threatening	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Death	0	0.0	(0.0, 0.9)	0	0.0	(0.0, 0.9)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (16:17)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s092_unb_eth1_ped6

14.18. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Race – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=970, TE[b]=3.9)			Placebo (N[a]=962, TE[b]=3.8)		
Adverse Event	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	83 (8.6)	21.3	(17.0, 26.4)	100 (10.4)	26.2	(21.3, 31.9)
Related[f]	29 (3.0)	7.5	(5.0, 10.7)	19 (2.0)	5.0	(3.0, 7.8)
Severe	10 (1.0)	2.6	(1.2, 4.7)	5 (0.5)	1.3	(0.4, 3.1)
Life-threatening	2 (0.2)	0.5	(0.1, 1.9)	1 (0.1)	0.3	(0.0, 1.5)
Any serious adverse event	7 (0.7)	1.8	(0.7, 3.7)	2 (0.2)	0.5	(0.1, 1.9)
Related[f]	0	0.0	(0.0, 0.9)	0	0.0	(0.0, 1.0)
Severe	5 (0.5)	1.3	(0.4, 3.0)	1 (0.1)	0.3	(0.0, 1.5)
Life-threatening	1 (0.1)	0.3	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.5)
Any nonserious adverse event	79 (8.1)	20.3	(16.1, 25.3)	98 (10.2)	25.7	(20.8, 31.3)
Related[f]	29 (3.0)	7.5	(5.0, 10.7)	19 (2.0)	5.0	(3.0, 7.8)
Severe	5 (0.5)	1.3	(0.4, 3.0)	4 (0.4)	1.0	(0.3, 2.7)
Life-threatening	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Any adverse event leading to withdrawal	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Related[f]	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Severe	0	0.0	(0.0, 0.9)	0	0.0	(0.0, 1.0)
Life-threatening	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Death	0	0.0	(0.0, 0.9)	0	0.0	(0.0, 1.0)

Note: All Others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. 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 the blinded follow-up period. 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:21)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s092_unb_race1_ped6

14.19. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Race – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=52, TE[b]=0.2)			Placebo (N[a]=57, TE[b]=0.3)		
Adverse Event	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	3 (5.8)	12.1	(2.5, 35.4)	3 (5.3)	11.5	(2.4, 33.6)
Related[f]	1 (1.9)	4.0	(0.1, 22.5)	3 (5.3)	11.5	(2.4, 33.6)
Severe	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)
Life-threatening	0	0.0	(0.0, 14.9)	0	0.0	(0.0, 14.1)
Any serious adverse event	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)
Related[f]	0	0.0	(0.0, 14.9)	0	0.0	(0.0, 14.1)
Severe	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)
Life-threatening	0	0.0	(0.0, 14.9)	0	0.0	(0.0, 14.1)
Any nonserious adverse event	3 (5.8)	12.1	(2.5, 35.4)	3 (5.3)	11.5	(2.4, 33.6)
Related[f]	1 (1.9)	4.0	(0.1, 22.5)	3 (5.3)	11.5	(2.4, 33.6)
Severe	0	0.0	(0.0, 14.9)	0	0.0	(0.0, 14.1)
Life-threatening	0	0.0	(0.0, 14.9)	0	0.0	(0.0, 14.1)
Any adverse event leading to withdrawal	0	0.0	(0.0, 14.9)	0	0.0	(0.0, 14.1)
Related[f]	0	0.0	(0.0, 14.9)	0	0.0	(0.0, 14.1)
Severe	0	0.0	(0.0, 14.9)	0	0.0	(0.0, 14.1)
Life-threatening	0	0.0	(0.0, 14.9)	0	0.0	(0.0, 14.1)
Death	0	0.0	(0.0, 14.9)	0	0.0	(0.0, 14.1)

Note: All Others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. 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 the blinded follow-up period. 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:21)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s092_unb_race1_ped6

14.20. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Race – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=109, TE[b]=0.4)			Placebo (N[a]=110, TE[b]=0.4)		
Adverse Event	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	9 (8.3)	20.8	(9.5, 39.4)	10 (9.1)	23.3	(11.2, 42.9)
Related[f]	6 (5.5)	13.8	(5.1, 30.1)	2 (1.8)	4.7	(0.6, 16.9)
Severe	2 (1.8)	4.6	(0.6, 16.7)	0	0.0	(0.0, 8.6)
Life-threatening	0	0.0	(0.0, 8.5)	0	0.0	(0.0, 8.6)
Any serious adverse event	2 (1.8)	4.6	(0.6, 16.7)	0	0.0	(0.0, 8.6)
Related[f]	0	0.0	(0.0, 8.5)	0	0.0	(0.0, 8.6)
Severe	1 (0.9)	2.3	(0.1, 12.8)	0	0.0	(0.0, 8.6)
Life-threatening	0	0.0	(0.0, 8.5)	0	0.0	(0.0, 8.6)
Any nonserious adverse event	7 (6.4)	16.1	(6.5, 33.3)	10 (9.1)	23.3	(11.2, 42.9)
Related[f]	6 (5.5)	13.8	(5.1, 30.1)	2 (1.8)	4.7	(0.6, 16.9)
Severe	1 (0.9)	2.3	(0.1, 12.8)	0	0.0	(0.0, 8.6)
Life-threatening	0	0.0	(0.0, 8.5)	0	0.0	(0.0, 8.6)
Any adverse event leading to withdrawal	0	0.0	(0.0, 8.5)	0	0.0	(0.0, 8.6)
Related[f]	0	0.0	(0.0, 8.5)	0	0.0	(0.0, 8.6)
Severe	0	0.0	(0.0, 8.5)	0	0.0	(0.0, 8.6)
Life-threatening	0	0.0	(0.0, 8.5)	0	0.0	(0.0, 8.6)
Death	0	0.0	(0.0, 8.5)	0	0.0	(0.0, 8.6)

Note: All Others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:21)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s092_unb_race1_ped6

14.21. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Sex – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=567, TE[b]=2.3)			Placebo (N[a]=585, TE[b]=2.3)		
Adverse Event	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	42 (7.4)	18.2	(13.1, 24.5)	57 (9.7)	24.4	(18.5, 31.7)
Related[f]	21 (3.7)	9.1	(5.6, 13.9)	12 (2.1)	5.1	(2.7, 9.0)
Severe	5 (0.9)	2.2	(0.7, 5.0)	4 (0.7)	1.7	(0.5, 4.4)
Life-threatening	1 (0.2)	0.4	(0.0, 2.4)	1 (0.2)	0.4	(0.0, 2.4)
Any serious adverse event	3 (0.5)	1.3	(0.3, 3.8)	2 (0.3)	0.9	(0.1, 3.1)
Related[f]	0	0.0	(0.0, 1.6)	0	0.0	(0.0, 1.6)
Severe	3 (0.5)	1.3	(0.3, 3.8)	1 (0.2)	0.4	(0.0, 2.4)
Life-threatening	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Any nonserious adverse event	39 (6.9)	16.9	(12.0, 23.1)	55 (9.4)	23.6	(17.8, 30.7)
Related[f]	21 (3.7)	9.1	(5.6, 13.9)	12 (2.1)	5.1	(2.7, 9.0)
Severe	2 (0.4)	0.9	(0.1, 3.1)	3 (0.5)	1.3	(0.3, 3.8)
Life-threatening	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Any adverse event leading to withdrawal	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Related[f]	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Severe	0	0.0	(0.0, 1.6)	0	0.0	(0.0, 1.6)
Life-threatening	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Death	0	0.0	(0.0, 1.6)	0	0.0	(0.0, 1.6)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:21)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s092_unb_sex1_ped6

14.22. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by Sex – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=564, TE[b]=2.3)			Placebo (N[a]=544, TE[b]=2.2)		
Adverse Event	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	53 (9.4)	23.5	(17.6, 30.7)	56 (10.3)	25.7	(19.4, 33.4)
Related[f]	15 (2.7)	6.6	(3.7, 11.0)	12 (2.2)	5.5	(2.8, 9.6)
Severe	8 (1.4)	3.5	(1.5, 7.0)	1 (0.2)	0.5	(0.0, 2.6)
Life-threatening	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Any serious adverse event	7 (1.2)	3.1	(1.2, 6.4)	0	0.0	(0.0, 1.7)
Related[f]	0	0.0	(0.0, 1.6)	0	0.0	(0.0, 1.7)
Severe	4 (0.7)	1.8	(0.5, 4.5)	0	0.0	(0.0, 1.7)
Life-threatening	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Any nonserious adverse event	50 (8.9)	22.1	(16.4, 29.2)	56 (10.3)	25.7	(19.4, 33.4)
Related[f]	15 (2.7)	6.6	(3.7, 11.0)	12 (2.2)	5.5	(2.8, 9.6)
Severe	4 (0.7)	1.8	(0.5, 4.5)	1 (0.2)	0.5	(0.0, 2.6)
Life-threatening	0	0.0	(0.0, 1.6)	0	0.0	(0.0, 1.7)
Any adverse event leading to withdrawal	0	0.0	(0.0, 1.6)	0	0.0	(0.0, 1.7)
Related[f]	0	0.0	(0.0, 1.6)	0	0.0	(0.0, 1.7)
Severe	0	0.0	(0.0, 1.6)	0	0.0	(0.0, 1.7)
Life-threatening	0	0.0	(0.0, 1.6)	0	0.0	(0.0, 1.7)
Death	0	0.0	(0.0, 1.6)	0	0.0	(0.0, 1.7)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:21)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s092_unb_sex1_ped6

14.23. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=46, TE[b]=0.2)			Placebo (N[a]=50, TE[b]=0.2)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	4 (8.7)	20.8	(5.7, 53.3)	4 (8.0)	19.2	(5.2, 49.1)
GASTROINTESTINAL DISORDERS	2 (4.3)	10.4	(1.3, 37.6)	0	0.0	(0.0, 17.7)
Diarrhoea	1 (2.2)	5.2	(0.1, 29.0)	0	0.0	(0.0, 17.7)
Nausea	1 (2.2)	5.2	(0.1, 29.0)	0	0.0	(0.0, 17.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	0.0	(0.0, 19.2)	1 (2.0)	4.8	(0.1, 26.7)
Fatigue	0	0.0	(0.0, 19.2)	1 (2.0)	4.8	(0.1, 26.7)
INFECTIONS AND INFESTATIONS	1 (2.2)	5.2	(0.1, 29.0)	0	0.0	(0.0, 17.7)
Ear infection	1 (2.2)	5.2	(0.1, 29.0)	0	0.0	(0.0, 17.7)
Otitis externa	1 (2.2)	5.2	(0.1, 29.0)	0	0.0	(0.0, 17.7)
Otitis media	1 (2.2)	5.2	(0.1, 29.0)	0	0.0	(0.0, 17.7)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	0.0	(0.0, 19.2)	2 (4.0)	9.6	(1.2, 34.6)
Musculoskeletal chest pain	0	0.0	(0.0, 19.2)	1 (2.0)	4.8	(0.1, 26.7)
Myalgia	0	0.0	(0.0, 19.2)	1 (2.0)	4.8	(0.1, 26.7)
NERVOUS SYSTEM DISORDERS	2 (4.3)	10.4	(1.3, 37.6)	1 (2.0)	4.8	(0.1, 26.7)
Dizziness	1 (2.2)	5.2	(0.1, 29.0)	1 (2.0)	4.8	(0.1, 26.7)
Syncope	1 (2.2)	5.2	(0.1, 29.0)	0	0.0	(0.0, 17.7)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	0.0	(0.0, 19.2)	1 (2.0)	4.8	(0.1, 26.7)
Rash	0	0.0	(0.0, 19.2)	1 (2.0)	4.8	(0.1, 26.7)

14.23. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=46, TE[b]=0.2)			Placebo (N[a]=50, TE[b]=0.2)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: MedDRA (v24.0) coding dictionary applied.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 12NOV2021 (15:38)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s131 unb base1 ped6

14.24. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1083, TE[b]=4.4)			Placebo (N[a]=1078, TE[b]=4.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	91 (8.4)	20.8	(16.8, 25.6)	109 (10.1)	25.4	(20.8, 30.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	9 (0.8)	2.1	(0.9, 3.9)	2 (0.2)	0.5	(0.1, 1.7)
Lymphadenopathy	9 (0.8)	2.1	(0.9, 3.9)	2 (0.2)	0.5	(0.1, 1.7)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Spine malformation	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
EAR AND LABYRINTH DISORDERS	1 (0.1)	0.2	(0.0, 1.3)	3 (0.3)	0.7	(0.1, 2.0)
Cerumen impaction	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Conductive deafness	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Ear pain	1 (0.1)	0.2	(0.0, 1.3)	1 (0.1)	0.2	(0.0, 1.3)
EYE DISORDERS	2 (0.2)	0.5	(0.1, 1.7)	1 (0.1)	0.2	(0.0, 1.3)
Eye pain	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Eyelid rash	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Retinal haemorrhage	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
GASTROINTESTINAL DISORDERS	12 (1.1)	2.7	(1.4, 4.8)	8 (0.7)	1.9	(0.8, 3.7)
Abdominal pain	2 (0.2)	0.5	(0.1, 1.7)	1 (0.1)	0.2	(0.0, 1.3)
Aphthous ulcer	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Constipation	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Diarrhoea	2 (0.2)	0.5	(0.1, 1.7)	1 (0.1)	0.2	(0.0, 1.3)
Gastritis	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Lip swelling	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Mouth swelling	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Mouth ulceration	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Nausea	4 (0.4)	0.9	(0.2, 2.3)	3 (0.3)	0.7	(0.1, 2.0)
Oral mucosal blistering	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Rectal prolapse	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Tooth impacted	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Toothache	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Vomiting	1 (0.1)	0.2	(0.0, 1.3)	1 (0.1)	0.2	(0.0, 1.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	17 (1.6)	3.9	(2.3, 6.2)	11 (1.0)	2.6	(1.3, 4.6)
Chills	2 (0.2)	0.5	(0.1, 1.7)	1 (0.1)	0.2	(0.0, 1.3)
Fatigue	8 (0.7)	1.8	(0.8, 3.6)	3 (0.3)	0.7	(0.1, 2.0)
Injection site pain	8 (0.7)	1.8	(0.8, 3.6)	8 (0.7)	1.9	(0.8, 3.7)
Injection site swelling	2 (0.2)	0.5	(0.1, 1.7)	0	0.0	(0.0, 0.9)
Nodule	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)

14.24. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1083, TE[b]=4.4)			Placebo (N[a]=1078, TE[b]=4.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Oedema peripheral	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Peripheral swelling	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Pyrexia	6 (0.6)	1.4	(0.5, 3.0)	0	0.0	(0.0, 0.9)
Vessel puncture site pain	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
IMMUNE SYSTEM DISORDERS	1 (0.1)	0.2	(0.0, 1.3)	1 (0.1)	0.2	(0.0, 1.3)
Food allergy	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Seasonal allergy	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
INFECTIONS AND INFESTATIONS	9 (0.8)	2.1	(0.9, 3.9)	9 (0.8)	2.1	(1.0, 4.0)
Anal abscess	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Appendicitis	0	0.0	(0.0, 0.8)	2 (0.2)	0.5	(0.1, 1.7)
Body tinea	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Candida infection	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Cellulitis	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Conjunctivitis	0	0.0	(0.0, 0.8)	2 (0.2)	0.5	(0.1, 1.7)
Ear infection	2 (0.2)	0.5	(0.1, 1.7)	0	0.0	(0.0, 0.9)
Focal peritonitis	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Infectious mononucleosis	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Paronychia	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Pilonidal cyst	1 (0.1)	0.2	(0.0, 1.3)	1 (0.1)	0.2	(0.0, 1.3)
Subcutaneous abscess	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Tinea capitis	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Vulval abscess	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Vulvovaginal mycotic infection	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	15 (1.4)	3.4	(1.9, 5.7)	25 (2.3)	5.8	(3.8, 8.6)
Accident	1 (0.1)	0.2	(0.0, 1.3)	1 (0.1)	0.2	(0.0, 1.3)
Ankle fracture	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Bone contusion	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Clavicle fracture	1 (0.1)	0.2	(0.0, 1.3)	1 (0.1)	0.2	(0.0, 1.3)
Concussion	3 (0.3)	0.7	(0.1, 2.0)	4 (0.4)	0.9	(0.3, 2.4)
Contusion	2 (0.2)	0.5	(0.1, 1.7)	2 (0.2)	0.5	(0.1, 1.7)
Fall	2 (0.2)	0.5	(0.1, 1.7)	5 (0.5)	1.2	(0.4, 2.7)
Femur fracture	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Foot fracture	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Hand fracture	1 (0.1)	0.2	(0.0, 1.3)	4 (0.4)	0.9	(0.3, 2.4)
Humerus fracture	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Ligament sprain	1 (0.1)	0.2	(0.0, 1.3)	4 (0.4)	0.9	(0.3, 2.4)

14.24. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1083, TE[b]=4.4)			Placebo (N[a]=1078, TE[b]=4.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Lip injury	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Meniscus injury	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Muscle strain	1 (0.1)	0.2	(0.0, 1.3)	1 (0.1)	0.2	(0.0, 1.3)
Patella fracture	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Procedural pain	2 (0.2)	0.5	(0.1, 1.7)	3 (0.3)	0.7	(0.1, 2.0)
Radius fracture	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Skin laceration	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Tibia fracture	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Tooth fracture	0	0.0	(0.0, 0.8)	2 (0.2)	0.5	(0.1, 1.7)
Upper limb fracture	1 (0.1)	0.2	(0.0, 1.3)	1 (0.1)	0.2	(0.0, 1.3)
INVESTIGATIONS	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
SARS-CoV-2 antibody test positive	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	8 (0.7)	1.8	(0.8, 3.6)	12 (1.1)	2.8	(1.4, 4.9)
Arthralgia	2 (0.2)	0.5	(0.1, 1.7)	4 (0.4)	0.9	(0.3, 2.4)
Back pain	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Joint swelling	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Musculoskeletal chest pain	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Myalgia	3 (0.3)	0.7	(0.1, 2.0)	1 (0.1)	0.2	(0.0, 1.3)
Neck pain	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Osteochondrosis	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Pain in extremity	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Tendonitis	0	0.0	(0.0, 0.8)	4 (0.4)	0.9	(0.3, 2.4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.1)	0.2	(0.0, 1.3)	3 (0.3)	0.7	(0.1, 2.0)
Fibroadenoma of breast	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Hair follicle tumour benign	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Melanocytic naevus	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Skin papilloma	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
NERVOUS SYSTEM DISORDERS	11 (1.0)	2.5	(1.3, 4.5)	12 (1.1)	2.8	(1.4, 4.9)
Dizziness	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Headache	5 (0.5)	1.1	(0.4, 2.7)	7 (0.6)	1.6	(0.7, 3.4)
Migraine	3 (0.3)	0.7	(0.1, 2.0)	0	0.0	(0.0, 0.9)
Paraesthesia	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Presyncope	1 (0.1)	0.2	(0.0, 1.3)	4 (0.4)	0.9	(0.3, 2.4)
Syncope	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
PSYCHIATRIC DISORDERS	17 (1.6)	3.9	(2.3, 6.2)	13 (1.2)	3.0	(1.6, 5.2)

14.24. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1083, TE[b]=4.4)			Placebo (N[a]=1078, TE[b]=4.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Anxiety	4 (0.4)	0.9	(0.2, 2.3)	6 (0.6)	1.4	(0.5, 3.0)
Attention deficit hyperactivity disorder	2 (0.2)	0.5	(0.1, 1.7)	4 (0.4)	0.9	(0.3, 2.4)
Conversion disorder	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Depression	6 (0.6)	1.4	(0.5, 3.0)	3 (0.3)	0.7	(0.1, 2.0)
Disorientation	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Generalised anxiety disorder	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Obsessive-compulsive disorder	0	0.0	(0.0, 0.8)	2 (0.2)	0.5	(0.1, 1.7)
Panic attack	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Sleep terror	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Suicidal ideation	4 (0.4)	0.9	(0.2, 2.3)	0	0.0	(0.0, 0.9)
Tic	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
RENAL AND URINARY DISORDERS	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Dysuria	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Amenorrhoea	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (0.3)	0.7	(0.1, 2.0)	8 (0.7)	1.9	(0.8, 3.7)
Epistaxis	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Nasal congestion	2 (0.2)	0.5	(0.1, 1.7)	3 (0.3)	0.7	(0.1, 2.0)
Rhinorrhoea	2 (0.2)	0.5	(0.1, 1.7)	4 (0.4)	0.9	(0.3, 2.4)
Sneezing	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	9 (0.8)	2.1	(0.9, 3.9)	15 (1.4)	3.5	(2.0, 5.8)
Acne	2 (0.2)	0.5	(0.1, 1.7)	3 (0.3)	0.7	(0.1, 2.0)
Dermatitis contact	2 (0.2)	0.5	(0.1, 1.7)	1 (0.1)	0.2	(0.0, 1.3)
Eczema	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Pityriasis rosea	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Rash	3 (0.3)	0.7	(0.1, 2.0)	4 (0.4)	0.9	(0.3, 2.4)
Rash maculo-papular	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Seborrhoeic dermatitis	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
Urticaria	2 (0.2)	0.5	(0.1, 1.7)	5 (0.5)	1.2	(0.4, 2.7)
SURGICAL AND MEDICAL PROCEDURES	1 (0.1)	0.2	(0.0, 1.3)	1 (0.1)	0.2	(0.0, 1.3)
Wisdom teeth removal	1 (0.1)	0.2	(0.0, 1.3)	1 (0.1)	0.2	(0.0, 1.3)

14.24. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1083, TE[b]=4.4)			Placebo (N[a]=1078, TE[b]=4.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: MedDRA (v24.0) coding dictionary applied.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 12NOV2021 (15:38)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s131 unb base1 ped6

14.25. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=132, TE[b]=0.6)			Placebo (N[a]=130, TE[b]=0.5)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	9 (6.8)	16.0	(7.3, 30.3)	16 (12.3)	29.8	(17.0, 48.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
Lymphadenopathy	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
EAR AND LABYRINTH DISORDERS	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)
Conductive deafness	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)
GASTROINTESTINAL DISORDERS	2 (1.5)	3.6	(0.4, 12.8)	1 (0.8)	1.9	(0.0, 10.4)
Abdominal pain	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
Constipation	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
Diarrhoea	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
Gastritis	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
Nausea	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)
Vomiting	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.8)	1.8	(0.0, 9.9)	1 (0.8)	1.9	(0.0, 10.4)
Injection site pain	1 (0.8)	1.8	(0.0, 9.9)	1 (0.8)	1.9	(0.0, 10.4)
Vessel puncture site pain	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)
INFECTIONS AND INFESTATIONS	3 (2.3)	5.3	(1.1, 15.6)	0	0.0	(0.0, 6.9)
Body tinea	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
Paronychia	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
Vulval abscess	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	0.0	(0.0, 6.6)	3 (2.3)	5.6	(1.2, 16.3)
Accident	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)
Ankle fracture	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)
Contusion	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)
Fall	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)
Hand fracture	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)
Lip injury	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)
Tooth fracture	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	0.0	(0.0, 6.6)	3 (2.3)	5.6	(1.2, 16.3)
Arthralgia	0	0.0	(0.0, 6.6)	2 (1.5)	3.7	(0.5, 13.5)
Musculoskeletal chest pain	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)

14.25. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=132, TE[b]=0.6)			Placebo (N[a]=130, TE[b]=0.5)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Melanocytic naevus	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)
NERVOUS SYSTEM DISORDERS	2 (1.5)	3.6	(0.4, 12.8)	3 (2.3)	5.6	(1.2, 16.3)
Headache	1 (0.8)	1.8	(0.0, 9.9)	3 (2.3)	5.6	(1.2, 16.3)
Paraesthesia	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
PSYCHIATRIC DISORDERS	2 (1.5)	3.6	(0.4, 12.8)	1 (0.8)	1.9	(0.0, 10.4)
Anxiety	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
Conversion disorder	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
Obsessive-compulsive disorder	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)
Suicidal ideation	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.8)	1.8	(0.0, 9.9)	6 (4.6)	11.2	(4.1, 24.3)
Acne	0	0.0	(0.0, 6.6)	2 (1.5)	3.7	(0.5, 13.5)
Dermatitis contact	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
Rash	0	0.0	(0.0, 6.6)	3 (2.3)	5.6	(1.2, 16.3)
Seborrhoeic dermatitis	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)
Urticaria	0	0.0	(0.0, 6.6)	1 (0.8)	1.9	(0.0, 10.4)

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (16:25)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s131_unb_eth1_ped6

14.26. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=997, TE[b]=4.0)			Placebo (N[a]=996, TE[b]=4.0)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	86 (8.6)	21.5	(17.2, 26.5)	96 (9.6)	24.2	(19.6, 29.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	8 (0.8)	2.0	(0.9, 3.9)	2 (0.2)	0.5	(0.1, 1.8)
Lymphadenopathy	8 (0.8)	2.0	(0.9, 3.9)	2 (0.2)	0.5	(0.1, 1.8)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Spine malformation	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
EAR AND LABYRINTH DISORDERS	1 (0.1)	0.2	(0.0, 1.4)	2 (0.2)	0.5	(0.1, 1.8)
Cerumen impaction	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Ear pain	1 (0.1)	0.2	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.4)
EYE DISORDERS	2 (0.2)	0.5	(0.1, 1.8)	1 (0.1)	0.3	(0.0, 1.4)
Eye pain	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Eyelid rash	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Retinal haemorrhage	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
GASTROINTESTINAL DISORDERS	12 (1.2)	3.0	(1.5, 5.2)	7 (0.7)	1.8	(0.7, 3.6)
Abdominal pain	1 (0.1)	0.2	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.4)
Aphthous ulcer	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Diarrhoea	2 (0.2)	0.5	(0.1, 1.8)	1 (0.1)	0.3	(0.0, 1.4)
Lip swelling	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Mouth swelling	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Mouth ulceration	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Nausea	5 (0.5)	1.2	(0.4, 2.9)	2 (0.2)	0.5	(0.1, 1.8)
Oral mucosal blistering	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Rectal prolapse	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Tooth impacted	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Toothache	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Vomiting	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	16 (1.6)	4.0	(2.3, 6.5)	11 (1.1)	2.8	(1.4, 5.0)
Chills	2 (0.2)	0.5	(0.1, 1.8)	1 (0.1)	0.3	(0.0, 1.4)
Fatigue	8 (0.8)	2.0	(0.9, 3.9)	4 (0.4)	1.0	(0.3, 2.6)
Injection site pain	7 (0.7)	1.7	(0.7, 3.6)	7 (0.7)	1.8	(0.7, 3.6)
Injection site swelling	2 (0.2)	0.5	(0.1, 1.8)	0	0.0	(0.0, 0.9)
Nodule	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Oedema peripheral	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Peripheral swelling	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Pyrexia	6 (0.6)	1.5	(0.6, 3.3)	0	0.0	(0.0, 0.9)

14.26. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=997, TE[b]=4.0)			Placebo (N[a]=996, TE[b]=4.0)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
IMMUNE SYSTEM DISORDERS	1 (0.1)	0.2	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.4)
Food allergy	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Seasonal allergy	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
INFECTIONS AND INFESTATIONS	7 (0.7)	1.7	(0.7, 3.6)	9 (0.9)	2.3	(1.0, 4.3)
Anal abscess	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Appendicitis	0	0.0	(0.0, 0.9)	2 (0.2)	0.5	(0.1, 1.8)
Candida infection	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Cellulitis	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Conjunctivitis	0	0.0	(0.0, 0.9)	2 (0.2)	0.5	(0.1, 1.8)
Ear infection	3 (0.3)	0.7	(0.2, 2.2)	0	0.0	(0.0, 0.9)
Focal peritonitis	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Infectious mononucleosis	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Otitis externa	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Otitis media	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Pilonidal cyst	1 (0.1)	0.2	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.4)
Subcutaneous abscess	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Tinea capitis	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Vulvovaginal mycotic infection	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	15 (1.5)	3.7	(2.1, 6.2)	22 (2.2)	5.6	(3.5, 8.4)
Accident	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Bone contusion	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Clavicle fracture	1 (0.1)	0.2	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.4)
Concussion	3 (0.3)	0.7	(0.2, 2.2)	4 (0.4)	1.0	(0.3, 2.6)
Contusion	2 (0.2)	0.5	(0.1, 1.8)	1 (0.1)	0.3	(0.0, 1.4)
Fall	2 (0.2)	0.5	(0.1, 1.8)	4 (0.4)	1.0	(0.3, 2.6)
Femur fracture	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Foot fracture	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Hand fracture	1 (0.1)	0.2	(0.0, 1.4)	3 (0.3)	0.8	(0.2, 2.2)
Humerus fracture	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Ligament sprain	1 (0.1)	0.2	(0.0, 1.4)	4 (0.4)	1.0	(0.3, 2.6)
Meniscus injury	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Muscle strain	1 (0.1)	0.2	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.4)
Patella fracture	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Procedural pain	2 (0.2)	0.5	(0.1, 1.8)	3 (0.3)	0.8	(0.2, 2.2)
Radius fracture	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Skin laceration	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)

14.26. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=997, TE[b]=4.0)			Placebo (N[a]=996, TE[b]=4.0)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Tibia fracture	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Tooth fracture	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Upper limb fracture	1 (0.1)	0.2	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.4)
INVESTIGATIONS	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
SARS-CoV-2 antibody test positive	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	8 (0.8)	2.0	(0.9, 3.9)	11 (1.1)	2.8	(1.4, 5.0)
Arthralgia	2 (0.2)	0.5	(0.1, 1.8)	2 (0.2)	0.5	(0.1, 1.8)
Back pain	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Joint swelling	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Musculoskeletal chest pain	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Myalgia	3 (0.3)	0.7	(0.2, 2.2)	2 (0.2)	0.5	(0.1, 1.8)
Neck pain	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Osteochondrosis	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Pain in extremity	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Tendonitis	0	0.0	(0.0, 0.9)	4 (0.4)	1.0	(0.3, 2.6)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.1)	0.2	(0.0, 1.4)	2 (0.2)	0.5	(0.1, 1.8)
Fibroadenoma of breast	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Hair follicle tumour benign	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Skin papilloma	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
NERVOUS SYSTEM DISORDERS	11 (1.1)	2.7	(1.4, 4.9)	10 (1.0)	2.5	(1.2, 4.6)
Dizziness	2 (0.2)	0.5	(0.1, 1.8)	1 (0.1)	0.3	(0.0, 1.4)
Headache	4 (0.4)	1.0	(0.3, 2.6)	4 (0.4)	1.0	(0.3, 2.6)
Migraine	3 (0.3)	0.7	(0.2, 2.2)	0	0.0	(0.0, 0.9)
Presyncope	1 (0.1)	0.2	(0.0, 1.4)	4 (0.4)	1.0	(0.3, 2.6)
Syncope	1 (0.1)	0.2	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.4)
PSYCHIATRIC DISORDERS	15 (1.5)	3.7	(2.1, 6.2)	12 (1.2)	3.0	(1.6, 5.3)
Anxiety	3 (0.3)	0.7	(0.2, 2.2)	6 (0.6)	1.5	(0.6, 3.3)
Attention deficit hyperactivity disorder	2 (0.2)	0.5	(0.1, 1.8)	4 (0.4)	1.0	(0.3, 2.6)
Depression	6 (0.6)	1.5	(0.6, 3.3)	3 (0.3)	0.8	(0.2, 2.2)
Disorientation	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Generalised anxiety disorder	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Obsessive-compulsive disorder	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Panic attack	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Sleep terror	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Suicidal ideation	3 (0.3)	0.7	(0.2, 2.2)	0	0.0	(0.0, 0.9)

14.26. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=997, TE[b]=4.0)			Placebo (N[a]=996, TE[b]=4.0)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Tic	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
RENAL AND URINARY DISORDERS	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Dysuria	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Amenorrhoea	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (0.3)	0.7	(0.2, 2.2)	8 (0.8)	2.0	(0.9, 4.0)
Epistaxis	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Nasal congestion	2 (0.2)	0.5	(0.1, 1.8)	3 (0.3)	0.8	(0.2, 2.2)
Rhinorrhoea	2 (0.2)	0.5	(0.1, 1.8)	4 (0.4)	1.0	(0.3, 2.6)
Sneezing	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	8 (0.8)	2.0	(0.9, 3.9)	9 (0.9)	2.3	(1.0, 4.3)
Acne	2 (0.2)	0.5	(0.1, 1.8)	1 (0.1)	0.3	(0.0, 1.4)
Dermatitis contact	1 (0.1)	0.2	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.4)
Eczema	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Rash	3 (0.3)	0.7	(0.2, 2.2)	2 (0.2)	0.5	(0.1, 1.8)
Rash maculo-papular	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
Urticaria	2 (0.2)	0.5	(0.1, 1.8)	4 (0.4)	1.0	(0.3, 2.6)
SURGICAL AND MEDICAL PROCEDURES	1 (0.1)	0.2	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.4)
Wisdom teeth removal	1 (0.1)	0.2	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.4)

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (16:25)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s131_unb_eth1_ped6

14.27. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=970, TE[b]=3.9)			Placebo (N[a]=962, TE[b]=3.8)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	83 (8.6)	21.3	(17.0, 26.4)	100 (10.4)	26.2	(21.3, 31.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	6 (0.6)	1.5	(0.6, 3.4)	1 (0.1)	0.3	(0.0, 1.5)
Lymphadenopathy	6 (0.6)	1.5	(0.6, 3.4)	1 (0.1)	0.3	(0.0, 1.5)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Spine malformation	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
EAR AND LABYRINTH DISORDERS	1 (0.1)	0.3	(0.0, 1.4)	2 (0.2)	0.5	(0.1, 1.9)
Cerumen impaction	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Ear pain	1 (0.1)	0.3	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.5)
EYE DISORDERS	2 (0.2)	0.5	(0.1, 1.9)	1 (0.1)	0.3	(0.0, 1.5)
Eye pain	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Eyelid rash	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Retinal haemorrhage	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
GASTROINTESTINAL DISORDERS	13 (1.3)	3.3	(1.8, 5.7)	7 (0.7)	1.8	(0.7, 3.8)
Abdominal pain	1 (0.1)	0.3	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.5)
Aphthous ulcer	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Constipation	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Diarrhoea	3 (0.3)	0.8	(0.2, 2.3)	0	0.0	(0.0, 1.0)
Gastritis	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Lip swelling	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Mouth swelling	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Mouth ulceration	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Nausea	5 (0.5)	1.3	(0.4, 3.0)	3 (0.3)	0.8	(0.2, 2.3)
Oral mucosal blistering	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Rectal prolapse	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Tooth impacted	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Toothache	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Vomiting	1 (0.1)	0.3	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.5)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	15 (1.5)	3.9	(2.2, 6.4)	10 (1.0)	2.6	(1.3, 4.8)
Chills	1 (0.1)	0.3	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.5)
Fatigue	7 (0.7)	1.8	(0.7, 3.7)	4 (0.4)	1.0	(0.3, 2.7)
Injection site pain	7 (0.7)	1.8	(0.7, 3.7)	6 (0.6)	1.6	(0.6, 3.4)
Injection site swelling	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Nodule	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)

14.27. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=970, TE[b]=3.9)			Placebo (N[a]=962, TE[b]=3.8)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Oedema peripheral	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Pyrexia	5 (0.5)	1.3	(0.4, 3.0)	0	0.0	(0.0, 1.0)
Vessel puncture site pain	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
IMMUNE SYSTEM DISORDERS	1 (0.1)	0.3	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.5)
Food allergy	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Seasonal allergy	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
INFECTIONS AND INFESTATIONS	9 (0.9)	2.3	(1.1, 4.4)	7 (0.7)	1.8	(0.7, 3.8)
Anal abscess	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Appendicitis	0	0.0	(0.0, 0.9)	2 (0.2)	0.5	(0.1, 1.9)
Candida infection	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Conjunctivitis	0	0.0	(0.0, 0.9)	2 (0.2)	0.5	(0.1, 1.9)
Ear infection	3 (0.3)	0.8	(0.2, 2.3)	0	0.0	(0.0, 1.0)
Focal peritonitis	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Infectious mononucleosis	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Otitis externa	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Otitis media	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Paronychia	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Pilonidal cyst	1 (0.1)	0.3	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.5)
Tinea capitis	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Vulval abscess	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Vulvovaginal mycotic infection	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	14 (1.4)	3.6	(2.0, 6.0)	24 (2.5)	6.3	(4.0, 9.4)
Accident	1 (0.1)	0.3	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.5)
Ankle fracture	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Bone contusion	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Clavicle fracture	1 (0.1)	0.3	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.5)
Concussion	3 (0.3)	0.8	(0.2, 2.3)	4 (0.4)	1.0	(0.3, 2.7)
Contusion	1 (0.1)	0.3	(0.0, 1.4)	2 (0.2)	0.5	(0.1, 1.9)
Fall	1 (0.1)	0.3	(0.0, 1.4)	5 (0.5)	1.3	(0.4, 3.1)
Femur fracture	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Foot fracture	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Hand fracture	1 (0.1)	0.3	(0.0, 1.4)	3 (0.3)	0.8	(0.2, 2.3)
Humerus fracture	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Ligament sprain	1 (0.1)	0.3	(0.0, 1.4)	4 (0.4)	1.0	(0.3, 2.7)
Lip injury	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Meniscus injury	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)

14.27. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=970, TE[b]=3.9)			Placebo (N[a]=962, TE[b]=3.8)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Muscle strain	1 (0.1)	0.3	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.5)
Patella fracture	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Procedural pain	2 (0.2)	0.5	(0.1, 1.9)	3 (0.3)	0.8	(0.2, 2.3)
Radius fracture	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Skin laceration	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Tibia fracture	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Tooth fracture	0	0.0	(0.0, 0.9)	2 (0.2)	0.5	(0.1, 1.9)
Upper limb fracture	1 (0.1)	0.3	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.5)
INVESTIGATIONS	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
SARS-CoV-2 antibody test positive	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	8 (0.8)	2.1	(0.9, 4.1)	13 (1.4)	3.4	(1.8, 5.8)
Arthralgia	2 (0.2)	0.5	(0.1, 1.9)	4 (0.4)	1.0	(0.3, 2.7)
Back pain	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Joint swelling	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Musculoskeletal chest pain	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Myalgia	3 (0.3)	0.8	(0.2, 2.3)	2 (0.2)	0.5	(0.1, 1.9)
Neck pain	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Osteochondrosis	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Pain in extremity	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Tendonitis	0	0.0	(0.0, 0.9)	4 (0.4)	1.0	(0.3, 2.7)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.1)	0.3	(0.0, 1.4)	2 (0.2)	0.5	(0.1, 1.9)
Hair follicle tumour benign	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Melanocytic naevus	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Skin papilloma	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
NERVOUS SYSTEM DISORDERS	11 (1.1)	2.8	(1.4, 5.1)	12 (1.2)	3.1	(1.6, 5.5)
Dizziness	2 (0.2)	0.5	(0.1, 1.9)	1 (0.1)	0.3	(0.0, 1.5)
Headache	5 (0.5)	1.3	(0.4, 3.0)	6 (0.6)	1.6	(0.6, 3.4)
Migraine	2 (0.2)	0.5	(0.1, 1.9)	0	0.0	(0.0, 1.0)
Presyncope	1 (0.1)	0.3	(0.0, 1.4)	4 (0.4)	1.0	(0.3, 2.7)
Syncope	1 (0.1)	0.3	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.5)
PSYCHIATRIC DISORDERS	14 (1.4)	3.6	(2.0, 6.0)	13 (1.4)	3.4	(1.8, 5.8)
Anxiety	3 (0.3)	0.8	(0.2, 2.3)	6 (0.6)	1.6	(0.6, 3.4)
Attention deficit hyperactivity disorder	2 (0.2)	0.5	(0.1, 1.9)	4 (0.4)	1.0	(0.3, 2.7)
Conversion disorder	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Depression	4 (0.4)	1.0	(0.3, 2.6)	3 (0.3)	0.8	(0.2, 2.3)

14.27. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=970, TE[b]=3.9)			Placebo (N[a]=962, TE[b]=3.8)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Disorientation	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Generalised anxiety disorder	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Obsessive-compulsive disorder	0	0.0	(0.0, 0.9)	2 (0.2)	0.5	(0.1, 1.9)
Panic attack	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Sleep terror	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Suicidal ideation	3 (0.3)	0.8	(0.2, 2.3)	0	0.0	(0.0, 1.0)
Tic	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
RENAL AND URINARY DISORDERS	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Dysuria	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Amenorrhoea	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	3 (0.3)	0.8	(0.2, 2.3)	7 (0.7)	1.8	(0.7, 3.8)
Epistaxis	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Nasal congestion	2 (0.2)	0.5	(0.1, 1.9)	3 (0.3)	0.8	(0.2, 2.3)
Rhinorrhoea	2 (0.2)	0.5	(0.1, 1.9)	3 (0.3)	0.8	(0.2, 2.3)
Sneezing	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	9 (0.9)	2.3	(1.1, 4.4)	13 (1.4)	3.4	(1.8, 5.8)
Acne	2 (0.2)	0.5	(0.1, 1.9)	2 (0.2)	0.5	(0.1, 1.9)
Dermatitis contact	2 (0.2)	0.5	(0.1, 1.9)	1 (0.1)	0.3	(0.0, 1.5)
Eczema	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Rash	3 (0.3)	0.8	(0.2, 2.3)	4 (0.4)	1.0	(0.3, 2.7)
Rash maculo-papular	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Seborrhoeic dermatitis	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
Urticaria	2 (0.2)	0.5	(0.1, 1.9)	5 (0.5)	1.3	(0.4, 3.1)
SURGICAL AND MEDICAL PROCEDURES	1 (0.1)	0.3	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.5)
Wisdom teeth removal	1 (0.1)	0.3	(0.0, 1.4)	1 (0.1)	0.3	(0.0, 1.5)

14.27. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=970, TE[b]=3.9)			Placebo (N[a]=962, TE[b]=3.8)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])

Note: MedDRA (v24.0) coding dictionary applied.
Note: All Others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. 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 the blinded follow-up period. 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.
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14.28. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=52, TE[b]=0.2)			Placebo (N[a]=57, TE[b]=0.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	3 (5.8)	12.1	(2.5, 35.4)	3 (5.3)	11.5	(2.4, 33.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	0	0.0	(0.0, 14.9)	1 (1.8)	3.8	(0.1, 21.3)
Lymphadenopathy	0	0.0	(0.0, 14.9)	1 (1.8)	3.8	(0.1, 21.3)
EAR AND LABYRINTH DISORDERS	0	0.0	(0.0, 14.9)	1 (1.8)	3.8	(0.1, 21.3)
Conductive deafness	0	0.0	(0.0, 14.9)	1 (1.8)	3.8	(0.1, 21.3)
GASTROINTESTINAL DISORDERS	0	0.0	(0.0, 14.9)	1 (1.8)	3.8	(0.1, 21.3)
Diarrhoea	0	0.0	(0.0, 14.9)	1 (1.8)	3.8	(0.1, 21.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)
Peripheral swelling	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)
INFECTIONS AND INFESTATIONS	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)
Body tinea	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)
Contusion	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)
Fall	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)
PSYCHIATRIC DISORDERS	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)
Anxiety	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)
Depression	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	0.0	(0.0, 14.9)	1 (1.8)	3.8	(0.1, 21.3)
Rhinorrhoea	0	0.0	(0.0, 14.9)	1 (1.8)	3.8	(0.1, 21.3)

Note: MedDRA (v24.0) coding dictionary applied.
Note: All Others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. 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 the blinded follow-up period. 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.
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14.29. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=109, TE[b]=0.4)			Placebo (N[a]=110, TE[b]=0.4)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	9 (8.3)	20.8	(9.5, 39.4)	10 (9.1)	23.3	(11.2, 42.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	3 (2.8)	6.9	(1.4, 20.2)	0	0.0	(0.0, 8.6)
Lymphadenopathy	3 (2.8)	6.9	(1.4, 20.2)	0	0.0	(0.0, 8.6)
GASTROINTESTINAL DISORDERS	1 (0.9)	2.3	(0.1, 12.8)	0	0.0	(0.0, 8.6)
Abdominal pain	1 (0.9)	2.3	(0.1, 12.8)	0	0.0	(0.0, 8.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.9)	2.3	(0.1, 12.8)	2 (1.8)	4.7	(0.6, 16.9)
Chills	1 (0.9)	2.3	(0.1, 12.8)	0	0.0	(0.0, 8.6)
Fatigue	1 (0.9)	2.3	(0.1, 12.8)	0	0.0	(0.0, 8.6)
Injection site pain	1 (0.9)	2.3	(0.1, 12.8)	2 (1.8)	4.7	(0.6, 16.9)
Injection site swelling	1 (0.9)	2.3	(0.1, 12.8)	0	0.0	(0.0, 8.6)
Pyrexia	1 (0.9)	2.3	(0.1, 12.8)	0	0.0	(0.0, 8.6)
INFECTIONS AND INFESTATIONS	0	0.0	(0.0, 8.5)	2 (1.8)	4.7	(0.6, 16.9)
Cellulitis	0	0.0	(0.0, 8.5)	1 (0.9)	2.3	(0.1, 13.0)
Subcutaneous abscess	0	0.0	(0.0, 8.5)	1 (0.9)	2.3	(0.1, 13.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	0.0	(0.0, 8.5)	1 (0.9)	2.3	(0.1, 13.0)
Hand fracture	0	0.0	(0.0, 8.5)	1 (0.9)	2.3	(0.1, 13.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	0.0	(0.0, 8.5)	1 (0.9)	2.3	(0.1, 13.0)
Musculoskeletal chest pain	0	0.0	(0.0, 8.5)	1 (0.9)	2.3	(0.1, 13.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	0.0	(0.0, 8.5)	1 (0.9)	2.3	(0.1, 13.0)
Fibroadenoma of breast	0	0.0	(0.0, 8.5)	1 (0.9)	2.3	(0.1, 13.0)
NERVOUS SYSTEM DISORDERS	2 (1.8)	4.6	(0.6, 16.7)	1 (0.9)	2.3	(0.1, 13.0)
Headache	0	0.0	(0.0, 8.5)	1 (0.9)	2.3	(0.1, 13.0)
Migraine	1 (0.9)	2.3	(0.1, 12.8)	0	0.0	(0.0, 8.6)
Paraesthesia	1 (0.9)	2.3	(0.1, 12.8)	0	0.0	(0.0, 8.6)
PSYCHIATRIC DISORDERS	2 (1.8)	4.6	(0.6, 16.7)	0	0.0	(0.0, 8.6)
Depression	1 (0.9)	2.3	(0.1, 12.8)	0	0.0	(0.0, 8.6)
Suicidal ideation	1 (0.9)	2.3	(0.1, 12.8)	0	0.0	(0.0, 8.6)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	0.0	(0.0, 8.5)	3 (2.7)	7.0	(1.4, 20.5)
Acne	0	0.0	(0.0, 8.5)	1 (0.9)	2.3	(0.1, 13.0)
Pityriasis rosea	0	0.0	(0.0, 8.5)	1 (0.9)	2.3	(0.1, 13.0)
Rash	0	0.0	(0.0, 8.5)	1 (0.9)	2.3	(0.1, 13.0)

14.29. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=109, TE[b]=0.4)			Placebo (N[a]=110, TE[b]=0.4)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])

Note: MedDRA (v24.0) coding dictionary applied.
Note: All Others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. 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 the blinded follow-up period. 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.
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14.30. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=567, TE[b]=2.3)			Placebo (N[a]=585, TE[b]=2.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	42 (7.4)	18.2	(13.1, 24.5)	57 (9.7)	24.4	(18.5, 31.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	8 (1.4)	3.5	(1.5, 6.8)	0	0.0	(0.0, 1.6)
Lymphadenopathy	8 (1.4)	3.5	(1.5, 6.8)	0	0.0	(0.0, 1.6)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Spine malformation	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
EAR AND LABYRINTH DISORDERS	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Ear pain	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
EYE DISORDERS	2 (0.4)	0.9	(0.1, 3.1)	1 (0.2)	0.4	(0.0, 2.4)
Eye pain	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Eyelid rash	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Retinal haemorrhage	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
GASTROINTESTINAL DISORDERS	6 (1.1)	2.6	(1.0, 5.6)	3 (0.5)	1.3	(0.3, 3.8)
Aphthous ulcer	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Diarrhoea	2 (0.4)	0.9	(0.1, 3.1)	1 (0.2)	0.4	(0.0, 2.4)
Lip swelling	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Mouth swelling	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Nausea	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Oral mucosal blistering	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Tooth impacted	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Toothache	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Vomiting	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	10 (1.8)	4.3	(2.1, 8.0)	7 (1.2)	3.0	(1.2, 6.2)
Fatigue	5 (0.9)	2.2	(0.7, 5.0)	2 (0.3)	0.9	(0.1, 3.1)
Injection site pain	5 (0.9)	2.2	(0.7, 5.0)	4 (0.7)	1.7	(0.5, 4.4)
Injection site swelling	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Nodule	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Oedema peripheral	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Pyrexia	3 (0.5)	1.3	(0.3, 3.8)	0	0.0	(0.0, 1.6)
IMMUNE SYSTEM DISORDERS	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Food allergy	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
INFECTIONS AND INFESTATIONS	3 (0.5)	1.3	(0.3, 3.8)	7 (1.2)	3.0	(1.2, 6.2)
Anal abscess	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)

14.30. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=567, TE[b]=2.3)			Placebo (N[a]=585, TE[b]=2.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Appendicitis	0	0.0	(0.0, 1.6)	2 (0.3)	0.9	(0.1, 3.1)
Candida infection	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Cellulitis	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Conjunctivitis	0	0.0	(0.0, 1.6)	2 (0.3)	0.9	(0.1, 3.1)
Ear infection	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Focal peritonitis	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Paronychia	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Pilonidal cyst	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	8 (1.4)	3.5	(1.5, 6.8)	13 (2.2)	5.6	(3.0, 9.5)
Accident	1 (0.2)	0.4	(0.0, 2.4)	1 (0.2)	0.4	(0.0, 2.4)
Bone contusion	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Clavicle fracture	1 (0.2)	0.4	(0.0, 2.4)	1 (0.2)	0.4	(0.0, 2.4)
Concussion	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Contusion	1 (0.2)	0.4	(0.0, 2.4)	1 (0.2)	0.4	(0.0, 2.4)
Fall	1 (0.2)	0.4	(0.0, 2.4)	2 (0.3)	0.9	(0.1, 3.1)
Hand fracture	0	0.0	(0.0, 1.6)	2 (0.3)	0.9	(0.1, 3.1)
Humerus fracture	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Ligament sprain	0	0.0	(0.0, 1.6)	2 (0.3)	0.9	(0.1, 3.1)
Lip injury	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Meniscus injury	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Muscle strain	1 (0.2)	0.4	(0.0, 2.4)	1 (0.2)	0.4	(0.0, 2.4)
Patella fracture	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Procedural pain	0	0.0	(0.0, 1.6)	2 (0.3)	0.9	(0.1, 3.1)
Radius fracture	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Skin laceration	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Tibia fracture	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Tooth fracture	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Upper limb fracture	1 (0.2)	0.4	(0.0, 2.4)	1 (0.2)	0.4	(0.0, 2.4)
INVESTIGATIONS	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
SARS-CoV-2 antibody test positive	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (0.7)	1.7	(0.5, 4.4)	8 (1.4)	3.4	(1.5, 6.8)
Arthralgia	1 (0.2)	0.4	(0.0, 2.4)	2 (0.3)	0.9	(0.1, 3.1)
Joint swelling	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Myalgia	2 (0.4)	0.9	(0.1, 3.1)	1 (0.2)	0.4	(0.0, 2.4)
Neck pain	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)

14.30. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=567, TE[b]=2.3)			Placebo (N[a]=585, TE[b]=2.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Pain in extremity	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Tendonitis	0	0.0	(0.0, 1.6)	3 (0.5)	1.3	(0.3, 3.8)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Hair follicle tumour benign	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
NERVOUS SYSTEM DISORDERS	5 (0.9)	2.2	(0.7, 5.0)	5 (0.9)	2.1	(0.7, 5.0)
Dizziness	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Headache	2 (0.4)	0.9	(0.1, 3.1)	2 (0.3)	0.9	(0.1, 3.1)
Paraesthesia	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Presyncope	1 (0.2)	0.4	(0.0, 2.4)	1 (0.2)	0.4	(0.0, 2.4)
Syncope	1 (0.2)	0.4	(0.0, 2.4)	1 (0.2)	0.4	(0.0, 2.4)
PSYCHIATRIC DISORDERS	5 (0.9)	2.2	(0.7, 5.0)	3 (0.5)	1.3	(0.3, 3.8)
Anxiety	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Depression	2 (0.4)	0.9	(0.1, 3.1)	2 (0.3)	0.9	(0.1, 3.1)
Disorientation	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Obsessive-compulsive disorder	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Panic attack	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Suicidal ideation	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.2)	0.4	(0.0, 2.4)	2 (0.3)	0.9	(0.1, 3.1)
Nasal congestion	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Rhinorrhoea	1 (0.2)	0.4	(0.0, 2.4)	1 (0.2)	0.4	(0.0, 2.4)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3 (0.5)	1.3	(0.3, 3.8)	11 (1.9)	4.7	(2.4, 8.4)
Acne	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Dermatitis contact	1 (0.2)	0.4	(0.0, 2.4)	1 (0.2)	0.4	(0.0, 2.4)
Eczema	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Pityriasis rosea	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Rash	2 (0.4)	0.9	(0.1, 3.1)	3 (0.5)	1.3	(0.3, 3.8)
Rash maculo-papular	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
Urticaria	0	0.0	(0.0, 1.6)	4 (0.7)	1.7	(0.5, 4.4)

14.30. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=567, TE[b]=2.3)			Placebo (N[a]=585, TE[b]=2.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:21)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s131 unb sex1 ped6

14.31. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=564, TE[b]=2.3)			Placebo (N[a]=544, TE[b]=2.2)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	53 (9.4)	23.5	(17.6, 30.7)	56 (10.3)	25.7	(19.4, 33.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.2)	0.4	(0.0, 2.5)	2 (0.4)	0.9	(0.1, 3.3)
Lymphadenopathy	1 (0.2)	0.4	(0.0, 2.5)	2 (0.4)	0.9	(0.1, 3.3)
EAR AND LABYRINTH DISORDERS	1 (0.2)	0.4	(0.0, 2.5)	2 (0.4)	0.9	(0.1, 3.3)
Cerumen impaction	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
Conductive deafness	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
Ear pain	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
GASTROINTESTINAL DISORDERS	8 (1.4)	3.5	(1.5, 7.0)	5 (0.9)	2.3	(0.7, 5.4)
Abdominal pain	2 (0.4)	0.9	(0.1, 3.2)	1 (0.2)	0.5	(0.0, 2.6)
Constipation	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Diarrhoea	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Gastritis	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Mouth ulceration	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
Nausea	4 (0.7)	1.8	(0.5, 4.5)	3 (0.6)	1.4	(0.3, 4.0)
Rectal prolapse	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Vomiting	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	7 (1.2)	3.1	(1.2, 6.4)	5 (0.9)	2.3	(0.7, 5.4)
Chills	2 (0.4)	0.9	(0.1, 3.2)	1 (0.2)	0.5	(0.0, 2.6)
Fatigue	3 (0.5)	1.3	(0.3, 3.9)	2 (0.4)	0.9	(0.1, 3.3)
Injection site pain	3 (0.5)	1.3	(0.3, 3.9)	4 (0.7)	1.8	(0.5, 4.7)
Injection site swelling	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Peripheral swelling	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Pyrexia	3 (0.5)	1.3	(0.3, 3.9)	0	0.0	(0.0, 1.7)
Vessel puncture site pain	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
IMMUNE SYSTEM DISORDERS	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Seasonal allergy	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
INFECTIONS AND INFESTATIONS	7 (1.2)	3.1	(1.2, 6.4)	2 (0.4)	0.9	(0.1, 3.3)
Body tinea	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Ear infection	2 (0.4)	0.9	(0.1, 3.2)	0	0.0	(0.0, 1.7)
Infectious mononucleosis	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
Otitis externa	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Otitis media	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Pilonidal cyst	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Subcutaneous abscess	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
Tinea capitis	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)

14.31. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=564, TE[b]=2.3)			Placebo (N[a]=544, TE[b]=2.2)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Vulval abscess	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Vulvovaginal mycotic infection	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	7 (1.2)	3.1	(1.2, 6.4)	12 (2.2)	5.5	(2.8, 9.6)
Ankle fracture	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
Concussion	2 (0.4)	0.9	(0.1, 3.2)	4 (0.7)	1.8	(0.5, 4.7)
Contusion	1 (0.2)	0.4	(0.0, 2.5)	1 (0.2)	0.5	(0.0, 2.6)
Fall	1 (0.2)	0.4	(0.0, 2.5)	3 (0.6)	1.4	(0.3, 4.0)
Femur fracture	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Foot fracture	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
Hand fracture	1 (0.2)	0.4	(0.0, 2.5)	2 (0.4)	0.9	(0.1, 3.3)
Ligament sprain	1 (0.2)	0.4	(0.0, 2.5)	2 (0.4)	0.9	(0.1, 3.3)
Procedural pain	2 (0.4)	0.9	(0.1, 3.2)	1 (0.2)	0.5	(0.0, 2.6)
Tooth fracture	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (0.7)	1.8	(0.5, 4.5)	6 (1.1)	2.8	(1.0, 6.0)
Arthralgia	1 (0.2)	0.4	(0.0, 2.5)	2 (0.4)	0.9	(0.1, 3.3)
Back pain	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
Musculoskeletal chest pain	1 (0.2)	0.4	(0.0, 2.5)	1 (0.2)	0.5	(0.0, 2.6)
Myalgia	1 (0.2)	0.4	(0.0, 2.5)	1 (0.2)	0.5	(0.0, 2.6)
Osteochondrosis	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Tendonitis	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	0.0	(0.0, 1.6)	3 (0.6)	1.4	(0.3, 4.0)
Fibroadenoma of breast	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
Melanocytic naevus	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
Skin papilloma	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
NERVOUS SYSTEM DISORDERS	8 (1.4)	3.5	(1.5, 7.0)	8 (1.5)	3.7	(1.6, 7.2)
Dizziness	2 (0.4)	0.9	(0.1, 3.2)	0	0.0	(0.0, 1.7)
Headache	3 (0.5)	1.3	(0.3, 3.9)	5 (0.9)	2.3	(0.7, 5.4)
Migraine	3 (0.5)	1.3	(0.3, 3.9)	0	0.0	(0.0, 1.7)
Presyncope	0	0.0	(0.0, 1.6)	3 (0.6)	1.4	(0.3, 4.0)
PSYCHIATRIC DISORDERS	12 (2.1)	5.3	(2.7, 9.3)	10 (1.8)	4.6	(2.2, 8.5)
Anxiety	4 (0.7)	1.8	(0.5, 4.5)	5 (0.9)	2.3	(0.7, 5.4)
Attention deficit hyperactivity disorder	2 (0.4)	0.9	(0.1, 3.2)	4 (0.7)	1.8	(0.5, 4.7)
Conversion disorder	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Depression	4 (0.7)	1.8	(0.5, 4.5)	1 (0.2)	0.5	(0.0, 2.6)

14.31. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=564, TE[b]=2.3)			Placebo (N[a]=544, TE[b]=2.2)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Generalised anxiety disorder	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Obsessive-compulsive disorder	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
Sleep terror	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Suicidal ideation	3 (0.5)	1.3	(0.3, 3.9)	0	0.0	(0.0, 1.7)
Tic	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
RENAL AND URINARY DISORDERS	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
Dysuria	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Amenorrhoea	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2 (0.4)	0.9	(0.1, 3.2)	6 (1.1)	2.8	(1.0, 6.0)
Epistaxis	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
Nasal congestion	2 (0.4)	0.9	(0.1, 3.2)	2 (0.4)	0.9	(0.1, 3.3)
Rhinorrhoea	1 (0.2)	0.4	(0.0, 2.5)	3 (0.6)	1.4	(0.3, 4.0)
Sneezing	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	6 (1.1)	2.7	(1.0, 5.8)	5 (0.9)	2.3	(0.7, 5.4)
Acne	2 (0.4)	0.9	(0.1, 3.2)	2 (0.4)	0.9	(0.1, 3.3)
Dermatitis contact	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Rash	1 (0.2)	0.4	(0.0, 2.5)	2 (0.4)	0.9	(0.1, 3.3)
Seborrhoeic dermatitis	0	0.0	(0.0, 1.6)	1 (0.2)	0.5	(0.0, 2.6)
Urticaria	2 (0.4)	0.9	(0.1, 3.2)	1 (0.2)	0.5	(0.0, 2.6)
SURGICAL AND MEDICAL PROCEDURES	1 (0.2)	0.4	(0.0, 2.5)	1 (0.2)	0.5	(0.0, 2.6)
Wisdom teeth removal	1 (0.2)	0.4	(0.0, 2.5)	1 (0.2)	0.5	(0.0, 2.6)

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:21)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s131_unb_sex1_ped6

14.32. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1131, TE[b]=4.6)			Placebo (N[a]=1129, TE[b]=4.5)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	36 (3.2)	7.9	(5.5, 10.9)	24 (2.1)	5.3	(3.4, 7.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	7 (0.6)	1.5	(0.6, 3.2)	1 (0.1)	0.2	(0.0, 1.2)
Lymphadenopathy	7 (0.6)	1.5	(0.6, 3.2)	1 (0.1)	0.2	(0.0, 1.2)
EAR AND LABYRINTH DISORDERS	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Conductive deafness	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
EYE DISORDERS	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Eyelid rash	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
GASTROINTESTINAL DISORDERS	11 (1.0)	2.4	(1.2, 4.3)	2 (0.2)	0.4	(0.1, 1.6)
Abdominal pain	2 (0.2)	0.4	(0.1, 1.6)	0	0.0	(0.0, 0.8)
Diarrhoea	2 (0.2)	0.4	(0.1, 1.6)	1 (0.1)	0.2	(0.0, 1.2)
Lip swelling	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Mouth swelling	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Nausea	5 (0.4)	1.1	(0.4, 2.6)	1 (0.1)	0.2	(0.0, 1.2)
Oral mucosal blistering	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Vomiting	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	16 (1.4)	3.5	(2.0, 5.7)	10 (0.9)	2.2	(1.1, 4.1)
Chills	2 (0.2)	0.4	(0.1, 1.6)	1 (0.1)	0.2	(0.0, 1.2)
Fatigue	8 (0.7)	1.7	(0.8, 3.4)	3 (0.3)	0.7	(0.1, 1.9)
Injection site pain	8 (0.7)	1.7	(0.8, 3.4)	8 (0.7)	1.8	(0.8, 3.5)
Injection site swelling	2 (0.2)	0.4	(0.1, 1.6)	0	0.0	(0.0, 0.8)
Peripheral swelling	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Pyrexia	6 (0.5)	1.3	(0.5, 2.9)	0	0.0	(0.0, 0.8)
INVESTIGATIONS	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
SARS-CoV-2 antibody test positive	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (0.4)	0.9	(0.2, 2.2)	1 (0.1)	0.2	(0.0, 1.2)
Musculoskeletal chest pain	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Myalgia	3 (0.3)	0.7	(0.1, 1.9)	1 (0.1)	0.2	(0.0, 1.2)
NERVOUS SYSTEM DISORDERS	5 (0.4)	1.1	(0.4, 2.6)	5 (0.4)	1.1	(0.4, 2.6)
Dizziness	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)
Headache	3 (0.3)	0.7	(0.1, 1.9)	3 (0.3)	0.7	(0.1, 1.9)

14.32. Incidence Rates of at Least 1 Related Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1131, TE[b]=4.6)			Placebo (N[a]=1129, TE[b]=4.5)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Migraine	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Presyncope	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
PSYCHIATRIC DISORDERS	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Disorientation	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Rhinorrhoea	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.2)	0.4	(0.1, 1.6)	7 (0.6)	1.6	(0.6, 3.2)
Rash	1 (0.1)	0.2	(0.0, 1.2)	2 (0.2)	0.4	(0.1, 1.6)
Rash maculo-papular	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Urticaria	1 (0.1)	0.2	(0.0, 1.2)	4 (0.4)	0.9	(0.2, 2.3)

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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.
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(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s131_rel_unb1_ped6

14.33. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1131, TE[b]=4.6)			Placebo (N[a]=1129, TE[b]=4.5)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	13 (1.1)	2.8	(1.5, 4.9)	5 (0.4)	1.1	(0.4, 2.6)
GASTROINTESTINAL DISORDERS	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Abdominal pain	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Constipation	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (0.2)	0.4	(0.1, 1.6)	1 (0.1)	0.2	(0.0, 1.2)
Fatigue	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Pyrexia	2 (0.2)	0.4	(0.1, 1.6)	0	0.0	(0.0, 0.8)
INFECTIONS AND INFESTATIONS	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)
Anal abscess	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Appendicitis	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.2)	0.4	(0.1, 1.6)	2 (0.2)	0.4	(0.1, 1.6)
Femur fracture	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Patella fracture	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Procedural pain	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Upper limb fracture	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Arthralgia	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
NERVOUS SYSTEM DISORDERS	2 (0.2)	0.4	(0.1, 1.6)	1 (0.1)	0.2	(0.0, 1.2)
Headache	1 (0.1)	0.2	(0.0, 1.2)	1 (0.1)	0.2	(0.0, 1.2)
Migraine	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
PSYCHIATRIC DISORDERS	4 (0.4)	0.9	(0.2, 2.2)	0	0.0	(0.0, 0.8)
Anxiety	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Depression	2 (0.2)	0.4	(0.1, 1.6)	0	0.0	(0.0, 0.8)
Suicidal ideation	2 (0.2)	0.4	(0.1, 1.6)	0	0.0	(0.0, 0.8)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Urticaria	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)

14.33. Incidence Rates of at Least 1 Severe Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1131, TE[b]=4.6)			Placebo (N[a]=1129, TE[b]=4.5)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:31)
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./nda2 unblinded/C4591001 S Peds/adae s131 sev unb1 ped6

14.34. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1131, TE[b]=4.6)			Placebo (N[a]=1129, TE[b]=4.5)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	2 (0.2)	0.4	(0.1, 1.6)	1 (0.1)	0.2	(0.0, 1.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Pyrexia	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
INFECTIONS AND INFESTATIONS	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Appendicitis	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
Focal peritonitis	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.2)
PSYCHIATRIC DISORDERS	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Suicidal ideation	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:31)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s131 lif unb1 ped6

14.35. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (02SEP2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1107, TE[b]=3.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])
Any event	18 (1.6)	5.4	(3.2, 8.5)
CARDIAC DISORDERS	1 (0.1)	0.3	(0.0, 1.7)
Tachycardia	1 (0.1)	0.3	(0.0, 1.7)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.1)	0.3	(0.0, 1.7)
Syringomyelia	1 (0.1)	0.3	(0.0, 1.7)
GASTROINTESTINAL DISORDERS	3 (0.3)	0.9	(0.2, 2.6)
Abdominal pain upper	2 (0.2)	0.6	(0.1, 2.2)
Aphthous ulcer	1 (0.1)	0.3	(0.0, 1.7)
Nausea	1 (0.1)	0.3	(0.0, 1.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4 (0.4)	1.2	(0.3, 3.1)
Fatigue	2 (0.2)	0.6	(0.1, 2.2)
Injection site pain	3 (0.3)	0.9	(0.2, 2.6)
Pain	1 (0.1)	0.3	(0.0, 1.7)
Pyrexia	2 (0.2)	0.6	(0.1, 2.2)
INFECTIONS AND INFESTATIONS	3 (0.3)	0.9	(0.2, 2.6)
Appendicitis	2 (0.2)	0.6	(0.1, 2.2)
Otitis media	1 (0.1)	0.3	(0.0, 1.7)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.2)	0.6	(0.1, 2.2)
Hand fracture	1 (0.1)	0.3	(0.0, 1.7)
Upper limb fracture	1 (0.1)	0.3	(0.0, 1.7)
NERVOUS SYSTEM DISORDERS	6 (0.5)	1.8	(0.7, 3.9)
Dizziness	2 (0.2)	0.6	(0.1, 2.2)
Headache	2 (0.2)	0.6	(0.1, 2.2)
Presyncope	2 (0.2)	0.6	(0.1, 2.2)
Syncope	1 (0.1)	0.3	(0.0, 1.7)
PSYCHIATRIC DISORDERS	1 (0.1)	0.3	(0.0, 1.7)
Anxiety	1 (0.1)	0.3	(0.0, 1.7)

14.35. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (02SEP2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1107, TE[b]=3.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from the unblinding date to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:31)
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14.36. Incidence Rates of at Least 1 Related Adverse Event From Unblinding Date to Data Cutoff Date (02SEP2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1107, TE[b]=3.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])
Any event	4 (0.4)	1.2	(0.3, 3.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4 (0.4)	1.2	(0.3, 3.1)
Fatigue	2 (0.2)	0.6	(0.1, 2.2)
Injection site pain	3 (0.3)	0.9	(0.2, 2.6)
Pain	1 (0.1)	0.3	(0.0, 1.7)
Pyrexia	2 (0.2)	0.6	(0.1, 2.2)
NERVOUS SYSTEM DISORDERS	2 (0.2)	0.6	(0.1, 2.2)
Dizziness	1 (0.1)	0.3	(0.0, 1.7)
Headache	2 (0.2)	0.6	(0.1, 2.2)

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from the unblinding date to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:41)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s131 rel ubct1 ped6

14.37. Incidence Rates of at Least 1 Severe Adverse Event From Unblinding Date to Data Cutoff Date (02SEP2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1107, TE[b]=3.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])
Any event	3 (0.3)	0.9	(0.2, 2.6)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.1)	0.3	(0.0, 1.7)
Syringomyelia	1 (0.1)	0.3	(0.0, 1.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2 (0.2)	0.6	(0.1, 2.2)
Pyrexia	2 (0.2)	0.6	(0.1, 2.2)

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from the unblinding date to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:41)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s131 sev ubct1 ped6

14.38. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	34 (3.1)	(2.1, 4.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	7 (0.6)	(0.3, 1.3)
Lymphadenopathy	7 (0.6)	(0.3, 1.3)
GASTROINTESTINAL DISORDERS	11 (1.0)	(0.5, 1.8)
Nausea	5 (0.4)	(0.1, 1.0)
Abdominal pain	2 (0.2)	(0.0, 0.6)
Diarrhoea	2 (0.2)	(0.0, 0.6)
Lip swelling	1 (0.1)	(0.0, 0.5)
Mouth swelling	1 (0.1)	(0.0, 0.5)
Oral mucosal blistering	1 (0.1)	(0.0, 0.5)
Vomiting	1 (0.1)	(0.0, 0.5)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	15 (1.3)	(0.8, 2.2)
Fatigue	8 (0.7)	(0.3, 1.4)
Injection site pain	8 (0.7)	(0.3, 1.4)
Pyrexia	5 (0.4)	(0.1, 1.0)
Chills	2 (0.2)	(0.0, 0.6)
Injection site swelling	2 (0.2)	(0.0, 0.6)
Peripheral swelling	1 (0.1)	(0.0, 0.5)
INVESTIGATIONS	1 (0.1)	(0.0, 0.5)
SARS-CoV-2 antibody test positive	1 (0.1)	(0.0, 0.5)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4 (0.4)	(0.1, 0.9)
Myalgia	3 (0.3)	(0.1, 0.8)
Musculoskeletal chest pain	1 (0.1)	(0.0, 0.5)
NERVOUS SYSTEM DISORDERS	5 (0.4)	(0.1, 1.0)
Headache	3 (0.3)	(0.1, 0.8)
Dizziness	1 (0.1)	(0.0, 0.5)
Migraine	1 (0.1)	(0.0, 0.5)
PSYCHIATRIC DISORDERS	1 (0.1)	(0.0, 0.5)
Disorientation	1 (0.1)	(0.0, 0.5)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.1)	(0.0, 0.5)
Urticaria	1 (0.1)	(0.0, 0.5)

14.38. Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects 12 Through 15 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1113)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])

Note: MedDRA (v24.0) 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.
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14.39. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 3 to 7 Days After Dose 3, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1010)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	198 (19.6)	(17.2, 22.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.1)	(0.0, 0.6)
Lymphadenitis	1 (0.1)	(0.0, 0.6)
EAR AND LABYRINTH DISORDERS	1 (0.1)	(0.0, 0.6)
Motion sickness	1 (0.1)	(0.0, 0.6)
GASTROINTESTINAL DISORDERS	9 (0.9)	(0.4, 1.7)
Nausea	7 (0.7)	(0.3, 1.4)
Vomiting	2 (0.2)	(0.0, 0.7)
Abdominal pain upper	1 (0.1)	(0.0, 0.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	178 (17.6)	(15.3, 20.1)
Injection site pain	131 (13.0)	(11.0, 15.2)
Fatigue	68 (6.7)	(5.3, 8.5)
Chills	29 (2.9)	(1.9, 4.1)
Pyrexia	28 (2.8)	(1.8, 4.0)
Pain	17 (1.7)	(1.0, 2.7)
Injection site erythema	3 (0.3)	(0.1, 0.9)
Injection site swelling	3 (0.3)	(0.1, 0.9)
Injection site bruising	2 (0.2)	(0.0, 0.7)
Malaise	2 (0.2)	(0.0, 0.7)
Injection site hypoaesthesia	1 (0.1)	(0.0, 0.6)
Non-cardiac chest pain	1 (0.1)	(0.0, 0.6)
Thirst	1 (0.1)	(0.0, 0.6)
INFECTIONS AND INFESTATIONS	1 (0.1)	(0.0, 0.6)
Paronychia	1 (0.1)	(0.0, 0.6)
Skin candida	1 (0.1)	(0.0, 0.6)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	2 (0.2)	(0.0, 0.7)
Joint injury	1 (0.1)	(0.0, 0.6)
Muscle strain	1 (0.1)	(0.0, 0.6)
INVESTIGATIONS	2 (0.2)	(0.0, 0.7)
Body temperature increased	2 (0.2)	(0.0, 0.7)
METABOLISM AND NUTRITION DISORDERS	1 (0.1)	(0.0, 0.6)
Decreased appetite	1 (0.1)	(0.0, 0.6)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	24 (2.4)	(1.5, 3.5)

14.39. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 3 to 7 Days After Dose 3, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1010)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Myalgia	18 (1.8)	(1.1, 2.8)
Pain in extremity	5 (0.5)	(0.2, 1.2)
Musculoskeletal stiffness	1 (0.1)	(0.0, 0.6)
NERVOUS SYSTEM DISORDERS	42 (4.2)	(3.0, 5.6)
Headache	40 (4.0)	(2.8, 5.4)
Dizziness	2 (0.2)	(0.0, 0.7)
Syncope	1 (0.1)	(0.0, 0.6)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.1)	(0.0, 0.6)
Rhinorrhoea	1 (0.1)	(0.0, 0.6)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.2)	(0.0, 0.7)
Hyperhidrosis	1 (0.1)	(0.0, 0.6)
Photosensitivity reaction	1 (0.1)	(0.0, 0.6)

Note: Dose 3 = first dose of BNT162b2 (30 µg).
Note: MedDRA (v24.0) 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.
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14.40. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 4 to 7 Days After Dose 4, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=992)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	138 (13.9)	(11.8, 16.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.1)	(0.0, 0.6)
Lymphadenopathy	1 (0.1)	(0.0, 0.6)
CARDIAC DISORDERS	1 (0.1)	(0.0, 0.6)
Myocarditis	1 (0.1)	(0.0, 0.6)
GASTROINTESTINAL DISORDERS	12 (1.2)	(0.6, 2.1)
Nausea	7 (0.7)	(0.3, 1.4)
Vomiting	5 (0.5)	(0.2, 1.2)
Abdominal pain upper	1 (0.1)	(0.0, 0.6)
Diarrhoea	1 (0.1)	(0.0, 0.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	120 (12.1)	(10.1, 14.3)
Injection site pain	60 (6.0)	(4.6, 7.7)
Fatigue	56 (5.6)	(4.3, 7.3)
Pyrexia	41 (4.1)	(3.0, 5.6)
Chills	21 (2.1)	(1.3, 3.2)
Pain	21 (2.1)	(1.3, 3.2)
Malaise	5 (0.5)	(0.2, 1.2)
Injection site bruising	2 (0.2)	(0.0, 0.7)
Injection site erythema	2 (0.2)	(0.0, 0.7)
Axillary pain	1 (0.1)	(0.0, 0.6)
Chest discomfort	1 (0.1)	(0.0, 0.6)
Chest pain	1 (0.1)	(0.0, 0.6)
Injection site reaction	1 (0.1)	(0.0, 0.6)
Injection site swelling	1 (0.1)	(0.0, 0.6)
INFECTIONS AND INFESTATIONS	3 (0.3)	(0.1, 0.9)
Appendicitis	1 (0.1)	(0.0, 0.6)
Pharyngitis streptococcal	1 (0.1)	(0.0, 0.6)
Sinusitis	1 (0.1)	(0.0, 0.6)
INVESTIGATIONS	2 (0.2)	(0.0, 0.7)
Body temperature increased	2 (0.2)	(0.0, 0.7)
METABOLISM AND NUTRITION DISORDERS	1 (0.1)	(0.0, 0.6)
Vitamin D deficiency	1 (0.1)	(0.0, 0.6)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	25 (2.5)	(1.6, 3.7)

14.40. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 4 to 7 Days After Dose 4, by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=992)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Myalgia	21 (2.1)	(1.3, 3.2)
Pain in extremity	3 (0.3)	(0.1, 0.9)
Arthralgia	2 (0.2)	(0.0, 0.7)
Musculoskeletal chest pain	1 (0.1)	(0.0, 0.6)
Neck pain	1 (0.1)	(0.0, 0.6)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1 (0.1)	(0.0, 0.6)
Skin papilloma	1 (0.1)	(0.0, 0.6)
NERVOUS SYSTEM DISORDERS	40 (4.0)	(2.9, 5.5)
Headache	38 (3.8)	(2.7, 5.2)
Dizziness	2 (0.2)	(0.0, 0.7)
Epilepsy	1 (0.1)	(0.0, 0.6)
PSYCHIATRIC DISORDERS	1 (0.1)	(0.0, 0.6)
Major depression	1 (0.1)	(0.0, 0.6)
RENAL AND URINARY DISORDERS	1 (0.1)	(0.0, 0.6)
Dysuria	1 (0.1)	(0.0, 0.6)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.1)	(0.0, 0.6)
Cough	1 (0.1)	(0.0, 0.6)
Nasal congestion	1 (0.1)	(0.0, 0.6)

Note: Dose 4 = second dose of BNT162b2 (30 µg).
Note: Subjects who did not receive Dose 4 or who received a different vaccine at Dose 3 and Dose 4 were excluded from this table.
Note: MedDRA (v24.0) 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:31)
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14.41. Incidence Rates of at Least 1 Related Adverse Event From Dose 3 to Data Cutoff Date (02SEP2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1010, TE[b]=2.9)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])
Any event	242 (24.0)	82.5	(72.4, 93.5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	2 (0.2)	0.7	(0.1, 2.5)
Lymphadenitis	1 (0.1)	0.3	(0.0, 1.9)
Lymphadenopathy	1 (0.1)	0.3	(0.0, 1.9)
GASTROINTESTINAL DISORDERS	18 (1.8)	6.1	(3.6, 9.7)
Abdominal pain upper	2 (0.2)	0.7	(0.1, 2.5)
Diarrhoea	1 (0.1)	0.3	(0.0, 1.9)
Nausea	12 (1.2)	4.1	(2.1, 7.1)
Vomiting	6 (0.6)	2.0	(0.8, 4.4)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	223 (22.1)	76.0	(66.3, 86.6)
Axillary pain	1 (0.1)	0.3	(0.0, 1.9)
Chills	45 (4.5)	15.3	(11.2, 20.5)
Fatigue	104 (10.3)	35.4	(29.0, 42.9)
Injection site bruising	3 (0.3)	1.0	(0.2, 3.0)
Injection site erythema	5 (0.5)	1.7	(0.6, 4.0)
Injection site hypoaesthesia	1 (0.1)	0.3	(0.0, 1.9)
Injection site pain	157 (15.5)	53.5	(45.5, 62.5)
Injection site reaction	1 (0.1)	0.3	(0.0, 1.9)
Injection site swelling	4 (0.4)	1.4	(0.4, 3.5)
Malaise	7 (0.7)	2.4	(1.0, 4.9)
Non-cardiac chest pain	1 (0.1)	0.3	(0.0, 1.9)
Pain	35 (3.5)	11.9	(8.3, 16.6)
Pyrexia	63 (6.2)	21.5	(16.5, 27.5)
Thirst	1 (0.1)	0.3	(0.0, 1.9)
INFECTIONS AND INFESTATIONS	1 (0.1)	0.3	(0.0, 1.9)
Appendicitis	1 (0.1)	0.3	(0.0, 1.9)
INVESTIGATIONS	3 (0.3)	1.0	(0.2, 3.0)
Body temperature increased	3 (0.3)	1.0	(0.2, 3.0)
METABOLISM AND NUTRITION DISORDERS	1 (0.1)	0.3	(0.0, 1.9)
Decreased appetite	1 (0.1)	0.3	(0.0, 1.9)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	46 (4.6)	15.7	(11.5, 20.9)
Arthralgia	2 (0.2)	0.7	(0.1, 2.5)
Musculoskeletal chest pain	1 (0.1)	0.3	(0.0, 1.9)

14.41. Incidence Rates of at Least 1 Related Adverse Event From Dose 3 to Data Cutoff Date (02SEP2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1010, TE[b]=2.9)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])
Musculoskeletal stiffness	1 (0.1)	0.3	(0.0, 1.9)
Myalgia	37 (3.7)	12.6	(8.9, 17.4)
Pain in extremity	8 (0.8)	2.7	(1.2, 5.4)
NERVOUS SYSTEM DISORDERS	73 (7.2)	24.9	(19.5, 31.3)
Dizziness	4 (0.4)	1.4	(0.4, 3.5)
Headache	70 (6.9)	23.8	(18.6, 30.1)
Syncope	1 (0.1)	0.3	(0.0, 1.9)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (0.1)	0.3	(0.0, 1.9)
Rhinorrhoea	1 (0.1)	0.3	(0.0, 1.9)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.1)	0.3	(0.0, 1.9)
Hyperhidrosis	1 (0.1)	0.3	(0.0, 1.9)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
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./nda2 unblinded/C4591001 S Peds/adae s131 rel cut1 ped6

14.42. Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Vaccination (Dose 3/4), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=1010)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	7 (0.7)	(0.3, 1.4)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	7 (0.7)	(0.3, 1.4)
Injection site pain	6 (0.6)	(0.2, 1.3)
Injection site erythema	1 (0.1)	(0.0, 0.6)

Note: Dose 3 = first dose of BNT162b2 (30 µg), Dose 4 = second dose of BNT162b2 (30 µg).
Note: MedDRA (v24.0) coding dictionary applied.
Note: Immediate AE refers to an AE reported in the 30-minute observation period after vaccination.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:31)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s130 imm cr1 ped6

14.43. Incidence Rates of at Least 1 Severe Adverse Event From Dose 3 to Data Cutoff Date (02SEP2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1010, TE[b]=2.9)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])
Any event	12 (1.2)	4.1	(2.1, 7.1)
CARDIAC DISORDERS	1 (0.1)	0.3	(0.0, 1.9)
Myocarditis	1 (0.1)	0.3	(0.0, 1.9)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	6 (0.6)	2.0	(0.8, 4.4)
Fatigue	2 (0.2)	0.7	(0.1, 2.5)
Malaise	1 (0.1)	0.3	(0.0, 1.9)
Pyrexia	3 (0.3)	1.0	(0.2, 3.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3 (0.3)	1.0	(0.2, 3.0)
Concussion	1 (0.1)	0.3	(0.0, 1.9)
Muscle strain	1 (0.1)	0.3	(0.0, 1.9)
Sunburn	1 (0.1)	0.3	(0.0, 1.9)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.1)	0.3	(0.0, 1.9)
Musculoskeletal chest pain	1 (0.1)	0.3	(0.0, 1.9)
Myalgia	1 (0.1)	0.3	(0.0, 1.9)
NERVOUS SYSTEM DISORDERS	1 (0.1)	0.3	(0.0, 1.9)
Somnolence	1 (0.1)	0.3	(0.0, 1.9)
PSYCHIATRIC DISORDERS	1 (0.1)	0.3	(0.0, 1.9)
Major depression	1 (0.1)	0.3	(0.0, 1.9)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:31)
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14.44. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Baseline SARS-CoV-2 Status – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1083, TE[b]=4.4)			Placebo (N[a]=1078, TE[b]=4.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	10 (0.9)	2.3	(1.1, 4.2)	2 (0.2)	0.5	(0.1, 1.7)
GASTROINTESTINAL DISORDERS	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Abdominal pain	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Constipation	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
INFECTIONS AND INFESTATIONS	1 (0.1)	0.2	(0.0, 1.3)	2 (0.2)	0.5	(0.1, 1.7)
Anal abscess	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Appendicitis	0	0.0	(0.0, 0.8)	2 (0.2)	0.5	(0.1, 1.7)
Focal peritonitis	0	0.0	(0.0, 0.8)	1 (0.1)	0.2	(0.0, 1.3)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Femur fracture	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
PSYCHIATRIC DISORDERS	8 (0.7)	1.8	(0.8, 3.6)	0	0.0	(0.0, 0.9)
Anxiety	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Conversion disorder	1 (0.1)	0.2	(0.0, 1.3)	0	0.0	(0.0, 0.9)
Depression	3 (0.3)	0.7	(0.1, 2.0)	0	0.0	(0.0, 0.9)
Suicidal ideation	4 (0.4)	0.9	(0.2, 2.3)	0	0.0	(0.0, 0.9)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: MedDRA (v24.0) coding dictionary applied.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 12NOV2021 (15:38)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s131 sae base1 ped6

14.45. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Ethnicity: Hispanic/Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=132, TE[b]=0.6)			Placebo (N[a]=130, TE[b]=0.5)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	2 (1.5)	3.6	(0.4, 12.8)	0	0.0	(0.0, 6.9)
GASTROINTESTINAL DISORDERS	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
Abdominal pain	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
Constipation	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
PSYCHIATRIC DISORDERS	2 (1.5)	3.6	(0.4, 12.8)	0	0.0	(0.0, 6.9)
Conversion disorder	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)
Suicidal ideation	1 (0.8)	1.8	(0.0, 9.9)	0	0.0	(0.0, 6.9)

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (16:25)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s131_sae_eth1_ped6

14.46. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Ethnicity – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Ethnicity: Non-Hispanic/Non-Latino

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=997, TE[b]=4.0)			Placebo (N[a]=996, TE[b]=4.0)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	8 (0.8)	2.0	(0.9, 3.9)	2 (0.2)	0.5	(0.1, 1.8)
INFECTIONS AND INFESTATIONS	1 (0.1)	0.2	(0.0, 1.4)	2 (0.2)	0.5	(0.1, 1.8)
Anal abscess	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Appendicitis	0	0.0	(0.0, 0.9)	2 (0.2)	0.5	(0.1, 1.8)
Focal peritonitis	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.4)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Femur fracture	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
PSYCHIATRIC DISORDERS	6 (0.6)	1.5	(0.6, 3.3)	0	0.0	(0.0, 0.9)
Anxiety	1 (0.1)	0.2	(0.0, 1.4)	0	0.0	(0.0, 0.9)
Depression	3 (0.3)	0.7	(0.2, 2.2)	0	0.0	(0.0, 0.9)
Suicidal ideation	3 (0.3)	0.7	(0.2, 2.2)	0	0.0	(0.0, 0.9)

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (16:25)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s131 sae eth1 ped6

14.47. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Race: White

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=970, TE[b]=3.9)			Placebo (N[a]=962, TE[b]=3.8)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	7 (0.7)	1.8	(0.7, 3.7)	2 (0.2)	0.5	(0.1, 1.9)
GASTROINTESTINAL DISORDERS	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Abdominal pain	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Constipation	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
INFECTIONS AND INFESTATIONS	1 (0.1)	0.3	(0.0, 1.4)	2 (0.2)	0.5	(0.1, 1.9)
Anal abscess	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Appendicitis	0	0.0	(0.0, 0.9)	2 (0.2)	0.5	(0.1, 1.9)
Focal peritonitis	0	0.0	(0.0, 0.9)	1 (0.1)	0.3	(0.0, 1.5)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Femur fracture	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
PSYCHIATRIC DISORDERS	5 (0.5)	1.3	(0.4, 3.0)	0	0.0	(0.0, 1.0)
Conversion disorder	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Depression	1 (0.1)	0.3	(0.0, 1.4)	0	0.0	(0.0, 1.0)
Suicidal ideation	3 (0.3)	0.8	(0.2, 2.3)	0	0.0	(0.0, 1.0)

Note: MedDRA (v24.0) coding dictionary applied.
Note: All Others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. 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 the blinded follow-up period. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (16:25)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s131_sae_race1_ped6

14.48. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Race: Black or African American

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=52, TE[b]=0.2)			Placebo (N[a]=57, TE[b]=0.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)
PSYCHIATRIC DISORDERS	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)
Anxiety	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)
Depression	1 (1.9)	4.0	(0.1, 22.5)	0	0.0	(0.0, 14.1)

Note: MedDRA (v24.0) coding dictionary applied.
Note: All Others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. 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 the blinded follow-up period. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (16:25)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s131_sae_race1_ped6

14.49. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Race – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Race: All Others

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=109, TE[b]=0.4)			Placebo (N[a]=110, TE[b]=0.4)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	2 (1.8)	4.6	(0.6, 16.7)	0	0.0	(0.0, 8.6)
PSYCHIATRIC DISORDERS	2 (1.8)	4.6	(0.6, 16.7)	0	0.0	(0.0, 8.6)
Depression	1 (0.9)	2.3	(0.1, 12.8)	0	0.0	(0.0, 8.6)
Suicidal ideation	1 (0.9)	2.3	(0.1, 12.8)	0	0.0	(0.0, 8.6)

Note: MedDRA (v24.0) coding dictionary applied.
Note: All Others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. 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 the blinded follow-up period. 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: 05OCT2021 (17:29) Source Data: adae Table Generation: 11NOV2021 (16:25)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s131_sae_race1_ped6

14.50. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Sex: Male

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=567, TE[b]=2.3)			Placebo (N[a]=585, TE[b]=2.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	3 (0.5)	1.3	(0.3, 3.8)	2 (0.3)	0.9	(0.1, 3.1)
INFECTIONS AND INFESTATIONS	1 (0.2)	0.4	(0.0, 2.4)	2 (0.3)	0.9	(0.1, 3.1)
Anal abscess	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Appendicitis	0	0.0	(0.0, 1.6)	2 (0.3)	0.9	(0.1, 3.1)
Focal peritonitis	0	0.0	(0.0, 1.6)	1 (0.2)	0.4	(0.0, 2.4)
PSYCHIATRIC DISORDERS	2 (0.4)	0.9	(0.1, 3.1)	0	0.0	(0.0, 1.6)
Depression	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)
Suicidal ideation	1 (0.2)	0.4	(0.0, 2.4)	0	0.0	(0.0, 1.6)

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:21)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s131_sae_sex1_ped6

14.51. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term, by Sex – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population Sex: Female

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=564, TE[b]=2.3)			Placebo (N[a]=544, TE[b]=2.2)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	7 (1.2)	3.1	(1.2, 6.4)	0	0.0	(0.0, 1.7)
GASTROINTESTINAL DISORDERS	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Abdominal pain	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Constipation	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Femur fracture	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
PSYCHIATRIC DISORDERS	6 (1.1)	2.7	(1.0, 5.8)	0	0.0	(0.0, 1.7)
Anxiety	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Conversion disorder	1 (0.2)	0.4	(0.0, 2.5)	0	0.0	(0.0, 1.7)
Depression	2 (0.4)	0.9	(0.1, 3.2)	0	0.0	(0.0, 1.7)
Suicidal ideation	3 (0.5)	1.3	(0.3, 3.9)	0	0.0	(0.0, 1.7)

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:21)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File:
./nda2 unblinded/C4591001 S Peds/adae s131 sae sex1 ped6

14.52. Incidence Rates of at Least 1 Serious Adverse Event From Unblinding Date to Data Cutoff Date (02SEP2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1107, TE[b]=3.3)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])
Any event	4 (0.4)	1.2	(0.3, 3.1)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.1)	0.3	(0.0, 1.7)
Syringomyelia	1 (0.1)	0.3	(0.0, 1.7)
INFECTIONS AND INFESTATIONS	2 (0.2)	0.6	(0.1, 2.2)
Appendicitis	2 (0.2)	0.6	(0.1, 2.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (0.1)	0.3	(0.0, 1.7)
Upper limb fracture	1 (0.1)	0.3	(0.0, 1.7)

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from the unblinding date to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:41)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_s131_sae_ubct1_ped6

14.53. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 12 Through 15 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=1131, TE[b]=4.6)			Placebo (N[a]=1129, TE[b]=4.5)		
System Organ Class Preferred Term	n[c] (%)	IR[d]	(95% CI[e])	n[c] (%)	IR[d]	(95% CI[e])
Any event	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)
Pyrexia	1 (0.1)	0.2	(0.0, 1.2)	0	0.0	(0.0, 0.8)

Note: MedDRA (v24.0) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
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 the blinded follow-up period. 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: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (10:31)
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2 unblinded/C4591001 S Peds/adae s131 wd unb1 ped6

SUPPLEMENTAL FIGURES

None

SUBJECT NARRATIVES

Primary Reason for Narrative	Unique Subject ID
Related Serious Adverse Event	C4591001 1156 11561357 (also Appendicitis)
Safety-Related Subject Withdrawal	C4591001 1147 11471327
Adverse Event of Clinical Interest	C4591001 1007 10071499 C4591001 1009 10091221 C4591001 1009 10091294 C4591001 1009 10091382 C4591001 1016 10161327 C4591001 1039 10391285 C4591001 1131 11311301 C4591001 1139 11391246 C4591001 1150 11501210 C4591001 1150 11501294 C4591001 1223 12231273
Appendicitis	C4591001 1005 10051449 C4591001 1007 10071581 C4591001 1091 10911447 C4591001 1147 11471281
COVID-19 Case (Severe and/or Multiple)	C4591001 1270 12701237

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